PLI'S COMPLETE LIBRARY OF TREATISE TITLES

ART LAW

BANKING & COMMERCIAL LAW
Asset-Based Lending: A Practical Guide to Secured Financing
Equipment Leasing–Leveraged Leasing
Hillman on Commercial Loan Documentation
Hillman on Documenting Secured Transactions: Effective Drafting and Litigation
Maritime Law Answer Book

BANKRUPTCY LAW
Bankruptcy Deskbook
Personal Bankruptcy Answer Book

BUSINESS, CORPORATE & SECURITIES LAW
Accountants' Liability
Anti-Money Laundering: A Practical Guide to Law and Compliance
Antitrust Law Answer Book
Broker-Dealer Regulation
Conducting Due Diligence in a Securities Offering
Consumer Financial Services Answer Book
Corporate Compliance Answer Book
Corporate Legal Departments: Practicing Law in a Corporation
Corporate Political Activities Deskbook
Corporate Whistleblowing in the Sarbanes-Oxley/Dodd-Frank Era
Covered Bonds Handbook
Cybersecurity: A Practical Guide to the Law of Cyber Risk
Derivatives Deskbook: Close-Out Netting, Risk Mitigation, Litigation
Deskbook on Internal Investigations, Corporate Compliance, and White Collar Issues
Directors' and Officers' Liability: Current Law, Recent Developments, Emerging Issues
Doing Business Under the Foreign Corrupt Practices Act
EPA Compliance and Enforcement Answer Book
Exempt and Hybrid Securities Offerings
Fashion Law and Business: Brands & Retailers
Financial Institutions Answer Book: Law, Governance, Compliance
Financial Product Fundamentals: Law, Business, Compliance
Financial Services Mediation Answer Book
Financial Services Regulation Deskbook
Financially Distressed Companies Answer Book
Global Business Fraud and the Law: Preventing and Remedying Fraud and Corruption
Hedge Fund Regulation
Initial Public Offerings: A Practical Guide to Going Public
Insider Trading Law and Compliance Answer Book
Insurance and Investment Management M&A Deskbook
International Corporate Practice: A Practitioner's Guide to Global Success
Investment Adviser Regulation: A Step-by-Step Guide to Compliance and the Law
Life at the Center: Reflections on Fifty Years of Securities Regulation
Mergers, Acquisitions and Tender Offers: Law and Strategies
Mutual Funds and Exchange Traded Funds Regulation
Outsourcing: A Practical Guide to Law and Business
Privacy Law Answer Book
Private Equity Funds: Formation and Operation
Prokauer on Privacy: A Guide to Privacy and Data Security Law in the Information Age
Public Company Deskbook: Complying with Federal Governance & Disclosure Requirements
SEC Compliance and Enforcement Answer Book
Securities Investigations: Internal, Civil and Criminal
Securities Law and Practice Handbook
The Securities Law of Public Finance
Securities Litigation: A Practitioner's Guide
Social Media and the Law
Soderquist on Corporate Law and Practice
Sovereign Wealth Funds: A Legal, Tax and Economic Perspective
A Starter Guide to Doing Business in the United States
Technology Transactions: A Practical Guide to Drafting and Negotiating Commercial Agreements
Variable Annuities and Variable Life Insurance Regulation

COMMUNICATIONS LAW
Advertising and Commercial Speech: A First Amendment Guide
Sack on Defamation: Libel, Slander, and Related Problems
Telecommunications Law Answer Book

EMPLOYMENT LAW
Employment Law Yearbook
ERISA Benefits Litigation Answer Book
Labor Management Law Answer Book

ESTATE PLANNING AND ELDER LAW
Blattmachr on Income Taxation of Estates and Trusts
Estate Planning & Chapter 14: Understanding the Special Valuation Rules
International Tax & Estate Planning: A Practical Guide for Multinational Investors
Manning on Estate Planning
New York Elder Law
Stocker on Drawing Wills and Trusts

HEALTH LAW
FDA Deskbook: A Compliance and Enforcement Guide
Health Care Litigation and Risk Management Answer Book
Health Care Mergers and Acquisitions Answer Book
Medical Devices Law and Regulation Answer Book
Pharmaceutical Compliance and Enforcement Answer Book

IMMIGRATION LAW
Fragomen on Immigration Fundamentals: A Guide to Law and Practice

INSURANCE LAW
Business Liability Insurance Answer Book
Insurance Regulation Answer Book
Reinsurance Law

INTELLECTUAL PROPERTY LAW
Copyright Law: A Practitioner's Guide
Faber on Mechanics of Patent Claim Drafting
How to Write a Patent Application
Intellectual Property Law Answer Book
Kane on Trademark Law: A Practitioner's Guide
Likelihood of Confusion in Trademark Law
Patent Claim Construction and Markman Hearings
Patent Licensing and Selling: Strategy, Negotiation, Forms
Patent Litigation
Pharmaceutical and Biotech Patent Law
Post-Grant Proceedings Before the Patent Trial and Appeal Board
Substantial Similarity in Copyright Law
Trade Secrets: A Practitioner's Guide
LITIGATION
American Arbitration: Principles and Practice
Class Actions and Mass Torts Answer Book
Electronic Discovery Deskbook
Essential Trial Evidence: Brought to Life by Famous Trials, Films, and Fiction
Expert Witness Answer Book
Evidence in Negligence Cases
Federal Bail and Detention Handbook
How to Handle an Appeal
Medical Malpractice: Discovery and Trial
Product Liability Litigation: Current Law, Strategies and Best Practices
Sinclair on Federal Civil Practice
Trial Handbook

REAL ESTATE LAW
Commercial Ground Leases
Friedman on Contracts and Conveyances of Real Property
Friedman on Leases
Holtzschue on Real Estate Contracts and Closings: A Step-by-Step Guide to Buying and Selling Real Estate
Net Leases and Sale-Leasebacks

TAX LAW
The Circular 230 Deskbook: Related Penalties, Reportable Transactions, Working Forms
The Corporate Tax Practice Series: Strategies for Acquisitions, Dispositions, Spin-Offs, Joint Ventures, Financings, Reorganizations & Restructurings
Foreign Account Tax Compliance Act Answer Book
Internal Revenue Service Practice and Procedure Deskbook
International Tax & Estate Planning: A Practical Guide for Multinational Investors
International Tax Controversies: A Practical Guide
International Trade Law Answer Book: U.S. Customs Laws and Regulations
Langer on Practical International Tax Planning
The Partnership Tax Practice Series: Planning for Domestic and Foreign Partnerships, LLCs, Joint Ventures & Other Strategic Alliances
Private Clients Legal & Tax Planning Answer Book
Transfer Pricing Answer Book

GENERAL PRACTICE PAPERBACKS
Anatomy of a Mediation: A Dealmaker’s Distinctive Approach to Resolving Dollar Disputes and Other Commercial Conflicts
Attorney-Client Privilege Answer Book
Drafting for Corporate Finance: Concepts, Deals, and Documents
Pro Bono Service by In-House Counsel: Strategies and Perspectives
Smart Negotiating: How to Make Good Deals in the Real World
Thinking Like a Writer: A Lawyer’s Guide to Effective Writing & Editing
Working with Contracts: What Law School Doesn’t Teach You

Order now at www.pli.edu
Or call (800) 260-4754 Mon.–Fri., 9 a.m.–6 p.m.

Practising Law Institute
1177 Avenue of the Americas
New York, NY 10036

When ordering, please use Priority Code NWS9-X.
About the Authors

David K. Barr, Partner — David Barr’s practice is concentrated in the areas of patent, trade secret, and unfair competition litigation and counseling, and intellectual property licensing. Mr. Barr has represented clients in litigation in federal and state courts and before the U.S. Patent and Trademark Office. Mr. Barr has litigated many complex patent infringement cases and has counseled clients on product development and strategic patent planning. He has also negotiated and drafted numerous intellectual property licenses and agreements. His patent matters have involved a variety of technologies, including biotechnology, pharmaceuticals, industrial chemistry, biomedical and mechanical devices, computer systems, telecommunications, and oil and natural gas drilling technologies. Mr. Barr has authored articles and has lectured on a variety of intellectual property issues. Mr. Barr received the 2004 Burton Award for Legal Achievement in Writing.

Daniel L. Reisner, Partner — Daniel Reisner’s practice is concentrated in patent and trade secret litigation, arbitration, and licensing. He has represented clients in matters involving pharmaceuticals, including new chemical entities, formulations, methods of treatment, and research tools, as well as in matters involving biotechnology, medical diagnostics, surgical devices, computers and computer networking, plastic injection molding, and aircraft systems. He has also negotiated and drafted numerous patent and technology licenses, and advised clients on patent misuse issues. Mr. Reisner has authored numerous articles on a variety of intellectual property issues, including contributions to special Intellectual Property and Biotechnology sections appearing in the New York Law Journal. He received the 2004 Burton Award for Legal Achievement in Writing.

David O. Bickart, Partner — David Bickart has represented an array of pharmaceutical companies on patent and data exclusivity issues under the Federal Food, Drug, and Cosmetic Act and the Patent Act both before the Food and Drug Administration, and U.S. courts, including the U.S. Courts of Appeals for the District of Columbia and the Federal Circuits. Mr. Bickart has also represented leading national advertisers and marketers before the Federal Trade Commission and state
consumer protection offices in litigations and investigations involving the advertising and labeling of consumer products. Prior to joining Kaye Scholer in 1981, Mr. Bickart served as Deputy General Counsel to the U.S. Environmental Protection Agency; Deputy Assistant Director for National Advertising, Bureau of Consumer Protection, Federal Trade Commission; law clerk to U.S. Supreme Court Chief Justice Warren E. Burger; and law clerk to Judge Inzer B. Wyatt, U.S. District Court, New York.

