

Zimmer / Zeman / Hammer / Goldbach / Allekotte

# Protecting and Enforcing Life Science Inventions in Europe

under EPC and EU Law  
– From Antibodies to Zebrafish –

Second Edition

C.H.BECK · Hart  
Nomos · Helbing Lichtenhahn

Zimmer • Zeman • Hammer • Goldbach • Allekotte  
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## Preface to the second edition

Eighteen years have passed since the first edition of this book was published in 1997. This period has witnessed rapid development in the life sciences. Many biotechnology companies then on the cutting edge of research and development no longer exist, while others have taken their place to push that edge yet further. The sequencing of the human genome, completed several years after the first edition of this book appeared, has ushered in a new era of therapeutics, based not only on the elucidation of the many new genes made available, but also on the genes belonging to any one particular individual. The result has been the dawn of personalized medicine. Biologics now make up a significant proportion of today's blockbuster drugs and of these, many are antibody-based therapeutics. Embryonic stem cells bear the potential to raise the standard of health in society, while simultaneously challenging that society with serious ethical questions. Advances in the genetic engineering of plants are rapidly changing our answers to one of the most ancient and fundamental questions of human survival: What do we and our children eat? Finally, transgenic animals have become indispensable tools in modeling diseases which threaten our health. Yet how do we strike an ethically defensible balance between our desire for better health and potential animal suffering?

These and other issues continue to occupy both researchers and Legislators at the beginning of the 21<sup>st</sup> century. Legislators and Boards of Appeal in the European Patent Office have invested considerable effort over the last two decades to adjust the law and practice governing life science inventions to the rapidly changing technological landscape. The number of changes in law and its interpretation during this period stands as testament to what an active field life science research continues to be. Motivated by these changes since this book's first edition, and encouraged by repeated inquiries from friends and colleagues around the world, we felt the time had come for an updated edition of our handbook on patenting in the life sciences.

Despite the many developments mentioned above, the basic nature and intended audience of our book remain unchanged. As for the first edition, the present second edition is intended as a practical handbook to assist those active in the life sciences who are interested in converting the fruits of their research into protective, enforceable rights in Europe. This book does not intend to present an exhaustive account of all legal developments and decisions within the life science field; other existing books admirably meet this call. Rather, we intend to convey a sense of the requirements for patentability as well as the issues influencing patent enforcement by presenting illustrative examples of relevant decisions and claims. In this way, we intend this book to serve as a starting point for those readers who may not have attorney training, but still require general

guidance as to the factors influencing patent protection for life science inventions, and examples of claim language used to capture them. As in the first edition, each section of the book contains both generic and specific examples of claim language to this end.

At the same time, the content of the second edition differs in several important aspects from its predecessor. In December 2007, the EPC-2000 went into force. The EPC-2000 represented the most comprehensive overhaul of the European Patent Convention since its inception in 1973, and included the incorporation of many new material provisions relevant to the life sciences. In fact, many major changes in the EPC related to the European Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. This Biotech Directive was not yet in force when the first edition went to press, and was only implemented in the EPC in 1999. Such fundamental statutory changes would alone have warranted an update of any book based on the old provisions of 1973.

Where the first edition focused primarily on biotechnological subject matter, the present edition addresses the broader field of life sciences. This includes a more detailed treatment of chemistry, particularly as relevant to small molecule therapeutics not offered in the first edition.

A further important difference between this second edition and its predecessor is the choice to now omit all treatment of German national law and practice. While Germany indeed continues to lead the European pharmaceutical market, Applicants increasingly prefer obtaining patent protection in Germany via a European patent application examined and granted centrally in the European Patent Office. By virtue of the simple volume of cases handled by the EPO, this office has become the clear trendsetter in the development of new case law relating to life science inventions. Under these circumstances an exclusive focus on Europe in the present edition seemed appropriate.

Finally, this second edition adds a chapter on the enforcement of patent rights throughout Europe. It is said that the real value of a patent becomes clear only when it is enforced. True to this notion, the new chapter addresses issues of enforcement both within and – especially important in Europe where borders are so close together – between European states. It is our hope that this new chapter will provide a helpful impression of the scope in which a patent may be enforced against a putative Infringer, as well as the factors to consider so that such enforcement has the best chances of succeeding.

