EXTENDED CONTENTS

List of figures xv
List of tables xvi
List of contributors xvii
Table of cases xix
Table of legislation xxxviii

1 Competition law and pharma: an economic perspective
Benoît Durand
1. INTRODUCTION 1.1
2. AN R&D INTENSIVE INDUSTRY 1.21
3. THE DETERMINANTS OF R&D INTENSITY IN THE PHARMACEUTICAL INDUSTRY 1.24
4. COMPETITION AND THE PATENT SYSTEM 1.28
5. DELAYING THE ENTRY OF GENERICS 1.35
   A. Strategic use of the patent system 1.41
   B. Product hopping 1.48
   C. Disparaging the generic version 1.52
6. THE EFFECTS OF PARALLEL TRADE 1.55
   A. The development of parallel imports in the EEA 1.60
   B. The effect of parallel imports on prices 1.65
   C. The effect of parallel imports on innovation 1.70
7. THE DEMAND AND PRICING OF PHARMACEUTICAL PRODUCTS 1.78
   A. Demand for pharmaceuticals: institutional details 1.80
   B. Countervailing buyer power in the pharmaceutical industry 1.84
   C. In-hospital and out-of-hospital pricing 1.93

2 Reverse payments: an EU and US perspective
Frank Maier-Rigaud, Nathan Blalock and Oliver Gannon
1. INTRODUCTION 2.1
   A. Overview of recent investigations by competition authorities 2.6
   B. Existence of beneficial reverse payment settlements 2.10
   C. Effects-based analysis of restrictions is required in the assessment of reverse payment settlements 2.12
2. SETTLEMENT AS THE OUTCOME OF IMPERFECT INFORMATION 2.15
3. WHAT ARE REVERSE PAYMENT SETTLEMENTS? 2.19
4. THE INCENTIVES OF ORIGINATORS AND GENERIC COMPANIES TO SETTLE 2.23
   A. Originators face numerous threats to profits prior to patent expiration 2.25
   B. Options for generic companies 2.46
5. FACT-SPECIFIC INQUIRY REQUIRED TO DETERMINE ANTICOMPETITIVENESS OF REVERSE PAYMENT SETTLEMENTS 2.51
   A. How do generic companies and originators evaluate the decision to enter into reverse payment settlements? An economic assessment 2.51
   B. How are the competitive effects of patent settlements without value transfers evaluated? 2.60
   C. How are the competitive effects of a reverse payment settlement evaluated with value transfers? 2.64
6. THE EUROPEAN APPROACH 2.77
   A. Overview of the regulatory assessment in Europe 2.77
   B. The Pharmaceutical Sector Inquiry 2.84
EXTENDED CONTENTS

3 Article 101 TFEU: horizontal cooperation agreements in the pharmaceutical sector
Soledad Blanco Thomas, Lilia Luchianov and Thomas Weck
1. INTRODUCTION 3.1
2. THE APPLICABLE EU COMPETITION RULES 3.6
   A. Article 101 TFEU 3.10
   B. Applicable EU regulations, guidelines and notices relevant for the assessment of horizontal cooperation 3.26
   C. Safe harbours, de minimis notice and block exemptions 3.28
   D. Ancillary restraints 3.44
   E. Individual assessment 3.46
3. THE RELEVANCE OF SECTOR INQUIRIES AND OTHER STUDIES ON COMPETITION IN THE PHARMACEUTICAL SECTOR 3.51
   A. EU Commission’s sector inquiries 3.52
   B. National sector inquiries and studies 3.60
4. SPECIFIC ISSUES OF HORIZONTAL AGREEMENTS IN THE PHARMACEUTICAL SECTOR 3.69
   A. Preliminary concepts 3.73
   B. Patent settlement agreements 3.95
   C. Co-promotion agreements 3.180
   D. Market sharing agreements 3.205
   E. Co-marketing agreements 3.217
   F. Agreements concerning the use of the patent system 3.227
   G. Other horizontal agreements 3.236
5. COMPETITION IN NEW PHARMACEUTICAL AREAS: BIOLOGICAL AND BIOSIMILAR MEDICINES 3.262