Richard G. Greco, Former Partner — Richard Greco has had extensive experience in complex patent litigation. He has represented major pharmaceutical, chemical, and biotechnology companies in patent litigations involving pharmaceutical compounds, recombinant proteins, pharmaceutical formulations and drug delivery systems, immunoassays and devices, nucleic acid testing, recombinant cell research tools, transgenic animals, and processes for producing recombinant products. He has also worked on cases concerning catalysts, computer displays, and electronic devices. His work includes several challenges to Abbreviated New Drug Applications on the world's leading cardiovascular drugs and antibiotics. Mr. Greco is an experienced trial attorney with extensive experience in patent and other commercial cases, as well as criminal trials.

Sylvia M. Becker, Partner — Sylvia Becker concentrates her practice in the areas of intellectual property litigation, including representation of major pharmaceutical companies in complex patent cases and foreign investment issues. Ms. Becker has litigated cases involving patents on methods of treatment, pharmaceutical compositions, antibodies, chemical compounds, and polymorphs. Ms. Becker is fluent in both German and French and has a working knowledge of Spanish. Earlier in her career, Ms. Becker was awarded the Robert Bosch Foundation Fellowship in Germany, during which she worked in the German Foreign Ministry and in both trial level and appellate courts responsible for intellectual property and competition cases.

Stephen J. Elliott, Special Counsel — Stephen Elliott’s practice focuses on complex commercial litigation in matters involving antitrust, intellectual property, and technology. As a patent litigator, he has focused on pharmaceutical patent infringement actions, primarily in the Hatch-Waxman context. He has also defended infringement claims concerning a variety of other technologies, including computer hardware and software, biotechnology, medical devices, and business methods. In the antitrust area, he has extensive
experience in negotiating and defending pharmaceutical patent litigation settlements, and has also defended Robinson-Patman and patent misuse claims. When representing clients on technology, patent, and litigation matters, Mr. Elliott draws on his years of experience as a chemical engineer in the semiconductor and biochemical industries. Mr. Elliott is co-chair of the Technology and Intellectual Property Litigation committee of the Commercial and Federal Litigation Section of the New York State Bar Association and Special Counsel at Sullivan & Cromwell LLP.

Sapna Walter Palla, Counsel — Sapna Palla’s practice focuses on counseling and representing clients in a variety of matters including intellectual property, antitrust, and complex commercial issues. Ms. Palla has practiced before both state and federal courts, including appeals to the Federal Circuit, and has experience in alternative dispute resolution such as arbitration and mediation. In the intellectual property area, Ms. Palla has a broad range of experience in all phases of patent litigation, and her practice encompasses an array of technologies, including pharmaceuticals and biotechnology.

Gerald Sobel, Special Counsel — Gerald Sobel focuses on patent, antitrust, and trade secret litigation. He also handles patent case appeals, particularly at the Federal Circuit. Mr. Sobel has litigated and tried many major cases in a variety of technologies throughout the country. In the medical area, for example, these have included litigation involving pharmaceuticals and diagnostics with among the highest sales, multiple parallel cases and foreign counterpart cases—litigation in which many billions were at stake. His cases include landmark wins creating fundamental patent law principles, and jury wins in the longest biotech patent trial and the longest federal civil jury trial. Mr. Sobel has lectured and published extensively on patent, antitrust, and litigation topics and taught as an adjunct professor at New York University Law School.

Aaron Stiefel, Partner — Aaron Stiefel concentrates his practice in the area of intellectual property litigation, drawing on his graduate degree in chemistry and his wealth of general litigation experience. Mr. Stiefel has represented leading research-based pharmaceutical and biotechnology companies in all aspects of complex patent litigations. His experience includes bringing and defending patent infringement actions concerning antibiotics, antihypertensives, antifungal medications, treatments for erectile dysfunction, the cloning of alpha-interferon, testing of blood for hepatitis C infection, monoclonal antibodies,
contact lenses, surgical devices, methods for producing transgenic mice, and data storage products. Mr. Stiefel litigates against other research-based companies and has also litigated claims brought against generic drug manufacturers under the Hatch-Waxman Act. He has also represented pharmaceutical companies with respect to false advertising and unfair competition claims. Mr. Stiefel also spent time as trial counsel in the office of the New York City Corporation Counsel.

**Betty A. Ryberg** — Betty A. Ryberg joined Novartis in 2008 as Vice President, US IP Litigation for Group Intellectual Property and leads Novartis Corporation’s IP group. Before joining Novartis, she enforced and defended pharmaceutical and biotech patents for major companies as a litigator for Kaye Scholer LLP from 2000 until 2008. At Kaye Scholer, she was instrumental in trial victories concerning a $4 billion hypertensive drug, and a summary judgment victory concerning a $2 billion antifungal. Ms. Ryberg also litigated patent infringement actions for another major New York City law firm. She also did patent and trademark prosecution and litigation at a boutique in Connecticut. Ms. Ryberg earned her Juris Doctor from Quinnipiac University in 1994, was a member of the Moot Court Honor Society and received awards for her writing skills. She graduated in three years from Auburn University in 1984 with a Bachelor of Chemical Engineering, earning an award for the highest grades in her mathematics courses, and played on Auburn’s competitive women’s volleyball team. Prior to attending law school, Ms. Ryberg worked as an engineer for 3M and Pitney Bowes for a combined total of twelve years and is an inventor on several important patents for the latter company. She is a member of the Dean’s Council at Quinnipiac University School of Law, and Auburn University’s Alumni Engineering Council where she is an active member of the Research Committee, and is a past President of the Connecticut Intellectual Property Law Association. She is a registered patent attorney and admitted to the bars of D.C., New York, and Connecticut, as well as the Federal Circuit and various other federal district and appellate courts.

**Dr. Laurence A. Borden** — Dr. Borden received his Ph.D. in Neurobiology from SUNY Health Science Center, Brooklyn, New York, his Bachelor’s Degree in Biology from Long Island University, and his M.S. in Investment Management from the Lubin School of Business, Pace University. He has extensive expertise in the disciplines of neurobiology, pharmacology, and cell biology, with a specialization in the mechanisms of action of drugs used to treat diseases of the nervous system. Previously, Dr. Borden was Director of
Pharmacology at Trophix Pharmaceutical, Inc., prior to which he was a Senior Scientist at Synaptic Pharmaceutical Corporation. Dr. Borden has been a member of the Society for Neuroscience, the International Society for Neurochemistry, and the American Association for the Advancement of Science. He has authored over twenty-five publications (including invited reviews) in peer-reviewed journals, and is a co-inventor of thirteen issued U.S. Patents.
### Table of Chapters

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 1</td>
<td>A Brief Introduction to the United States Patent System</td>
</tr>
<tr>
<td>Chapter 3</td>
<td>Utility and Patentable Subject Matter Requirements</td>
</tr>
<tr>
<td>Chapter 4</td>
<td>Inventorship</td>
</tr>
<tr>
<td>Chapter 5</td>
<td>Patentability</td>
</tr>
<tr>
<td>Chapter 6</td>
<td>Biological Deposits</td>
</tr>
<tr>
<td>Chapter 7</td>
<td>Types of Biological and Pharmaceutical Patents</td>
</tr>
<tr>
<td>Chapter 8</td>
<td>The Hatch-Waxman Act</td>
</tr>
<tr>
<td>Chapter 9</td>
<td>Claim Construction</td>
</tr>
<tr>
<td>Chapter 10</td>
<td>Patent Infringement</td>
</tr>
<tr>
<td>Chapter 11</td>
<td>Experimental Use Defense to Patent Infringement</td>
</tr>
<tr>
<td>Chapter 12</td>
<td>Government Funded Research: Bayh-Dole and Other Acts</td>
</tr>
<tr>
<td>Chapter 13</td>
<td>Antitrust, FTC, and State Competition Law</td>
</tr>
<tr>
<td>Chapter 14</td>
<td>Biologic and Biosimilar Drug Products</td>
</tr>
</tbody>
</table>
# Table of Contents

**About the Authors** ................................................................. vii  
**Table of Chapters** ................................................................. xiii  
**Preface** .................................................................................. li  
**Acknowledgments** ................................................................ liii

## Chapter 1  A Brief Introduction to the United States Patent System

*David K. Barr*

$§ 1:1$ Constitutional Basis of the Patent System and Sources of Governing Authority .................................................. 1-2  
$§ 1:1.1$ Constitutional Basis ...................................................... 1-2  
$§ 1:1.2$ Sources of Governing Authority .................................... 1-2  
$§ 1:1.3$ The America Invents Act ............................................. 1-4  
$§ 1:2$ Patentable Subject Matter ............................................. 1-5  
$§ 1:3$ The Patent Application ..................................................... 1-5  
$§ 1:3.1$ Examination of Patent Applications .............................. 1-7  
[A] General............................................................................. 1-7  
[B] PTO Office Actions ......................................................... 1-8  
[C] Satisfaction of Requirements As of Filing Date................. 1-9  
[D] One Invention per Patent ................................................. 1-10  
[E] One Patent per Invention .................................................. 1-10  
$§ 1:3.2$ Claims to Priority.......................................................... 1-11  
$§ 1:3.3$ Publication of Patent Applications ............................... 1-11  
$§ 1:4$ Patent Term..................................................................... 1-12  
$§ 1:5$ Post-Grant Actions.......................................................... 1-13  
$§ 1:5.1$ Reissue [35 U.S.C. § 251] ............................................. 1-13  
$§ 1:5.3$ Inter Partes Review [35 U.S.C. §§ 311–318] ................. 1-15  
$§ 1:5.5$ Supplemental Examinations [35 U.S.C. § 257] ......... 1-18  
$§ 1:5.6$ Certificates of Correction ............................................. 1-19  
$§ 1:5.7$ Disclaimers................................................................. 1-19  
$§ 1:6$ Interferences and Interfering Patents; Transition from “First to Invent” to “First to File” ....... 1-19  
$§ 1:7$ Derivation Proceedings and Derived Patents ............... 1-20