The further development of life science technology and law will not cease with the publication of this second edition; the field is in constant flux, and this flux is a good thing. For the purposes of preparing the present manuscript, however, we were forced to draw a line, beyond which further developments could no longer be considered. We drew this line at August 1, 2014. Legal developments and case law after this date could not be taken into account in this edition.

The present book thus represents a practical snapshot of the legal landscape surrounding the patenting and enforcement of life science inventions in Europe up to late 2014. It is our hope that this book will assist the interested reader with his or her entry into this exciting field.

Munich, September 2014

Franz-Josef Zimmer  
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Jens Hammer  
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# Table of Contents

Preface to the second edition . . . . .	V
Abbreviations . . . . .	XVII
<b>A. Life Science Matter . . . . .</b>	<b>1</b>
<b>A.I. Summary of historical development . . . . .</b>	<b>1</b>
<b>A.II. Definition of life science matter . . . . .</b>	<b>2</b>
<b>B. Legal Provisions . . . . .</b>	<b>3</b>
<b>B.I. European Patent Convention (EPC) . . . . .</b>	<b>3</b>
<b>B.II. EU Law . . . . .</b>	<b>5</b>
B.II.1. EU Biotech Directive and its Implementation into the EPC . . . . .	5
B.II.2. EU Regulations Concerning the Creation of a Supplementary Protection Certificate (SPC) for Medicinal Products (MSPC), Pediatric Extension of Duration for Medicinal Products (PE) and Plant Protection Products (PSPC) . . . . .	5
B.II.3. Council Regulation on Community Plant Variety Rights (CPVR) . . . . .	6
B.II.4. EU Bolar Directive . . . . .	6
<b>C. General Aspects on Protection . . . . .</b>	<b>7</b>
<b>C.I. Protection under the EPC . . . . .</b>	<b>7</b>
C.I.1. Non-patentable matter . . . . .	7
C.I.1.a. Discoveries . . . . .	7
C.I.2. Exceptions to patentability . . . . .	9
C.I.2.a. Inventions contrary to “ordre public” or morality . . . . .	9
C.I.2.b. Plant and animal varieties . . . . .	14
C.I.2.b.a. Plant Varieties . . . . .	14
C.I.2.b.b. Animal Varieties . . . . .	15
C.I.2.c. Essentially biological processes for the production of plants or animals . . . . .	16
C.I.2.d. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body . . . . .	20
C.I.3. Requirements for grant . . . . .	27
C.I.3.a. Novelty, inventive step and industrial application . . . . .	27
C.I.3.a.a. Naturally occurring products . . . . .	27
C.I.3.a.b. Products for use in methods for treatment of the human or animal body by surgery, therapy or diagnostic methods practiced on the human or animal body . . . . .	28
C.I.3.a.c. Processes of analogy . . . . .	28
C.I.3.b. Sufficiency of disclosure . . . . .	29
C.I.3.b.a. Nucleotide and amino acid sequences . . . . .	37
C.I.3.b.b. Microorganisms . . . . .	38

