

Contents

IP Issues of Therapeutic Antibodies	1
Ulrich Storz	
1 Introduction	1
2 Compound Protection	3
2.1 Specification by Target	4
2.2 Specification by Target-Independent Functional Properties	6
2.3 Specification by Epitope	6
2.4 Specification by Target-Dependent Functional Properties	7
2.5 Specification by Sequence	7
2.6 Specification by Deposited Cell Line or Product-by-Process	9
3 Other Types of Follow-Up Protection	9
3.1 Second Medical Use	10
3.2 Combination Therapy	10
3.3 Dosage Regimen	11
3.4 Formulation and Galenics	12
4 New Antibody Formats	12
5 Antibody Mimetics	14
6 Conclusion	16
References	16
Peptide Vaccines and Peptide Therapeutics	17
Wolfgang Flasche	
1 Introduction	17
2 Definition of Peptides	18
3 Market Overview	18
4 Therapeutic Peptides in Patents	19
5 Peptides in Vaccines	19

6	Alignment	25
7	The Skilled Artisan	26
8	Fusion Proteins	26
9	Unity of the Invention	27
	9.1 Markush Claims	28
	9.2 What About Peptides?	30
10	Definitions and Problems Related to Definitions	33
	10.1 Homology	34
	10.2 Variants	34
	10.3 Analogs	37
	10.4 Chemical Modifications	38
	10.5 Decisions of the Board of the Appeal of the European Patent Office Concerning Pharmaceutical Active Peptides	41
	10.6 Examples of Specific Problems Related to Peptide-Related Inventions	42
11	The Situation in the USA	49
	11.1 Patentable Subject Matter	50
	11.2 35 U.S.C. 112, First Paragraph: Written Description and Enablement	53
	11.3 Restriction Practice and “Improper Markush” Rejections	59
	11.4 Obviousness	62
12	Patenting Peptide-Related Inventions in China	64
	12.1 Peptide-Related Inventions are Patentable Subject Matter in China	65
	12.2 Novelty and Inventiveness of Peptide-Related Inventions	65
	12.3 Sufficiency of Disclosure Under Chinese Law	66
	12.4 Submission of Post-Filing Data	67
	12.5 Unity of Invention	68
	12.6 Experimental Use Exemption to Patent Infringement	69
13	Conclusion	70
	References	70
	Patent Landscape in Molecular Diagnostics	73
	Johanna Driehaus	
	1 Introduction	73
	2 Legal Background	74
	3 Key Technologies	76
	3.1 Polymerase Chain Reaction	76
	3.2 Reverse Transcriptase PCR	78
	3.3 Real-Time PCR	80
	3.4 Sequencing	81

Contents	ix
3.5 Pyrosequencing	82
3.6 Nucleic Acid Extraction.	83
3.7 Recombinant DNA and Molecular Cloning	86
3.8 DNA Methylation	90
4 Key Applications.	91
4.1 Infectious Diseases	91
4.2 Cancer-Related Applications.	93
4.3 Further Important Patents.	97
4.4 Laser Microdissection	99
4.5 Forensics	100
5 Outlook	101
6 Considerations Concerning Patent Protection	102
6.1 Introduction	102
6.2 Biological Compounds.	103
7 Drafting Recommendations Concerning Molecular Diagnostics	103
7.1 Nucleic Acid Patents.	103
7.2 Depositing a Cell Line.	105
7.3 Claim Wording.	105
References	105
About the Authors.	107