Gerald Sobel & Daniel L. Reisner

§ 2:1 General............................................................................. 2-2
§ 2:2 Research Teams ................................................................ 2-4
  § 2:2.2 Government-Funded Research: The Bayh-Dole Act ...... 2-5
  § 2:2.3 Joint Inventions Made by Federal Employees and Private Parties ............................................. 2-6
§ 2:3 Research ........................................................................... 2-6
  § 2:3.1 Early-Stage Research ................................................... 2-6
  § 2:3.2 Drug Discovery........................................................... 2-7
§ 2:4 Development .................................................................... 2-8
  § 2:4.1 Preclinical Development............................................. 2-8
  [A] Form of the Active Compound....................................... 2-9
  [A][1] Stereoisomers ........................................................... 2-11
  [A][2] Polymorphs ............................................................. 2-11
  [A][3] Salt Forms .............................................................. 2-11
  [A][4] Particle Size ............................................................ 2-11
  [A][5] In Vivo Conversion.................................................... 2-12
  [B] Formulation.............................................................. 2-12
  [C] Manufacturing Process ............................................. 2-12
  [D] Combination Therapies.............................................. 2-13
  [E] Methods of Treatment.............................................. 2-13
  § 2:4.2 Clinical Trials........................................................... 2-13
  [A] The FDA Approval Process......................................... 2-14
  [A][1] Clinical Studies and Trials ....................................... 2-14
  [A][2] Patent Term Restoration for FDA Delay .................. 2-16
  [B][1] ANDA Litigation.................................................. 2-16
  [B][2] Data Exclusivity ................................................... 2-17
§ 2:5 Patent Protection for Pharmaceutical and Biotech Inventions............................................. 2-17
Chapter 4 Inventorship

Richard G. Greco & Daniel L. Reisner

§ 4:1 General Principles of Inventorship ........................................ 4-2
§ 4:1.1 Overview of Statutory Provisions ...................................... 4-4
[A] Priority Disputes and the AIA ............................................. 4-4
[B] Priority Disputes [Pre-AIA] ................................................. 4-4
[C] AIA’s Elimination of Priority Disputes ................................. 4-5
§ 4:1.2 Conception ..................................................................... 4-6
[A] Requirements ...................................................................... 4-6
[B] Proof of Conception Requires Corroboration ....................... 4-8
[C] Is There a Requirement That the Inventor Know That His Invention Will Work for Conception to Be Complete? ................................................................. 4-10
[D] Unrecognized Accidental Creation Not Invention .................. 4-14
[E] Examples ............................................................................ 4-15
[E][1] General Goal with No Specific Means for Implementation: Amax Fly Ash Corp. v. United States ................................................................. 4-15
[E][2] Providing Goal to Be Achieved without Direction: Morgan v. Hirsch ......................................................... 4-15
[E][3] Carrying Out Confirming Experiments: Stern v. Trustees of Columbia University ............................ 4-16
§ 4:1.3 Reduction to Practice ..................................................... 4-16
[A] Requirements ...................................................................... 4-16
[B] Proof of Reduction to Practice Requires Corroboration .......... 4-17
§ 4:1.4 Simultaneous Conception and Reduction to Practice ............ 4-18
§ 4:1.5 Priority ......................................................................... 4-19
[A] Abandoned, Suppressed, or Concealed .................................. 4-20
[B] Diligence in Reducing Invention to Practice ......................... 4-21
§ 4:2 Joint Inventorship: Distinguishing Inventive from Non-Inventive Contributions ................................................. 4-21
§ 4:2.1 Statutory Provision: Sections 101, 116, and 256 .................. 4-22
§ 4:2.2 Requirements for Joint Invention ..................................... 4-22
[A] Determining Co-Inventorship .............................................. 4-23
[B] Assistance and Knowledge from One of Ordinary Skill Does Not Make One an Inventor ............................ 4-23
§ 4:3 Incorrect Inventorship ................................................. 4-28
  § 4:3.1 Statutory Overview and Standard of Proof ............... 4-28
  § 4:3.2 Consequences of Naming the Wrong Inventors ....... 4-28
  § 4:3.3 Correction of Inventorship ................................... 4-29
    [A] Statutory Basis: Section 256 ................................ 4-29
    [B] Deceptive Intent ................................................. 4-29
    [C] Comment: An Odd Policy .................................... 4-30
    [D] Correction of Inventorship Versus Inequitable Conduct ..................................................... 4-31
  § 4:3.4 Procedure for Correcting Inventorship ................. 4-31
    [A] Correction During Litigation ................................. 4-31
    [B] Correcting Inventorship in the Patent Office .......... 4-32
  § 4:3.5 Adding Inventors Can Add Joint Owners ............... 4-32
    [A] Examples ................................................................ 4-33
      [A][1] Ethicon, Inc. v. U.S. Surgical Corp .................... 4-33
      [A][2] Burroughs Wellcome Co. v. Barr Laboratories, Inc 4-34
      [A][3] Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc. .... 4-35
  § 4:4 Inventorship Issues for Particular Types of Inventions ... 4-35
    § 4:4.1 Chemical Inventions ........................................ 4-35
    § 4:4.2 Nucleic Acid and Sequence Claims ..................... 4-38
  § 4:5 Inventorship and Ownership .................................... 4-42
    § 4:5.1 Inventions by Employees ................................... 4-42
      [A] Employment Agreements ..................................... 4-42
      [B] Shop Rights ..................................................... 4-44
      [C] The Rights of Joint Inventors in the Absence of Agreement or Shop Rights ............ 4-45
        [C][1] Joint Ownership ........................................... 4-45
  § 4:6 Anticipating and Resolving Joint Invention Issues .......... 4-48
    § 4:6.1 Putting Agreements in Place ............................ 4-48
    § 4:6.2 Including Warranties of Freedom to Assign .......... 4-49
    § 4:6.3 Inventorship Checklists Before Research Begins .... 4-49

Chapter 5 Patentability

Daniel L. Reisner, Aaron Stiefel, Richard G. Greco, Krista M. Rycroft & Sapna Walter Palla

§ 5:1 Introduction .................................................................. 5-9
  § 5:1.1 Presumption of Validity ........................................ 5-10
  § 5:1.2 Independent and Dependent Claims ....................... 5-13
  § 5:1.3 Claim Construction Issues Relevant to Validity ....... 5-13
  § 5:1.4 Grounds for Invalidity .......................................... 5-15
§ 5:2 Anticipation: An Invention Must Be Something New .............................................................. 5-16

§ 5:2.1 Statutory Provisions: Sections 101 and 102 and the AIA ............................................................... 5-16
[A] Section 102 [Pre-AIA] .................................................................................................................. 5-17
[B] Section 102 [AIA] ......................................................................................................................... 5-18
[B][1] Overview .................................................................................................................................. 5-18
[B][2] Scope of Prior Art ..................................................................................................................... 5-18
[B][3] Exceptions to Defined Scope of Prior Art .............................................................................. 5-19
[C] Differences Between Pre-AIA and AIA Versions of Section 102 .............................................. 5-20
[C][1] Change from First-to-Invent to First-to-File-or-Disclose ..................................................... 5-20
[C][2] First-to-File-or-Disclose Examples ....................................................................................... 5-20
[C][3] New Geographic Scope for Scope of Prior Art ..................................................................... 5-22
[C][4] Summary of Changes ............................................................................................................. 5-22
[D] Determining Which Version of Section 102 Applies ................................................................ 5-24

§ 5:2.2 Requirements for Anticipation ............................................................................................... 5-24
[A] Art Must Include All Elements of a Claim to Anticipate ............................................................ 5-24
[B] Art May Anticipate Based Only on Limited Consideration of Information Beyond the Reference .................................................................................................................. 5-25
[C] Art Must Be Enabling to Anticipate ............................................................................................ 5-26
[C][1] Level of Disclosure ................................................................................................................ 5-26
[C][2] Enablement for Section 102(b) Art ...................................................................................... 5-27
[D] Art May Anticipate by Inherency ................................................................................................. 5-28
[D][1] Examples of Inherent Anticipation ....................................................................................... 5-29
[D][2] Examples of No Anticipation by Inherency .......................................................................... 5-31
[E] Art Disclosed Species Anticipates Genus Claim ....................................................................... 5-33
[F] Art Disclosed Genus Generally Does Not Anticipate Species Claim ........................................ 5-33
[G] Art’s Use of Equivocal Language Generally Does Not Defeat Anticipation .......................... 5-35
[H] Art Need Not Be in Same Field As Invention to Anticipate ..................................................... 5-36
[I] Device May Anticipate Claim to Method of Making ................................................................ 5-37

§ 5:2.3 Types of Prior Art .................................................................................................................... 5-37
[A] Printed Publications ..................................................................................................................... 5-37
[A][1] Accessibility of Publication ..................................................................................................... 5-37
[A][2] Publication Date ....................................................................................................................... 5-38
[A][3] Examples .................................................................................................................................. 5-39
[A][3][a] Publication on FTP Site or Newsgroup .................................................................................. 5-39
[A][3][b] Presentation at a Conference .............................................................................................. 5-39
Table of Contents