C.I.3.c.	Priority . . . . .	40
C.I.3.d.	Person skilled in the art . . . . .	43
C.I.3.e.	Claims . . . . .	45
C.I.3.e.a.	Claim categories . . . . .	46
C.I.3.e.b.	Clarity of claims . . . . .	47
C.I.3.e.c.	Support of claims by description . . . . .	49
C.I.3.e.d.	Claims for medicinal products . . . . .	51
C.I.3.e.e.	Unity of invention . . . . .	52
C.I.3.f.	Description . . . . .	54
C.I.3.f.a.	Selection inventions . . . . .	54
C.I.3.f.b.	Divisional applications . . . . .	56
C.I.3.f.c.	Quality and filing of data . . . . .	58
<b>C.II.</b>	<b>Protection under the EU Regulations . . . . .</b>	<b>61</b>
C.II.1.	SPCs . . . . .	61
C.II.2.	Protecting plants under the CPVR . . . . .	66
C.II.2.a.	General background . . . . .	66
C.II.2.b.	Formal and substantive requirements for grant of a new plant variety right; legal recourse . . . . .	67
C.II.2.c.	Form and duration of the Community Plant Variety Right . . . . .	68
<b>D.</b>	<b>Protectable Matter in the Life Sciences . . . . .</b>	<b>71</b>
<b>D.I.</b>	<b>Small Molecules and Polymers . . . . .</b>	<b>71</b>
D.I.1.	Product claims for low molecular products and polymers . . . . .	73
D.I.2.	Process claims for low molecular products and polymers . . . . .	77
D.I.3.	Use claims/purpose-limited product claims for low molecular products and polymers . . . . .	78
<b>D.II.</b>	<b>Nucleic acids . . . . .</b>	<b>79</b>
D.II.1.	Introduction . . . . .	79
D.II.2.	Protecting nucleic acids under the EPC . . . . .	80
D.II.2.a.	Discoveries . . . . .	80
D.II.2.b.	Morality and “ordre public” . . . . .	81
D.II.2.c.	Methods of treatment . . . . .	82
D.II.2.d.	Novelty . . . . .	82
D.II.2.e.	Inventive Step . . . . .	87
D.II.2.f.	Industrial application . . . . .	96
D.II.2.g.	Sufficiency of disclosure . . . . .	97
D.II.2.h.	Clarity and support of claims . . . . .	106
D.II.2.i.	Product claims for nucleic acids . . . . .	109
D.II.2.i.a.	Product claims characterizing a nucleic acid by functional terms . . . . .	111
D.II.2.i.b.	Product claims characterizing a nucleic acid by part or all of the amino acid sequence of the encoded protein . . . . .	117
D.II.2.i.c.	Product claims characterizing a nucleic acid by part or all of the nucleic acid sequence itself . . . . .	119
D.II.2.i.d.	Product claims characterizing a nucleic acid by parameters . . . . .	122
D.II.2.i.e.	Product claims characterizing a nucleic acid by reference to a deposited microorganism or deposited DNA . . . . .	124
D.II.2.i.f.	Product claims characterizing a nucleic acid by a process for its preparation . . . . .	125
D.II.2.i.g.	Product claims comprising nucleic acids as essential elements . . . . .	127