4 The competitive assessment of IP licensing agreements in the pharmaceutical sector
Pierre Moullet
1. INTRODUCTION 4.1
2. COMPETITION ENFORCEMENT IN INNOVATIVE INDUSTRIES 4.7
   A. Static v. dynamic competition 4.7
   B. Relationships between competition and IP law 4.12
3. APPLICATION OF ARTICLE 101 TFEU TO TECHNOLOGY LICENSING AGREEMENTS 4.19
   A. Within the TTBER 4.20
   B. Outside the TTBER 4.42

5 Article 102 TFEU: patent filings as an abuse of dominant position after AstraZeneca: the patent–antitrust interface under a new perspective
Francisco Hernández
1. INTRODUCTION 5.1
2. THE APPLICATION OF ARTICLE 102 TFEU TO PATENT RIGHTS: THE TRADITIONAL APPROACH 5.14
3. THE NEW ANTITRUST ACTIVISM IN THE PHARMACEUTICAL MARKETS 5.27
   A. The Pharmaceutical Sector Inquiry, Final Report 5.28
   B. The judgment of the Court of Justice in AstraZeneca 5.36
   C. The Pfizer case 5.45
4. EUROPEAN COMPETITION LAW IN THE TWENTY-FIRST CENTURY: THE FRAMEWORK FOR A NEW PATENT–ANTITRUST INTERFACE 5.54
### 5. The Application of Article 102 to Patent Filings up to Date: The Weakness of the AstraZeneca Approach

5.76

### 6. Conclusion: The Pharmaceutical Market Experience – A New Frame for the IP–Antitrust Interface in Europe?

5.92

### 6 Mergers in the Pharmaceutical Sector

**Pablo Figueroa and Alejandro Guerrero**

1. **Introduction**
   6.1

2. **Market Definition**
   6.2
   - A. Product market definition for finished dose pharmaceutical products
   - B. Markets upstream and downstream from finished pharmaceuticals
   6.31

3. **Geographic Market Definition**
   6.40
   - A. Finished pharmaceuticals
   - B. Markets upstream of finished pharmaceuticals
   - C. Markets downstream of finished pharmaceuticals
   6.43

4. **Competitive Analysis in the Pharmaceutical Sector**
   6.45
   - A. Preliminary considerations
   - B. The Commission’s approach to affected markets
   - C. Key competitive drivers in the pharmaceutical markets
   - D. Remedies and commitments in merger control
   6.61

5. **Conclusions**
   6.67

### 7 Mergers in the Medical Devices Sector

**Jan Heithecker**

1. **Introduction and Overview**
   7.1

2. **Market Definition**
   7.6
   - A. Introduction and overview
   - B. In-vitro diagnostics devices
   - C. Diagnostic imaging devices
   - D. Orthopaedic devices
   - E. Cardiovascular devices
   - F. Other medical capital goods
   - G. Consumable medical devices
   - H. Geographic market definition
   7.78

3. **Competitive Assessment**
   7.83
   - A. Introduction and overview
   - B. Horizontal concerns
   - C. Non-horizontal concerns
   7.106

### 8 Antitrust Practices in Pharmaceutical Public Procurement

**Antonio Miño López**

1. **Introduction**
   8.1

2. **Bid Rigging: Concept and Essential Features**
   8.6
   - A. Concept: paradigm of cartels
   - B. Restriction by object
   - C. Unifying purpose and stability
   - D. Massive harmful potential
   - E. The *non bis in idem* principle
   - F. Public policies inducing parallel behaviour: the *Ethicon* case
   8.27

3. **Types of Collusive Practices in the Public Procurement of Drugs and Related Markets**
   8.32
   - A. Introduction
   - B. Information exchange
   - C. Price fixing
   8.42

4. **Abuse of Dominant Position**
   8.124
   - A. Introduction
   - B. Market definition
   - C. Dominant position
   - D. Abusive practices
   8.153
5. ANTITRUST LIABILITY OF CONTRACTING AUTHORITIES
   A. ECJ’s FENIN/Selex doctrine: dismissal of liability on the basis of the
   “not-for-the-market” use of the purchased products
   B. Different national solutions
   C. United Kingdom singularity
6. IS THERE ANY WAY TO AVOID BID RIGGING?
7. CONCLUSIONS