[A][3][c] Nonconfidential but Limited Distribution ...............5-40
[A][3][d] Thesis in University Library .................................. 5-41
[A][3][e] Publicly Available Patent Prosecution Documents .......... 5-42
[B] Known or Used by Others in This Country .................. 5-42
[B][1] Known by Others ........................................... 5-42
[B][2] Public Use .................................................. 5-43
[B][2][a] Experimental Use Can Negate Prior Public Use .................. 5-44
[B][2][b] Burden of Proof ...................................... 5-45
[B][2][c] Evidentiary Factors ......................................... 5-45
[B][2][d] When Do Clinical Trials Fall Within the Experimental Use Doctrine and Negate Public Use? .................. 5-46
[C] On-Sale Bar .................................................. 5-48
[C][1] "Subject of a Commercial Sale" ............................ 5-48
[C][1][a] General Principles ...................................... 5-48
[C][1][a][i] Commercial Offer or Sale .................................. 5-49
[C][1][a][ii] Offer for the Patented Invention ...................... 5-49
[C][1][b] Research Agreements ...................................... 5-50
[C][1][c] Granting Licenses .......................................... 5-51
[C][1][d] Method Claims ............................................ 5-51
[C][2] "Ready for Patenting" ...................................... 5-52
[D] First Patented in a Foreign Country ......................... 5-52
[E] Admitted Prior Art ............................................. 5-53

§ 5:3 Obviousness .................................................. 5-53
§ 5:3.1 Statutory Provision: Section 103 ......................... 5-53
[A] The Obviousness Standard: Section 103[a] ............... 5-53
[B] Biotechnology Processes: Section 103[b] ............... 5-54
[C] The Co-Ownership/Joint Venture Exception to Prior Art .................. 5-56
[C][1] Pre-AIA Section 103[c] ...................................... 5-56
[C][2] AIA Section 102[b][2][C] ...................................... 5-58
[D] Incorporation of Section 102 Definition of Prior Art .................. 5-58
[D][1] Pre-AIA .................................................. 5-58
[D][2] AIA .................................................. 5-59

§ 5:3.2 Overview of the Obviousness Question ...................... 5-59
[A] The Graham Factors .......................................... 5-59
[B] A Landmark Decision: KSR v. Teleflex ......................... 5-60

§ 5:3.3 Criterion for Obviousness .................................. 5-62
[A] Combination of References/Prior Art Suggestion of the Invention .................. 5-64
[A][1] Problem Solved by Invention .................................. 5-64
[A][2] Hindsight .................................................. 5-65

xxi
Number of References by Itself Does Not Determine Obviousness .............................. 5-66
Uncorroborated Expert Testimony Not Evidence of Obviousness ........................................ 5-66
Art That Teaches Away from Invention ......................... 5-67
Prior Art Must Be Read As a Whole ............................. 5-69
Inherency ................................................................ 5-69
Predictability/Reasonable Expectation of Success ........ 5-70
"Obvious to Try" .................................................. 5-73
Enablement of Obvious Teaching Required .................. 5-74
Unexpected Results .................................................. 5-75
General Rule .......................................................... 5-75
Application to Pharmaceutical Patents ....................... 5-76
Questions of Law and Fact ...................................... 5-77
Scope and Content of the Prior Art ............................... 5-78
Analogous Art ........................................................ 5-78
Defining the Problem ............................................... 5-79
"Ordinary Skill in the Art" Under Section 103 .............. 5-80
Six Factors ............................................................. 5-80
Skill in the Pharmaceutical Arts ............................... 5-81
Relevance of the Inventor in Determining "Ordinary Skill in the Art" ................................. 5-84
Practical Evidence of Nonobviousness:
The Secondary Considerations .................................. 5-85
Long-Felt Need/Failure of Others ............................... 5-88
Application Rule ....................................................... 5-88
Application to Pharmaceutical Patents ....................... 5-89
Commercial Success ................................................ 5-91
General Rule .......................................................... 5-91
Application to Pharmaceutical Patents ....................... 5-93
Licensing ................................................................. 5-96
General Rule .......................................................... 5-96
Application to Pharmaceutical Patents ....................... 5-97
Copying ................................................................. 5-98
General Rule .......................................................... 5-98
Application to Pharmaceutical Patents ....................... 5-98
Near-Simultaneous Invention .................................... 5-99
General Rule .......................................................... 5-99
Application to Pharmaceutical Patents ....................... 5-99
Prior Art Disclosure of Genus Containing Claimed Species ........................................ 5-100
Written Description ................................................ 5-100
Statutory Provision: Section 112 ................................. 5-100
Written Description Is a Separate Requirement .......... 5-100
Table of Contents

[B] Controversy over Status of Written Description Requirement ........................................................... 5-101
[C] Written Description Requirement Applies to Priority Determinations and to Adequacy of Original Disclosure ........................................................... 5-102
[C][1] Later Claims and Later Applications ................................. 5-102
[C][2] Unsupported Original Claims ............................................. 5-103

§ 5:4.2 The Requirement .......................................................... 5-103
[A] The Purpose of the Requirement ........................................... 5-103
[B] The Standard Set Forth by the Federal Circuit ......................... 5-104
[B][1] Basic Test .................................................................... 5-104
[B][2] Predictability and Other Factors ........................................ 5-105
[B][3] Acceptable Forms of Description ........................................ 5-106
[B][4] Fact Determination .......................................................... 5-108
[C] Conception and Written Description ..................................... 5-109

§ 5:4.3 Genus and Species .......................................................... 5-110
[A] Claim Scope Must Correspond to Disclosure: Gentry Gallery ........................................................................ 5-110
[A][1] Limiting Gentry .......................................................... 5-111
[A][2] Applying Gentry .......................................................... 5-112
[B] Species Based on a Disclosed Genus ........................................ 5-113
[C] Genus Based on Disclosed Species or Examples .................. 5-113
[D] Genus Based on Generic Description ...................................... 5-115
[E] Range Cases ...................................................................... 5-116
[F] Negative Limitations .......................................................... 5-117
[G] Unclaimed Optional Features ................................................. 5-118

§ 5:4.4 Inherency ........................................................................ 5-119
§ 5:4.5 Application to Particular Inventions ................................ 5-120
[A] Compound and Composition Claims ........................................ 5-120
[B] DNA ................................................................................. 5-121
[B][1] General Rule .................................................................. 5-121
[B][2] Deposits ......................................................................... 5-123
[B][3] Genus Claims .................................................................. 5-123
[B][4] Possession of Polypeptides ................................................. 5-125
[C] Antibodies .......................................................................... 5-125
[D] Other Biological Material ...................................................... 5-126

§ 5:5 Enablement ........................................................................ 5-126
§ 5:5.1 Statutory Provision: Section 112 ........................................ 5-127
§ 5:5.2 The Policy Behind Enablement .......................................... 5-127
§ 5:5.3 Enablement: Question of Law ........................................... 5-128
§ 5:5.4 Role of the Specification .................................................... 5-128
[A] General Principles ............................................................. 5-128
[B] Means-Plus-Function Claims ................................................. 5-130
§ 5:5.5 The Person Skilled in the Art ............................................. 5-131
[A] Who Is the Person Skilled in the Art? ........................................ 5-131
[B] What General Knowledge Does the Person Skilled in the Art Possess? ......................................................... 5-131
[C] Time Frame for Determining Enablement .......... 5-132
[C][1] Enablement Measured As of Filing Date.......... 5-132
[C][2] Using Post-Filing References to Show
State of the Art at Filing ............................... 5-132
[C][3] Nascent Technology Must Be Disclosed............. 5-133
[C][4] Loss of Material Needed to Practice
Invention................................................................ 5-134
§ 5:5.6 Requirements for Enablement .................... 5-135
[A] How to Make the Claimed Invention ................ 5-135
[A][1] Compound and Composition of Matter
Claims............................................................. 5-136
[A][2] Method of Use Claims................................ 5-137
[B] How to Use the Claimed Invention ................... 5-138
[B][1] Practical Utility ........................................... 5-138
[B][2] Satisfying the How to Use Requirement .......... 5-139
[B][3] Inoperability May Negate Enablement .......... 5-141
§ 5:5.7 Enabling the Full Scope of the Claim............. 5-142
§ 5:5.8 No Enablement If Undue Experimentation
Required .......................................................... 5-144
[A] Undue Experimentation: The Wands Factors ...... 5-144
[A][1] Quantity of Experimentation Needed ............ 5-145
[A][2] Direction or Guidance Provided/Working
Examples and Teaching Away ........................... 5-147
[A][3] Nature of the Invention/State of Prior
Art/Level of Skill in the Art ................... 5-149
[A][4] Predictability in the Art ............................. 5-149
[A][5] Breadth of the Claim ................................. 5-150
[B] Routine Experimentation Is Allowed ............... 5-151
§ 5:5.9 Use of Deposits to Satisfy Enablement .......... 5-151
§ 5:6 Best Mode.................................................. 5-153
§ 5:6.1 Overview.................................................. 5-153
[A] Statutory Provision: Section 112 ..................... 5-153
[B] AIA’s Elimination of Best Mode As Grounds for
Invalidity or Unenforceability ......................... 5-154
§ 5:6.2 Purpose of the Best Mode Requirement ........ 5-155
§ 5:6.3 Best Mode Distinguished from Enablement .... 5-156
§ 5:6.4 Best Mode: A Two-Prong Inquiry ............... 5-156
[A] Subjective Inquiry: Did the Inventor
Contemplate a Best Mode? .............................. 5-157
[A][1] Evidence of Inventor Preference ................. 5-158
[A][2] Alternative Embodiments Does Not
Mean There Is a Best Mode ............................. 5-158
[A][3] Relevance of Inventor’s Intent to Conceal ...... 5-159
[A][4] Intentional Concealment—Inequitable
Conduct.......................................................... 5-160
[B] Patent Does Not Identify Test to Measure Claimed Property................................. 5-183