D.II.2.i.h.	Product claims for certain types of nucleic acids and methods of using same . . . . .	129
D.II.2.j.	Process claims for nucleic acids . . . . .	131
D.II.2.j.a.	Process claims involving genetic engineering or synthesis . . . . .	132
D.II.2.j.b.	Process claims involving isolation from a nucleic acid source . . . . .	132
D.II.2.k.	Use claims/purpose-limited product claims for nucleic acids . . . . .	135
<b>D.III.</b>	<b>Proteins</b> . . . . .	137
D.III.1.	Introduction . . . . .	137
D.III.2.	Protecting proteins under the EPC . . . . .	137
D.III.2.a.	Discoveries . . . . .	138
D.III.2.b.	Morality and “ordre public” . . . . .	139
D.III.2.c.	Methods of treatment . . . . .	139
D.III.2.d.	Novelty . . . . .	139
D.III.2.e.	Inventive step . . . . .	145
D.III.2.f.	Industrial application . . . . .	154
D.III.2.g.	Sufficiency of disclosure . . . . .	156
D.III.2.h.	Clarity and support of claims . . . . .	161
D.III.2.i.	Product claims for proteins . . . . .	166
D.III.2.i.a.	Product claims characterizing a protein by functional terms . . . . .	166
D.III.2.i.b.	Product claims characterizing a protein by parameters . . . . .	168
D.III.2.i.c.	Product claims characterizing a protein by the coding capacity of a certain DNA . . . . .	171
D.III.2.i.d.	Product claims characterizing a protein by its structure . . . . .	172
D.III.2.i.e.	Product claims characterizing a protein by a process for its preparation . . . . .	175
D.III.2.i.f.	Product claims comprising proteins as essential elements . . . . .	177
D.III.2.j.	Process claims for proteins . . . . .	179
D.III.2.j.a.	Process claims involving isolation from a natural environment . . . . .	179
D.III.2.j.b.	Process claims involving synthesis by recombinant host cells . . . . .	180
D.III.2.k.	Use claims/purpose-limited product claims for proteins . . . . .	183
<b>D.IV.</b>	<b>Antibodies</b> . . . . .	184
D.IV.1.	Introduction . . . . .	184
D.IV.2.	Protecting antibodies under the EPC . . . . .	184
D.IV.2.a.	Discoveries . . . . .	185
D.IV.2.b.	Morality and “ordre public” . . . . .	186
D.IV.2.c.	Methods of treatment . . . . .	186
D.IV.2.d.	Novelty . . . . .	186
D.IV.2.e.	Inventive Step . . . . .	189
D.IV.2.f.	Industrial application . . . . .	195
D.IV.2.g.	Sufficiency of disclosure . . . . .	195
D.IV.2.h.	Clarity and support of claims . . . . .	200
D.IV.2.i.	Product claims for antibodies . . . . .	203
D.IV.2.i.a.	Product claims characterizing an antibody by functional terms . . . . .	205
D.IV.2.i.b.	Product claims characterizing an antibody by parameters . . . . .	209
D.IV.2.i.c.	Product claims characterizing an antibody by the coding sequence of a certain DNA . . . . .	210
D.IV.2.i.d.	Product claims characterizing an antibody by its structure . . . . .	210
D.IV.2.i.e.	Product claims characterizing an antibody by a process for its preparation . . . . .	213
D.IV.2.i.f.	Product claims comprising antibodies as essential elements . . . . .	215
D.IV.2.j.	Process claims for antibodies . . . . .	216
D.IV.2.j.a.	Process claims involving isolation from a natural environment . . . . .	216

D.IV.2.j.b.	Process claims involving synthesis by a recombinant host cell . . . . .	216
D.IV.2.j.c.	Process claims involving secretion by hybridomas . . . . .	217
D.IV.2.k.	Use claims/purpose-limited product claims for antibodies . . . . .	218
<b>D.V.</b>	<b>Microorganisms</b> . . . . .	219
D.V.1.	Introduction . . . . .	219
D.V.2.	Protecting microorganisms under the EPC . . . . .	219
D.V.2.a.	Discoveries . . . . .	220
D.V.2.b.	Morality and “ordre public” . . . . .	221
D.V.2.c.	Methods of treatment . . . . .	221
D.V.2.d.	Novelty . . . . .	221
D.V.2.e.	Inventive step . . . . .	222
D.V.2.e.a.	Inventive step in cases where the microorganism is a hybridoma . . . . .	222
D.V.2.e.b.	Inventive step in cases where the microorganism is not a hybridoma . . . . .	224
D.V.2.f.	Sufficiency of disclosure . . . . .	226
D.V.2.f.a.	Necessity of a deposit . . . . .	226
D.V.2.f.b.	Other requirements for sufficiency of disclosure . . . . .	229
D.V.2.f.c.	Reproducibility with certainty . . . . .	233
D.V.2.g.	Clarity and support of claims . . . . .	235
D.V.2.g.a.	Functional features in claims . . . . .	235
D.V.2.g.b.	Clarity and the view of the skilled person . . . . .	236
D.V.2.h.	Product claims for microorganisms . . . . .	238
D.V.2.h.a.	Product claims characterizing a microorganism by functional terms . . . . .	239
D.V.2.h.b.	Product claims characterizing a microorganism by a certain DNA or plasmid . . . . .	240
D.V.2.h.c.	Product claims characterizing a microorganism by parameters . . . . .	242
D.V.2.h.d.	Product claims characterizing a microorganism by a process for its preparation . . . . .	243
D.V.2.h.e.	Product claims characterizing a microorganism by its deposit number . . . . .	244
D.V.2.i.	Process claims for microorganisms . . . . .	245
D.V.2.i.a.	Process claims for preparing a microorganism . . . . .	245
D.V.2.i.b.	Process claims involving use of a microorganism . . . . .	248
D.V.2.j.	Use claims/purpose-limited product claims for microorganisms . . . . .	251
<b>D.VI.</b>	<b>Plants</b> . . . . .	252
D.VI.1.	Introduction . . . . .	252
D.VI.2.	Protecting plants under the EPC . . . . .	253
D.VI.2.a.	Morality and “ordre public” . . . . .	253
D.VI.2.b.	Plant varieties and essentially biological processes . . . . .	253
D.VI.2.b.a.	Plant varieties . . . . .	254
D.VI.2.b.b.	Essentially biological processes . . . . .	256
D.VI.2.c.	Sufficiency of disclosure . . . . .	260
D.VI.2.d.	Clarity and support of claims . . . . .	264
D.VI.2.e.	Natural plants . . . . .	266
D.VI.2.e.a.	Product claims for natural plants . . . . .	266
D.VI.2.e.b.	Process claims for natural plants . . . . .	270
D.VI.2.e.c.	Use claims/purpose-limited product claims for natural plants . . . . .	273
D.VI.2.f.	Hybrid plants . . . . .	274
D.VI.2.f.a.	Product claims for hybrid plants . . . . .	274
D.VI.2.f.b.	Process claims for hybrid plants . . . . .	276
D.VI.2.f.c.	Use claims/purpose-limited product claims for hybrid plants . . . . .	278