9 EU trade law and pharmaceuticals
   Pascale Hecker
   1. INTRODUCTION
   2. BACKGROUND: TRIPS AND ACCESS TO ESSENTIAL MEDICINES
   A. Harmful consequences of the entry into force of TRIPS for access to essential
   medicines in developing countries
   B. The Doha Declaration and the Waiver Decision: an attempt at mitigating the
   harmful effects of TRIPS
   C. Willingness to impose TRIPS-plus obligations on developing countries
   3. AN ANALYSIS OF EU TRADE MEASURES THAT FAVOUR IP PROTECTION OVER
   ACCESS TO ESSENTIAL MEDICINES
   A. EU rules on customs enforcement of IP rights
   B. The EU-India free trade agreement: an example of EU’s policy with regard to the
   inclusion of IP chapters in bilateral trade agreements
   4. AN ANALYSIS OF EU TRADE MEASURES THAT FAVOUR ACCESS TO ESSENTIAL
   MEDICINES OVER IP PROTECTION
   A. Regulation 953/2003 setting up a tiered-pricing mechanism: a very seldom used
   mechanism
   B. Regulation 816/2006 on compulsory licence of generic medicines: an unused
   mechanism
   5. CONCLUSION

10 The pharmaceutical sector and parallel trade
   Edurne Navarro Varona and Cristina Caballero Candelario
   1. THE PHARMACEUTICAL SECTOR AND PARALLEL TRADE
   A. Introduction
   B. Disparate prices and access to pharmaceutical products
   C. Concept of parallel trade
   D. Parallel trade in the pharmaceutical sector and competition law
   2. THE ECONOMICS OF PARALLEL TRADE
   A. Parallel trade and consumers’ welfare
   B. Parallel trade and innovation
   3. CONCLUSION

11 Free movement and competition in the European market for pharmaceuticals
   Pedro Caro de Sousa
   1. INTRODUCTION
   2. THE STRUCTURE OF THE EUROPEAN MARKET FOR PHARMACEUTICAL PRODUCTS
   A. Supply side
   B. Demand side
   3. FREE MOVEMENT LAW AND PHARMACEUTICAL PRODUCTS
   A. Supply side
   B. Demand side
   4. CONCLUSIONS – FREE MOVEMENT AND COMPETITION IN PHARMACEUTICALS

12 IP law and pharmaceuticals: patents and supplementary protection certificates in
   the pharmaceutical sector
   Rais Amils
   1. INTRODUCTION
   2. PATENTS IN THE PHARMACEUTICAL SECTOR
   A. Routes to apply for a patent
B. Requisites of patentability: novelty, inventive step, industrial application and sufficiency of disclosure 12.23
C. Patent infringement: reference made to literal and by equivalence infringement, and to direct and contributory infringement 12.64
D. Exemptions to the patentee’s ius prohibendi: experimental use and Bolar clause 12.79

3. SUPPLEMENTARY PROTECTION CERTIFICATES FOR PHARMACEUTICAL PRODUCTS 12.92
A. Scope of the SPC Regulation 12.95
B. Subject-matter of protection and effects of the SPC 12.98
C. Conditions to be met in order for an SPC to be granted 12.100
D. Duration of an SPC 12.115
E. Grounds for the invalidity of an SPC 12.122

4. CONCLUSION 12.123

13 The EU regulatory framework for medicinal products for human use
Marc Martens and Nicolas Carbonnelle

1. INTRODUCTION 13.1
2. OVERVIEW OF THE EU PHARMACEUTICAL REGULATORY ENVIRONMENT AND ITS MAIN ADMINISTRATIVE ACTORS 13.7
A. Legal framework 13.7
B. Main stakeholders 13.13

3. MEDICINAL PRODUCTS AND BORDERLINE PRODUCTS 13.18
A. Definition 13.18
B. Borderline products 13.20

4. SPECIFIC CATEGORIES OF MEDICINAL PRODUCTS AND THEIR PARTICULARITIES 13.23
A. Biological medicinal products 13.23
B. Radiopharmaceuticals 13.43
C. Homeopathic medicinal products 13.46
D. Herbal medicinal products 13.50
E. Traditional herbal medicinal products 13.52
F. Paediatrics 13.56
G. Orphan drugs 13.60

5. MARKET ACCESS FOR MEDICINAL PRODUCTS 13.64
A. Common traits of the procedures: dossier requirements 13.66
B. The centralised MA procedure 13.69
C. The national routes 13.84
D. Term of validity of an MA and renewal 13.89
E. Variations and extensions 13.91
F. Exceptions to the obligation to obtain a marketing authorisation 13.93
G. Scientific advice and protocol assistance 13.96
H. Latest developments 13.99