[B][1] Examples of Claims Found Indefinite.......... 5-183

[B][1][a] Leading Example: Honeywell International v. International Trade Commission.................................................... 5-183

[B][1][b] Other Examples............................................. 5-184

[B][2] Examples of Claims Found Definite .......... 5-184

[B][2][a] Leading Example: PPG Industries, Inc. v. Guardian Industries Corp. ........... 5-184

[B][2][b] Other Examples............................................. 5-185

[C] Single Claim to Both Method and Apparatus Indefinite .................................................... 5-185

[D] Claims Requiring Knowledge or Intent .......... 5-188

[E] Means-Plus-Function Claims ......................... 5-188

[F] Drafting Errors in Claim Language .................. 5-189

[F][1] Claims Found Indefinite ............................... 5-190

[F][2] Claims Not Found Indefinite ......................... 5-190

[F][3] Lack of Antecedent Basis............................. 5-190

§ 5:8 Double Patenting ................................................ 5-191

§ 5:8.1 Two Forms of Double Patenting:
Statutory and Non-Statutory ........................................ 5-191

§ 5:8.2 The Policy Behind Double Patenting .......... 5-192

[A] Policy Prior to URAA ........................................... 5-193

[B] Continued Applicability of Obviousness-Type Double Patenting Post-URAA ..................... 5-194

§ 5:8.3 Double Patenting Requires Common Inventorship or Ownership .................... 5-194

§ 5:8.4 Situations in Which Double Patenting May Arise ........................................... 5-195

[A] Prosecution, Reexamination, and Post-Issuance .... 5-195

[B] Later Issuing, Earlier Expiring Reference Patent .... 5-195

[C] Claims Canceled After Issuance May Still Be Reference Claims................................. 5-196

§ 5:8.5 Non-Statutory Double Patenting .................... 5-197

[A] Anticipation and Obviousness ......................... 5-197

[B] Genus and Species ............................................. 5-198

[C] The Test for Double Patenting ......................... 5-199

[C][1] Two-Part Test.................................................. 5-199

[C][2] Limited Use of the Specification ................. 5-200

[C][3] Use of Prior Art............................................. 5-201

[C][4] Use of Post-Filing-Date Art ......................... 5-202

[C][5] Claim-by-Claim Analysis ............................... 5-203

[D] Who Is the Same Person for Purposes of Double Patenting? ........................................ 5-203
Curing Double Patenting by Filing Terminal Disclaimers

Effect of Filing a Terminal Disclaimer

Need for Common Ownership of Patent and Its Reference Patent

The Timing of a Terminal Disclaimer Filing

Effect of a Terminal Disclaimer on a Patent Term Extension

Effect of a Terminal Disclaimer on a Patent Term Adjustment

Effect of a Disclaimer of Claims

The Two-Way Double Patenting Test

Requirements to Qualify for the Two-Way Test

Satisfying the Two-Way Test

Overlapping Claims

Safe Harbor Provision Involving Double Patenting

The Safe Harbor Requires a Prior Restriction by the Examiner

The Safe Harbor Requires Consonance Between the Restriction Requirement and the Later Claims in the Later Application

The Safe Harbor Requires Filing of a Subsequent Application Denominated a "Divisional"

Double Patenting Issues in Pharmaceutical Patents

Method Patents over Prior Compound Patents

Examples

Inequitable Conduct

Introduction

Inequitable Conduct Requires Proof of Materiality and Intent

The Materiality Requirement

Standard for Materiality Before Therasense

The Materiality Standard Under Therasense

The Intent Requirement

Actual Intent Required; Negligence Not Enough

There Must Be a Specific Intent to Deceive

The Intent Requirement Under Therasense

Proving Intent Before Therasense

Ferring B.V. v. Barr Laboratories, Inc.

Proving Intent After Therasense
Whether the Actual Intent Standard Requires That at Least One Individual Have the Requisite Culpable State of Mind

§ 5:9.5 Categories of Inequitable Conduct

[A] References

[A][1] Non-Disclosed References

[A][2] References Before the Examiner

[A][3] Disclosure Only of Abstracts

[A][4] Potential Double-Patenting References

[A][5] Argument About a Reference

[B] Descriptions of Data and Experiments

[C] Representations Regarding Inventorship

[D] Related Proceedings

[D][1] Related Patent Office Proceedings

[D][2] Related Litigations

[E] Miscellaneous Types of Inequitable Conduct

[E][1] Application for Expedited Treatment

[E][2] Payment of Maintenance Fees

[E][3] Disclosure of Relationships Between Declarant and Applicant

[E][4] Notes About a Presentation

[E][5] Concealment of Best Mode

[E][6] Litigation Misconduct

§ 5:9.6 Late and Corrected Disclosures

[A] Late Disclosures

[B] Correcting a Disclosure During Prosecution

[C] Disclosure in Reissue Proceedings

§ 5:9.7 Practical Problems in Pharmaceutical Patent Prosecution

§ 5:9.8 Practical Advice for Defeating Inequitable Conduct Allegations

[A] Disclosure of References

[B] Disclosure of Experimental Details

[C] Disclosure of Experimental Data

[D] Care in Patent Prosecution

§ 5:9.9 The Legal Effect of a Finding of Inequitable Conduct

[A] Inequitable Conduct Renders a Patent Unenforceable

[B] Inequitable Conduct May Result in Assessment of Attorneys’ Fees

[C] Inequitable Conduct May Have Antitrust Consequences

§ 5:9.10 Procedural Aspects

[A] Inequitable Conduct Is an Issue of Equity Decided by the Court, Not a Jury

[B] Standard of Review
Chapter 6 Biological Deposits

Daniel L. Reisner

§ 6:1 Introduction ..................................................................... 6-1
§ 6:2 The Evolution of Biological Deposits ............................... 6-2
§ 6:3 Biological Deposits Can Satisfy Disclosure
  Requirements................................................................. 6-3
  § 6:3.1 Written Description.................................................... 6-3
  § 6:3.2 Enablement................................................................. 6-4
  § 6:3.3 Best Mode................................................................... 6-4
§ 6:4 Biological Deposits Not Required If Disclosure
  Otherwise Adequate ......................................................... 6-5
§ 6:5 Making and Maintaining Biological Deposits ............... 6-5

Chapter 7 Types of Biological and Pharmaceutical Patents

David K. Barr, Sylvia M. Becker, Patricia Carson,
Richard G. Greco, Daniel L. Reisner & Aaron Stiefel

§ 7:1 Research Tools................................................................. 7-8
  § 7:1.1 What Is a Research Tool Patent? ................................ 7-8
  § 7:1.2 Utility Requirement for Patenting Research Tools.....7-10
  § 7:1.3 Research Tools Used to Obtain Data for FDA
    Submissions: Section 271[e][1]................................. 7-11
  § 7:1.4 Off Shore Development Work:
    Section 271[f] and [g] ................................................... 7-13
    [A] Section 271[f] ........................................................... 7-14
    [A][1] The Statute ......................................................... 7-14
    [A][2] Legislative History............................................... 7-14
    [B] Section 271[g].......................................................... 7-15
    [B][1] The Statute ......................................................... 7-15
    [B][2] Legislative History............................................... 7-16
    [B][3] Applying Section 271[g] to Research Tools...........7-16
§ 7:2 Patentability of Chemical Compounds ....................... 7-17
  § 7:2.1 Novelty of a Claim to a Chemical Compound
    Over the Prior Art: The Requirement That an
    Anticipating Reference Be Enabling................................ 7-18
  § 7:2.2 Obviousness of a Claim to a Chemical
    Entity and the Impact of the Supreme Court’s
    Decision in KSR ........................................................... 7-20
    [A] Prima Facie Obviousness........................................ 7-23
    [A][1] An Evidentiary Mechanism................................. 7-23
    [A][2] Demonstrating Prima Facie Obviousness............. 7-24
[A][2][a] Properties of Claimed and Prior Art Compounds.................................7-25

[A][2][a][i] New Property Alone Does Not Defeat a Prima Facie Case..........................7-25

[A][2][a][ii] To Demonstrate Prima Facie Obviousness, a Prior Art Compound Must Suggest Some Useful Property......................................................7-26

[A][2][a][iii] In re Dillon.................................................................7-26

[A][2][b] Prima Facie Obviousness Based on Similarity in Structure:
   “Structural Obviousness”..............................................................7-27

[A][2][b][i] Pre-KSR Federal Circuit Decisions ..................................7-27

[A][2][b][ii] Post-KSR Federal Circuit Decisions..............................7-34

[A][2][b][iii] Post-KSR District Court Decisions.................................7-46

[A][2][c] Reason to Combine ............................................................7-51


[A][4] Examples from Pre-KSR Decisions .....................................7-53

[A][4][a] Finding Structural Obviousness.........................................7-53

[A][4][b] Finding No Structural Obviousness......................................7-56

[B] Rebutting a Prima Facie Case of Obviousness ......................7-59

[B][1] Unexpected Results Require a Showing of Actual Differences ........................................7-59

[B][2] Compared to Closest Prior Art .............................................7-60

[B][3] Differences Must Match Scope of Claim ................................7-61


[B][5] Multiple Properties..............................................................7-62

[B][6] Evidence of Unexpected Properties Not Limited to Specification ......................7-64

[B][6][a] Evidence Need Not Be in Specification ............................7-64

[B][6][b] Unexpected Property Need Not Be in Specification ...............7-65

[B][7] Illustrative Cases.................................................................7-66

[B][7][a] Prima Facie Obviousness Rebutted.....................................7-66

[B][7][b] Prima Facie Obviousness Not Rebutted ................................7-67