D.VI.2.g.	Transgenic plants . . . . .	278
D.VI.2.g.a.	Product claims for transgenic plants . . . . .	278
D.VI.2.g.b.	Process claims for transgenic plants . . . . .	284
D.VI.2.g.c.	Use claims/purpose-limited product claims for transgenic plants . . . . .	288
D.VI.2.h.	Parts of plants . . . . .	288
D.VI.2.h.a.	Highly differentiated parts of plants . . . . .	290
D.VI.2.h.a.a.	Product claims for highly differentiated parts of plants . . . . .	290
D.VI.2.h.a.b.	Process claims for highly differentiated parts of plants . . . . .	292
D.VI.2.h.a.c.	Use claims/purpose-limited product claims for highly differentiated parts of plants . . . . .	294
D.VI.2.h.b.	Undifferentiated or poorly differentiated parts of plants . . . . .	295
D.VI.2.h.b.a.	Product claims for undifferentiated or poorly differentiated parts of plants . . . . .	295
D.VI.2.h.b.b.	Process claims for undifferentiated or poorly differentiated parts of plants . . . . .	298
D.VI.2.h.b.c.	Use claims/purpose-limited product claims for undifferentiated or poorly differentiated parts of plants . . . . .	299
D.VI.2.i.	Summary . . . . .	299
<b>D.VII.</b>	<b>Animals</b> . . . . .	300
D.VII.1.	Introduction . . . . .	300
D.VII.2.	Protecting animals under the EPC . . . . .	301
D.VII.2.a.	Sufficiency of disclosure . . . . .	302
D.VII.2.b.	Natural animals . . . . .	303
D.VII.2.b.a.	Product claims for natural animals . . . . .	303
D.VII.2.b.b.	Process claims for natural animals . . . . .	305
D.VII.2.b.c.	Use claims/purpose-limited product claims for natural animals . . . . .	309
D.VII.2.c.	Transgenic animals . . . . .	311
D.VII.2.c.a.	Product claims for transgenic animals . . . . .	311
D.VII.2.c.a.a.	Morality and “ordre public” . . . . .	311
D.VII.2.c.a.b.	Animal varieties and essentially biological processes . . . . .	315
D.VII.2.c.b.	Process claims for transgenic animals . . . . .	318
D.VII.2.c.c.	Use claims/purpose-limited product claims for transgenic animals . . . . .	321
D.VII.2.d.	Parts of animals . . . . .	322
D.VII.2.d.a.	Product claims for parts of animals . . . . .	322
D.VII.2.d.b.	Process claims for parts of animals . . . . .	324
D.VII.2.d.c.	Use claims/purpose-limited product claims for parts of animals . . . . .	327
D.VII.2.e.	Summary . . . . .	328
<b>D.VIII.</b>	<b>Human Body</b> . . . . .	329
D.VIII.1.	Introduction . . . . .	329
D.VIII.2.	Protecting the human body under the EPC . . . . .	329
D.VIII.2.a.	Human body . . . . .	330
D.VIII.2.a.a.	Product claims for the human body . . . . .	330
D.VIII.2.a.b.	Process claims for the human body . . . . .	330
D.VIII.2.a.c.	Use claims/purpose-limited product claims for the human body . . . . .	332
D.VIII.2.b.	Parts of the human body . . . . .	333
D.VIII.2.b.a.	Product claims for parts of the human body . . . . .	333
D.VIII.2.b.b.	Process claims for parts of the human body . . . . .	335
D.VIII.2.b.c.	Use claims/purpose-limited product claims for parts of the human body . . . . .	337
D.VIII.2.b.d.	Human stem cells . . . . .	337
D.VIII.2.b.d.a.	Introduction . . . . .	337