6. ABRIDGED PROCEDURES 13.105
A. Generics 13.108
B. Biosimilars 13.111
C. Bibliographic procedure 13.115
D. Informed consent procedure 13.116
E. Hybrid procedure 13.117

7. CLINICAL TRIALS 13.118
A. Applicable legislation 13.118
B. The requirements under Directive 2001/20/EC 13.123
C. The new Clinical Trials Regulation 13.160

8. PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS: A NON-HARMONISED MATTER 13.168
A. General points 13.168
B. Provisions relating to pricing 13.171
C. Provisions relating to reimbursement schemes 13.175
EXTENDED CONTENTS

9. PHARMACOVIGILANCE 13.184
   A. Duties of the Member States and the EMA 13.187
   B. MAH obligations 13.193
10. CONCLUSION AND PERSPECTIVES 13.208

14 Antitrust and the pharmaceutical industry in the United States
   George A. Hay
   1. INTRODUCTION 14.1
   2. REVERSE PAYMENTS 14.6
      A. The first wave of reverse payment cases 14.14
   3. PRODUCT-HOPPING 14.24
      A. The cases 14.28
   4. EXCESSIVE PRICING 14.49
   5. “INVERSION” MERGERS 14.57
   6. PHARMACY-BENEFIT-MANAGER (“PBM”) MERGERS 14.59
   7. CONCLUSION 14.64

15 UK competition and trade in the pharma sector
   Paula Riedel
   1. LEGISLATION 15.1
   2. INDUSTRY AND REGULATORY BACKDROP 15.8
   3. COMPETITION ACT 1998 15.16
      A. Napp Pharmaceutical Holdings Limited (“Napp”) 15.16
      B. Genzyme Limited (“Genzyme”) 15.44
      C. Reckitt Benckiser (“Reckitt Benckiser”) 15.60
      D. Paroxetine 15.76
      E. Phenytoin Sodium 15.104
   4. MARKET STUDIES AND MARKET INVESTIGATIONS IN THE PHARMACEUTICAL SECTOR 15.127
      A. The control of entry regulations and retail pharmacy services in the UK (“Control of Entry market study”) 15.128
      B. OFT market study: the Pharmaceutical Price Regulation Scheme (“PPRS market study”) 15.136
      C. OFT market study: Medicines Distribution (“Medicines Distribution”) 15.144

16 Competition law and pharma: China
   Andrew L. Foster
   1. COMPETITION LAW IN CHINA 16.1
   2. RELEVANT COMPETITION AND PHARMACEUTICAL REGULATORY REGIMES 16.4
      A. Relevant competition legislation and extraterritorial application 16.4
      B. Competition enforcement in China 16.7
      C. Regulatory pharmaceutical pricing regime in China 16.14
   3. ANTICOMPETITIVE AGREEMENTS BETWEEN COMPETITORS (HORIZONTAL) 16.15
      A. Relevant legislation 16.15
      B. Enforcement and penalties 16.22
      C. Significant enforcement activity in the pharmaceutical industry 16.26
   4. ANTICOMPETITIVE AGREEMENTS BETWEEN TRADING PARTNERS (VERTICAL) 16.30
      A. Relevant legislation 16.30
      B. Enforcement and penalties 16.35
      C. Significant enforcement activity 16.39
   5. MARKET DOMINANCE 16.48
      A. Relevant legislation 16.48
      B. Significant enforcement activities in the pharmaceutical industry 16.66
   6. INVESTIGATIONS OF PHARMACEUTICAL PRICING BEHAVIOUR 16.73
      A. Relevant legislation 16.74
      B. Recent NDRC enforcement activity 16.92
      C. Other recent national and local enforcement activities 16.98
   7. ADMINISTRATIVE MONOPOLY 16.102
      A. Relevant legislation 16.102
      B. Significant enforcement activity 16.106
EXTENDED CONTENTS

B. Agreements and concerted practices aimed at restricting third party access to pharmaceutical marketing data 20.25
C. Unilateral conduct aimed at restricting third party access to pharmaceutical marketing data 20.25
4. DATA AND MERGER CONTROL 20.43
   A. The issue of merger control thresholds 20.43
   B. Data in merger control matters 20.49
5. CONCLUSION 20.50

Index 761