§ 7:2.3 Genus and Species Inventions........................................7-70

[A] Anticipation of a Chemical Genus by a Prior Art Species.................................7-71

[A][1] Prior Species Anticipates Genus............................................7-71

[A][2] Conception of Species Before Prior Art Can Defeat Anticipation of Broader Genus ....7-72

[B] Validity of a Claimed Species Over a Prior Art Genus..............................7-73

[B][1] Anticipation of Chemical Species by a Prior Art Genus........................7-73

[B][1][a] General Rule.................................................................7-73

xxx
Table of Contents

[B][1][b] Exception for Small Prior Art Genus:  
*In re Petering* ................................................................. 7-74

[B][2] Obviousness of a Chemical Species Over a  
Prior Art Genus................................................................. 7-75

[B][2][a] General Rule............................................................ 7-75

[B][2][b] Prima Facie Case Based on Prior Art Genus  
Can Be Rebutted............................................................... 7-76

[B][2][c] Size of Prior Art Genus and Nature of  
Examples May Negate Prima Facie Case........... 7-76

[B][2][c][i] *In re Jones* .......................................................... 7-77

[B][2][c][ii] *In re Baird* .......................................................... 7-77

[C] Written Description Support for Genus and  
Species Composition Claims........................................ 7-78

[C][1] Species or Subgenus Claims.............................. 7-78

[C][2] Genus Claims ............................................................ 7-78

§ 7:2.4 Stereoisomers, Enantiomers, and Diastereomers .... 7-79

[A] Introduction ................................................................. 7-79

[B] Patentability of Stereoisomers ................................. 7-83

[B][1] Anticipation............................................................... 7-83

[B][2] Obviousness ............................................................... 7-85

[C] Claim Construction and Infringement.................... 7-90

§ 7:2.5 Polymorphs.............................................................. 7-91

[A] What Is a Polymorph? .................................................. 7-91

[B] Techniques for Identifying Polymorphs .................... 7-93

[B][1] X-Ray Powder Diffraction......................................... 7-93

[B][2] Single Crystal X-Ray Crystallographic Analysis .... 7-93

[B][3] Infrared Absorption Analysis................................. 7-93

[C] Infringement............................................................... 7-94

[C][1] Evidentiary Issues...................................................... 7-94

[C][2] Quantity Required .................................................... 7-96

[C][3] Conversion .............................................................. 7-98

[C][4] Claim Construction ................................................... 7-100

[D] Validity ..................................................................... 7-100

[D][1] Inherent Anticipation .............................................. 7-100

[D][2] On-Sale Bar .............................................................. 7-101

§ 7:2.6 Pharmaceutical Salts of Active Ingredients .......... 7-102


[B] Development of Pharmaceutical Salts .................... 7-102

[C] Patentability of New Salts .......................................... 7-103

[C][1] Determinations of Obviousness/Nonobviousness  
of New Salt Forms of Compounds ............................. 7-103

[C][2] Most Common Salt Form Used for Known  
Active Found Obvious in Obviousness-Type  
Double Patenting Analysis ............................................. 7-108

§ 7:2.7 Infringement by Conversion to a Patented Form..... 7-109

[A] *In Vivo* Conversion......................................................... 7-110

[A][1] Claim Construction ..................................................... 7-110
Infringement and Anticipation ............................................. 7-112

Schering v. Geneva ..................................................... 7-112

Pre-Schering District Court Decisions ................................ 7-113

Marion Merrell Dow ................................................... 7-114

Omeprazole .............................................................. 7-115

Buspirone ................................................................. 7-117

Conversion Outside the Body: Polymorphic Form Conversion ............................................. 7-118

§ 7:2.8 Particle Size of Active Ingredient ............................................. 7-119

What Is Particle Size? ..................................................... 7-119

Infringement of Particle Size Patents ............................................. 7-120

Measured on the API Raw Material or in the Formulation ............................................. 7-120

Infringement of Particle Size Patents in Hatch-Waxman Cases ........................................ 7-122

Method of Measurement .............................................. 7-123

Infringement Under the Doctrine of Equivalents ............................................. 7-124

Validity ................................................................. 7-124

Obviousness ............................................................ 7-124

Written Description ................................................. 7-125

§ 7:3 Pharmaceutical Formulations ............................................. 7-126

§ 7:3.1 What Is a Pharmaceutical Formulation? ............................................. 7-126

§ 7:3.2 Claim Construction Issues ............................................. 7-132

“Solubilizer” Limited to Surfactants ............................................. 7-132

“Lipophilic Component” Construed to Include More Than Surfactants ............................................. 7-133

Claim Not Limited to Particular Grade of an Excipient ............................................. 7-133

Purity Limitations ......................................................... 7-134

“Hydrosol” Limited to “Medicinal Preparation” ............................................. 7-134

“Saccharides” Includes “Polysaccharides” ............................................. 7-135

§ 7:3.3 Literal Infringement and Infringement Under the Doctrine of Equivalents ............................................. 7-136

Using Different Excipients ............................................. 7-137

Non-Equivalence ......................................................... 7-137

Equivalence ............................................................ 7-138

Prosecution History Estoppel ............................................. 7-138

Controlled Release Formulations: Foreseeability of Substitution ............................................. 7-138

Prosecution History Estoppel Bars Equivalence ............................................. 7-138

No Prosecution History Estoppel ............................................. 7-139

Controlled Release Formulations: Prosecution History Estoppel ............................................. 7-140

Infringement by Equivalents: No Dedication of Equivalent Excipient ............................................. 7-141
Table of Contents

§ 7:3.4 Patent Validity ........................................................ 7-143
[A] Obviousness ............................................................ 7-143
[A][1] Combinations of Excipients ............................... 7-143
[A][2] Combination Therapies ....................................... 7-144
[A][2][a] Obvious Combination .................................... 7-145
[A][2][b] Nonobvious Combination .............................. 7-145
[A][3] Pharmacokinetic/Pharmacodynamic
Limitations ................................................................ 7-146
[B] Written Description ................................................ 7-147
[C] Enablement ............................................................. 7-148

§ 7:3.5 Bibliography of Pharmaceutical Formulation
Treatises and Texts ..................................................... 7-148

§ 7:4 Method of Treatment ................................................... 7-149
§ 7:4.1 What Is a Method of Treatment Claim? ............... 7-149
§ 7:4.2 Patentability of Method of Treatment Claims ......... 7-150
§ 7:4.3 Conception ............................................................ 7-152
§ 7:4.4 Claim Construction Issues ................................. 7-152
[A] Preambles ............................................................... 7-152
[A][1] Preambles Can Be Limiting ................................. 7-153
[A][2] Construing Preambles in Method of
Treatment Claims .................................................... 7-153
[A][3] Adding Method of Treatment Preamble
Language by Amendment Can Render
Preamble Limiting .................................................... 7-154
[B] Specific Claim Terms ............................................. 7-155
[B][1] “Treat” ................................................................. 7-155
[B][2] “Effective Amount” ............................................. 7-156
[B][3] “Co-Administration” ........................................... 7-156

§ 7:4.5 Anticipation and Obviousness .............................. 7-157
[A] Inherent Anticipation .............................................. 7-157
[A][1] Examples of Inherency ....................................... 7-157
[A][2] Examples of No Inherency ................................. 7-161
[B] Prior Art Need Not Disclose Efficacy to
Anticipate ................................................................. 7-163
[C] Obviousness .......................................................... 7-164
[C][1] Methods of Using New Compounds ..................... 7-164
[C][2] New Methods of Using Old Compounds .......... 7-165
[C][3] Genus of Methods of Treatment Could
Render Included Species Obvious ............................ 7-165
[C][4] Instructional Limitations .................................... 7-166

§ 7:4.6 Written Description ................................................ 7-167
[A] Examples of Method of Treatment Cases
Involving Written Description ................................... 7-167
[B] Field of Use Claim ................................................... 7-167
[C] Dosing ................................................................. 7-168
§ 7:4.7 Enablement............................................................. 7-168
[A] Compound Needed to Practice Claim Must Be
   Enabled................................................................... 7-168
[B] Dosing .................................................................... 7-169
§ 7:4.8 Best Mode............................................................... 7-170
[B] Suing the Maker of the Therapeutic:
   Indirect Infringement ............................................. 7-170
[B] Suing on Method of Treatment Claims
   Against an ANDA Defendant................................. 7-170
§ 7:5 Pharmaceutical Manufacturing .................................... 7-171
§ 7:5.1 Intermediates.......................................................... 7-172
[A] Definition and Purpose .......................................... 7-172
[B] Utility Required...................................................... 7-172
§ 7:5.2 Product-By-Process Claims..................................... 7-175
[A] Definition and Purpose .......................................... 7-175
[B] Construction of Product-By-Process Claims........... 7-176
[B][1] Patent Office Examination of Pending
   Product-By-Process Claims...................................... 7-176
[B][2] Construction of Issued Product-By-Process
   Claims in Patent Infringement Litigation .............. 7-177
§ 7:5.3 Process Claims ....................................................... 7-180
[A] Definition and Purpose .......................................... 7-180
[B] Patentability of Process Claims .............................. 7-180
[C] Biotechnological Processes...................................... 7-181
§ 7:6 Nucleic Acid Patents .................................................... 7-182
§ 7:6.1 The Promise of Genomics...................................... 7-182
[A] First Recombinant DNA Organism........................ 7-182
[B] Cellular Factors for Making Proteins...................... 7-182
[C] Genetic Basis of Disease......................................... 7-183
[D] Gene Therapy......................................................... 7-183
[E] Our Expanding Knowledge of Genes ...................... 7-184
[F] Biotechnology Patents............................................. 7-185
§ 7:6.2 Eligibility of Nucleic Acid Sequences for
   Patenting............................................................... 7-186
[A] Product of Nature Exception to Patentability ......... 7-186
[A][1] Patentability of Man-Made Living Organisms:
   Diamond v. Chakrabarty ............................................. 7-187
[A][2] Purified and Isolated (prior to Myriad) ................. 7-188
[A][2][a] Kuehmsted v. Farbenfabriken of Eberfield ...... 7-189
[A][2][b] Merck & Co. v. Olin Mathieson ....................... 7-189
[B] Cases Suggesting Natural DNA Sequences Not
   Patentable (prior to Myriad).................................... 7-190
[B][1] Funk Bros. v. Kalo ............................................... 7-191
### § 7:6.3 Utility Requirement for Nucleic Acid Patents