D.VIII.2.b.d.b.	Totipotent human stem cells . . . . .	339
D.VIII.2.b.d.c.	Pluripotent human stem cells . . . . .	339
D.VIII.2.b.d.d.	Cells obtained by somatic cellular nuclear transfer (SCNT) . . . . .	339
D.VIII.2.b.d.e.	Stem cells obtained by parthenogenesis . . . . .	340
D.VIII.2.b.d.f.	Adult stem cells . . . . .	340
D.VIII.2.b.d.g.	Examples for allowed claims in the field of human stem cells . . . . .	340
D.VIII.2.c	Summary . . . . .	342
<b>E.</b>	<b>Patent Infringement</b> . . . . .	343
<b>E.I.</b>	<b>Introduction</b> . . . . .	343
E.I.1.	Pre-Suit Considerations . . . . .	343
E.I.2.	Cross-Border Issues . . . . .	345
E.I.2.a.	General Principles – limited territorial reach . . . . .	345
E.I.2.b.	Cross-Border Injunction . . . . .	346
E.I.2.c.	Torpedo Actions . . . . .	347
<b>E.II.</b>	<b>Scope of Protection</b> . . . . .	348
E.II.1.	Claim Construction and Literal Infringement . . . . .	348
E.II.2.	Equivalent Infringement and Purposive Construction . . . . .	350
E.II.3.	Specific Claim Categories . . . . .	355
E.II.3.a.	Product Claims/Compound Claims . . . . .	355
E.II.3.b.	Composition claims . . . . .	356
E.II.3.c.	Product-by-Process Claims . . . . .	357
E.II.3.d.	(Second Medical) Use Claims/“Off label” Use . . . . .	358
E.II.3.e.	Companion Diagnostic Claims . . . . .	361
E.II.3.f.	Screening Processes and Reach Through Claims . . . . .	356
E.II.3.g.	SPCs . . . . .	365
E.II.3.h.	Plant Variety Rights . . . . .	366
E.II.4.	Effects of the Patent – Overview . . . . .	367
E.II.5.	Issues particular to the life sciences . . . . .	368
E.II.5.a.	Bolar Provision . . . . .	368
E.II.5.b.	Experimental Use . . . . .	371
E.II.5.c.	Research Tools . . . . .	372
E.II.5.d.	EU Biotech Directive . . . . .	373
E.II.5.e.	Limitations of patent protection available to gene sequences – the Monsanto decision . . . . .	374
<b>E.III.</b>	<b>Enforcement options</b> . . . . .	375
E.III.1.	Introduction . . . . .	375
E.III.2.	Cease and Desist Letter . . . . .	375
E.III.3.	Criminal Proceedings . . . . .	375
E.III.4.	Border Seizure . . . . .	376
E.III.5.	Decision on the merits . . . . .	377
E.III.5.a.	Bifurcation . . . . .	377
E.III.5.b.	Discovery . . . . .	378
E.III.5.c.	Preliminary Relief/Preliminary Injunctions . . . . .	379
<b>E.IV.</b>	<b>Antitrust</b> . . . . .	382
E.IV.1.	Introduction . . . . .	382
E.IV.2.	Sector Inquiry (Pharmaceuticals) . . . . .	383
E.IV.3.	“Pay-for-delay”/Lundbeck decision . . . . .	384
<b>E.V.</b>	<b>Unitary Patent and Unified Patent Court</b> . . . . .	385
E.V.1.	Introduction . . . . .	385
E.V.2.	Language . . . . .	385