- [A] PTO Board of Patent Appeals Decisions
- [B] The PTO's Utility Examination Guidelines and Training Materials
  - [B][1] The 1995 Utility Guidelines
  - [B][2] The 1999 Revised Utility Guidelines
  - [B][4] The Utility Guidelines Training Materials
    - [B][4][a] “Specific” Utility
    - [B][4][b] “Substantial” Utility
    - [B][4][c] “Credible” Utility
    - [B][4][d] “Well-Established” Utility
  - [B][5] The Nucleic Acid Examples of the Training Materials
    - [B][5][a] “DNA Fragments”
    - [B][5][b] “DNA Fragment Encoding a Full Open Reading Frame (ORF)”

### § 7:6.4 Written Description of Nucleic Acids

- [A] Satisfying the Written Description Requirement
  - [A][2] Fiers v. Revel
- [B] Heightened Written Description Requirement for Biotechnology and DNA Sequence Patents?
    - (Enzo I)
    - (Enzo II)
- [C] Practical Implications of the Federal Circuit's Written Description Jurisprudence

### § 7:6.5 Other Grounds for Invalidity of Nucleic Acid Inventions

- [A] Anticipation
- [B] Obviousness
  - [B][1] Amino Acid Sequences
  - [B][2] Nucleic Acid Sequences
  - [B][2][a] Post-KSR
  - [B][2][b] Pre-KSR
- [C] Indefiniteness
- [D] Enablement
- [E] Best Mode
- [F] Inventorship and Conception
§ 7:6.6 Claim Construction of Nucleic Acid Claims..................7-222
§ 7:7 Antibodies ........................................................................7-225
§ 7:7.1 What Is an Antibody? ..............................................7-225
[A] Introduction ....................................................................7-225
[B] Monoclonal Antibodies .............................................7-226
[C] Commercial Applications for Antibodies ....................7-228
§ 7:7.2 Obviousness .............................................................7-229
[A] Monoclonal Antibodies .............................................7-229
[B] Sandwich Assay .........................................................7-230
[C] 35 U.S.C. § 103(b) .....................................................7-230
§ 7:7.3 Written Description ..................................................7-231
[A] Describing Antibodies by Describing Their Target ..........................................................7-231
[A][1] Overview of Written Description Requirement ......................................................7-231
[A][2] Antibodies and DNA ................................................7-232
[A][3] Requirement for Describing the Antigen ................................................................7-233
[A][4] Antibodies That Bind to Particular Epitopes ..........7-233
[B] Describing Antibodies in Terms of Their Corresponding DNA or Amino Acid Sequences ....7-233
[B][1] Describing Antibodies in Terms of Previously Known Sequences ................................7-233
[B][2] Describing Antibody Genus in Terms of Amino Acid Sequences ................................7-234
[C] Chimeric Antibodies: Chiron v. Genentech .............7-235
§ 7:7.4 Enablement .................................................................7-236
[A] Enablement Supported by the Prior Art .........................7-236
[A][1] Evidence of Enablement from the Prior Art .............7-236
[A][2] Enablement Based on Level of Skill in the Art: No Undue Experimentation ..............7-237
[B] Failed Attempts Do Not Necessarily Show Lack of Enablement .....................................7-238
[C] Nascent Technology .......................................................7-238
§ 7:7.5 Claim Construction ......................................................7-239
[A] Chimeric and Humanized Antibodies .........................7-239

Chapter 8 The Hatch-Waxman Act

David O. Bickart

§ 8:1 Patent Protection and Litigation ......................................8-6
§ 8:1.1 Introduction ..............................................................8-6
[A] Background of the Hatch-Waxman Act ......................8-6
[B] Hatch-Waxman Act Overview .....................................8-7
[C] Requirements for Filing an ANDA ............................8-8
[C][1] Labeling .................................................................8-10
[C][2] Active Ingredient ...................................................8-11
Table of Contents

[C][3] Route of Administration, Dosage Form, and Strength .......................................................... 8-11
[C][4] Bioequivalence .................................................................................................................. 8-12
[C][5] Drug Master File References ......................................................................................... 8-13
[D] “Suitability Petitions” for Variant Dosage Forms and Strengths .................................................. 8-13
[E] Paper NDAs: Section 505(b)(2) Applications ................................................................................. 8-14
§ 8:1.2 Orange Book Listing .......................................................................................................... 8-16
[A] What Patent Information Must Be Submitted .......................................................................... 8-16
[A][1] “Drug Product” (Formulation or Composition) Patents ................................................................. 8-17
[A][2] “Drug Substance” (Active Ingredient) Patents ............................................................................. 8-18
[A][3] Patents Claiming “Polymorphs” .......................................................................................... 8-19
[A][4] Method of Use Patents ........................................................................................................... 8-20
[A][5] Method of Manufacture Patents ............................................................................................. 8-20
[C] Patent Certification and Duty of Care ....................................................................................... 8-21
[D] Consequences of False Certification ...................................................................................... 8-22
[E] Resolution of Orange Book Listing Disputes ........................................................................... 8-22
[F] Orange Book Delisting Limitations ............................................................................................ 8-23
[G] Reissue Patents .......................................................................................................................... 8-23
§ 8:1.3 Patent Certifications by ANDA or 505(b)(2) Applicant: Paragraphs I, II, III, and IV ...................................................... 8-24
[A] Patent Certifications by ANDA Applicant ................................................................................. 8-24
[B] Patent Certifications by Section 505(b)(2) Applicant ................................................................ 8-25
[C][1] Contents of Notice .................................................................................................................. 8-25
[C][2] When Served .......................................................................................................................... 8-26
[C][3] Who Served ............................................................................................................................. 8-26
§ 8:1.4 ANDA Filing As “Artificial Act of Infringement” Under 35 U.S.C. § 271(e)(2) ............................................. 8-26
[A] Statutory Provisions .................................................................................................................. 8-26
[B] Elements of Section 271(e)(2) Infringement Claim .................................................................... 8-27
[B][1] “submit an application” ........................................................................................................... 8-27
[B][2] “under Section 505(j) . . . or described in Section 505(b)(2)” .................................................... 8-28
[B][3] “for a drug claimed in a patent or the use of which is claimed in a patent” ................................. 8-29
[B][3][a] “drug claimed in a patent” .................................................................................................. 8-29
[B][3][a][i] Patents on Different Formulations ............................................................................... 8-29
[B][3][a][ii] Patents on Methods of Manufacture ......................................................................... 8-30
[B][3][a][iii] Product-by-Process Patents .......................................................................................... 8-30
[B][3][a][iv] Patents on Different Polymorphs .................................................................................. 8-30
[B][3][a][v] Patents on Metabolites ..................................................................................................... 8-31
[B][3][a][vi] Patents on Intermediates ............................................................................................... 8-31