E.V.3.	Unified Patent Court . . . . .	386
E.V.3.a.	Introduction . . . . .	386
E.V.3.b.	Structure . . . . .	386
E.V.3.c.	Jurisdiction . . . . .	387
E.V.3.d.	Transitional Period and “opt out” . . . . .	388
E.V.3.e.	Panels . . . . .	389
E.V.4.	Sources of Law . . . . .	389
E.V.5.	Provisional Measures . . . . .	390
E.V.6.	Parties and their Representation before the UPC . . . . .	390
E.V.7.	Procedural Issues . . . . .	391
<b>Annexes</b>		
Annex 1	EPC: Articles . . . . .	393
Annex 2	EPC: Rules – Patentability . . . . .	400
Annex 3	EPC: Rules – Biological sequences . . . . .	402
Annex 4	EPC: Rules – Biological deposits . . . . .	410
Annex 5	EPC: Rules – Form of claims . . . . .	413
Annex 6	EU-Directive 98/44/EC – Biotech Directive . . . . .	415
Annex 7	EU Regulations on SPCs (Medicinal products/Plant protection products) . . . . .	419
Annex 8	EU and international regulations relating to plant varieties . . . . .	421
Annex 9	Bolar Directives . . . . .	433
Annex 10	Register of cited decisions . . . . .	434
<b>Index</b>	. . . . .	443



## Abbreviations

Art.	Article
BeckRS	Beck-Rechtsprechung (Beck-Case Law)
BIE	Bijblad bij De Industriële Eigendom (since March 2010: Berichten Industriële Eigendom)
BGH	Bundesgerichtshof (German Federal Court of Justice)
CJEU	Court of Justice of the European Union
CPVO	Community Plant Variety Office
CPVR	EU Regulation on Community Plant Variety Rights
EC	European Community
EMA	European Medicine Agency
RGZ	Entscheidungen des Reichsgerichts
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EWCA	England and Wales Court of Appeal Decisions
EWHC	England and Wales High Court of Justice Decisions
FSR	Fleet Street Reports
GRUR	Gewerblicher Rechtsschutz und Urheberrecht (Intellectual Property and Copyright Law)
GRUR Int.	Gewerblicher Rechtsschutz und Urheberrecht – International Part
GRUR-RR	Gewerblicher Rechtsschutz und Urheberrecht – Rechtsprechungs – Report (Case Law Report)
Guidelines	Guidelines for Examination in the EPO
IIC	International Review of Industrial Property and Copyright Law, Since 2004: International Review of Intellectual Property and Competition Law
InstGE	Entscheidungen der Instanzgerichte zum Recht des geistigen Eigentums (Decisions of courts concerning intellectual property)
JW	Juristische Woche (Journal)
LS	Die Leitsatzkartei des deutschen Rechts (Catalog of headnotes from German law)
MSPC	Supplementary Protection Certificate for Medicinal Products
OJ EPO	Official Journal of the EPO
OJL	Official Journal of the European Union (L series)
PCT	Patent Cooperation Treaty
PE	Pediatric Extension
RGZ	Entscheidungen des Reichsgerichts
SPSP	Supplementary Protection Certificate for Plant Protection Products
RGZ	Entscheidungen des Reichsgerichts in Zivilsachen (Decisions by the former Supreme Court in civil cases)
RPC	Reports of Patent, Design and Trade Mark Cases
Rule	Rule from Implementing Regulations to the EPC on the Grant of European Patents
Sec.	Section
SPC	Supplementary Protection Certificate

TRIPS	.....	Agreement on Trade-Related Aspects of Intellectual Property Rights
UKHL	.....	United Kingdom House of Lords Decisions
UPOV	.....	International Union for the Protection of New Varieties of Plants
WIPO	.....	World Intellectual Property Organization