xxxvii
or the use of which is claimed in a patent”... 8-31
Enforcement of Non-Orange Book Patents .......... 8-34
The Section 271(e)(2) Infringement Analysis........ 8-35
Similarities to Standard Infringement Actions..... 8-35
Differences from Standard Infringement
Actions ................................................................. 8-36
Overview........................................................... 8-36
Pre-Suit Investigation ....................................... 8-37
Determining Infringement Based on ANDA...... 8-37
Determining Infringement Based on
Evidence Beyond the ANDA............................. 8-39
Determining Infringement for
Method Claims............................................... 8-39
Procedural Considerations in ANDA Litigation ... 8-39
Proper Plaintiff ..................................................... 8-39
Proper Defendants.............................................. 8-40
Jurisdiction and Venue ......................................... 8-41
Pretrial Proceedings ............................................ 8-43
No Jury Trial ....................................................... 8-43
Orange Book Listing Is Prerequisite to
Thirty-Month Stay ............................................. 8-44
Beginning of the Thirty-Month Stay ................. 8-45
Calculated from Receipt of Notice ..................... 8-45
The Forty-Five-Day Window .............................. 8-45
Adjustment of Thirty-Month Stay ...................... 8-45
Termination of Thirty-Month Stay ..................... 8-46
Judgment of Non-Infringement, Invalidity or
Unenforceability ............................................... 8-46
Effect of Settlement ............................................. 8-47
Order Precluding FDA Approval of ANDA
Until Patent Expiration ..................................... 8-48
Injunctive Relief ................................................. 8-48
Damages Only upon Commercial Sales of
Infringing Product ............................................. 8-49
Attorney Fees ...................................................... 8-49
Statutory Provisions: Sections 271(e)(4)
and 285 ........................................................... 8-49
Factors for Determining Exceptional Case ........ 8-49
Hatch-Waxman Act Exceptional Case Litigation... 8-50
Baseless Certification......................................... 8-50
Willfulness ......................................................... 8-52
Opinions by Patent Counsel.............................. 8-54
§ 8:2.5 Exclusivity Period Begins Only upon First Applicant’s “Commercial Marketing” .......................... 8-77
§ 8:2.6 “Forfeiture” of 180-Day Exclusivity .............................................. 8-78
[A] “Failure to Market” ........................................................................ 8-79
[B] First Filer’s ANDA Is Withdrawn or Rejected.................................. 8-80
[C] First Filer’s ANDA Is Not “Tentatively Approved” Within Thirty Months.............................................. 8-80
[D] All Challenged Patents Have Expired ............................................. 8-81
[E] First Applicant Withdraws All Paragraph IV Certifications ...................... 8-81
[F] Collusive Agreement ......................................................................... 8-82
§ 8:2.7 180-Day Exclusivity Under the Pre-MMA Hatch-Waxman Act ................. 8-82
[A] Pre-MMA Statutory Text ..................................................................... 8-82
[B] Exclusivity for Pre-MMA ANDAs ................................................... 8-83
[B][1] “patent-by-patent” Exclusivity ..................................................... 8-83
[B][2] “shared” Exclusivity ..................................................................... 8-85
[C] When Does 180-Day Period Begin? ................................................ 8-86
[C][1] “first commercial marketing” ...................................................... 8-86
[C][2] “a decision of a court . . . holding” .................................................. 8-86
[C][2][a] What “Holding”? ................................................................. 8-86
[C][2][b] What Parties? ........................................................................ 8-87
[C][2][c] What Products? ...................................................................... 8-87
[C][2][d] What Court? ........................................................................... 8-87
[D] Loss of Exclusivity ............................................................................ 8-88
§ 8:2.8 Waiver and Transfer of Exclusivity .............................................. 8-88
§ 8:3 “Data” Exclusivity Under the FD&C Act ........................................ 8-89
§ 8:3.1 Introduction .................................................................................. 8-89
§ 8:3.2 New Chemical Entity Exclusivity ............................................... 8-89
[A] Statutory Basis: Section 355(c)(3)(E)(ii) and Section 355(j)(5)(F)(ii) .................................................. 8-89
[B] Eligibility Criteria for NCE Exclusivity ........................................... 8-90
[B][1] “Active Ingredient” Means “Active Moiety” .............................. 8-90
[B][2] Novel Combinations ................................................................... 8-91
[B][3] New Forms of Previously Approved Ingredients ........................ 8-93
[B][3][a] Polymorphs ........................................................................... 8-93
[B][3][b] Stereoisomers ......................................................................... 8-93
[C] Extra Exclusivity for Certain New Antibiotics ............................... 8-94
§ 8:3.3 “Other Significant Changes” Exclusivity .................................... 8-94
[A] Statutory Basis: Section 355(j)(5)(F)(iii) and (iv) ............................ 8-94
[B] Eligibility Criteria for OSC Exclusivity .......................................... 8-95
[B][1] “new clinical investigations” ....................................................... 8-95
[B][2] “conducted or sponsored by the applicant” .............................. 8-95
[B][3] “essential to approval” ................................................................. 8-95
[C] “Carve-Out” Option for ANDAs .................................................... 8-96
§ 8:3.4 “Orphan Drug” Exclusivity ........................................... 8-97
[A] Statutory Basis: Sections 360aa–360cc .................................. 8-97
[C] Scope of Orphan Drug Exclusivity .................................. 8-98
[C][1] “same drug” ................................................................ 8-98
[C][1][a] “same” Structure .............................................. 8-98
[C][1][b] “same” Clinical Performance .................................. 8-99
§ 8:3.5 Pediatric “Exclusivity” ............................................. 8-99
[B] Eligibility for Pediatric Exclusivity .................................. 8-100
[C] Interim Extension ..................................................... 8-101
[D] Label Revision Not Required ........................................ 8-101
[E] Scope of Pediatric Extension ......................................... 8-102
[E][1] Extension of Data-Based Exclusivity ....................... 8-102
§ 8:4 Patent Term Restoration ................................................. 8-104
§ 8:4.1 Introduction ............................................................ 8-104
§ 8:4.2 Eligibility for Patent Term Restoration ....................... 8-106
[A] Threshold Requirement .............................................. 8-106
[B] Five Conditions for Extension Eligibility ..................... 8-107
[C] The “First Permitted Commercial Marketing
or Use of the Product” ............................................. 8-108
[C][1] Need Not Be the First Product Covered by
the Patent to Receive Regulatory Approval .............. 8-108
[C][2] Patent Cannot Merely Claim a
New Formulation of a Previously
Approved Active Ingredient .................................... 8-109
[C][3] Patent Cannot Claim an Active Ingredient
if Any Salt or Ester of That Active Ingredient
Has Been Previously Approved ............................... 8-109
[C][4] Patent Cannot Claim Combination of
Two Previously Approved Drugs ............................... 8-110
[D] Section 156 and the Uruguay Round
Agreements Act ....................................................... 8-111
§ 8:4.3 Scope of Protection During Restoration
Period ....................................................................... 8-112
[A] The Scope of Protection During the Extension
Period ....................................................................... 8-112
§ 8:4.4 Mechanics of Patent Term Restoration ....................... 8-115
[B] Roles of PTO and FDA in Handling
Patent Term Restoration Applications ..................... 8-116
[C] Interim Extensions ................................................. 8-117
**Chapter 9  Claim Construction**

*Richard G. Greco, Betty A. Ryberg & Martina Schuster*

| § 9:1 | General ........................................................................................................... 9-2 |
| § 9:1.1 | The Purpose of Claims ........................................................................... 9-2 |
| § 9:1.2 | Role of Jury, District Court and Appellate Courts .................... 9-3 |
| [A] | Claim Construction Is a Matter of Law ..................................... 9-3 |
| [B] | Standards of Review for Claim Constructions .......................... 9-3 |
| § 9:1.3 | Claim Construction Is a Predicate for ...................................... 9-4 |
| [A] | Infringement and Invalidity ......................................................... 9-4 |
| § 9:1.4 | Procedure for Claim Construction ................................................... 9-5 |
| § 9:2 | Sources for Interpreting Claims ......................................................... 9-8 |
| § 9:2.1 | Precedent Prior to *Phillips v. AWH* ........................................... 9-8 |
| [A] | Hierarchy of Evidence ........................................................................ 9-8 |
| [A][1] | Intrinsic Evidence ............................................................................. 9-9 |
| [A][2] | Extrinsic Evidence .............................................................................. 9-9 |
| [B] | Superseded Focus on Ordinary Meaning .................................... 9-10 |
| § 9:2.2 | *Phillips v. AWH* ................................................................................. 9-11 |
| § 9:2.3 | Post-Phillips Rules of Claim Construction ....................................... 9-13 |
| [A] | Patentee Acting As a Lexicographer ............................................ 9-13 |
| [B] | Extrinsic Evidence .............................................................................. 9-14 |
| [C] | Disclosed Embodiments .................................................................... 9-15 |
| [D] | Construction Preferably Does Not Render Terms Superfluous or Differences in Terminology Meaningless .......................... 9-15 |
| [E] | Order of Method Steps ...................................................................... 9-16 |
| [F] | Range Claims ......................................................................................... 9-16 |
| [G] | Disavowal or Disclaimer .................................................................. 9-16 |
| § 9:3 | Interpretation of Common Claim Terms ........................................... 9-17 |
| § 9:3.1 | Preambles .............................................................................................. 9-17 |
| [A] | Preamble Recites Essential Structure ............................................ 9-18 |
| [B] | Preamble Recites Important Steps .................................................. 9-18 |
| [C] | Preamble Provides Antecedent Basis ............................................. 9-18 |
| [D] | Reliance on Preamble During Prosecution ..................................... 9-19 |
| § 9:3.2 | Transition Phrases ................................................................................. 9-19 |
| [A] | “Comprising” ......................................................................................... 9-19 |
| [B] | “Consisting of” ..................................................................................... 9-20 |
| [C] | “Consisting essentially of” ................................................................. 9-20 |
| [D] | “Group of,” “Group consisting of,” *Markush* Group ......................................................... 9-21 |
| [E] | “Whereby” ............................................................................................. 9-22 |
| § 9:3.3 | Articles and Conjunctions ................................................................. 9-22 |
| [A] | “a” or “an” ........................................................................................... 9-22 |
| [B] | “the” .................................................................................................... 9-23 |
| [C] | “and’’/’’or” ............................................................................................ 9-23 |
§ 9:4 Construction of Means-Plus-Function Claims .............. 9-24
§ 9:5 Disclaimer of Subject Matter That Literally Falls
Within Claim Language ................................................. 9-24
§ 9:6 Pharmaceutical Patents .................................................. 9-25
§ 9:6.1 Planning for Claim Construction During
Prosecution ........................................................................... 9-25
§ 9:6.2 Common Construction Issues in Pharmaceutical
Patents .................................................................................. 9-26

Chapter 10 Patent Infringement

David K. Barr

§ 10:1 Introduction ................................................................. 10-2
§ 10:2 Acts Constituting Infringement ..................................... 10-3
§ 10:2.1 Direct Infringement .................................................. 10-3
§ 10:2.2 Inducing Infringement .............................................. 10-4
[A] Elements of Inducing Infringement ............................ 10-4
[B] Inducement Under Section 271(e)(2) ....................... 10-6
§ 10:2.3 Contributory Infringement ....................................... 10-6
§ 10:2.4 Section 271(f): Infringement by Shipment from
the United States of Component of a Patented
Invention to Be Assembled Abroad .......................... 10-7
§ 10:2.5 Section 271(g): Infringement of a U.S. Process
Patent by Importing into the United States or
Offering to Sell, Selling, or Using a Product
Made by the Patented Process .................................. 10-8
§ 10:2.6 “Divided” Infringement of Method Claim ......... 10-10
§ 10:3 Infringement Under the Doctrine of Equivalents ........ 10-12
§ 10:3.1 The “All Elements” Rule ........................................... 10-13
§ 10:3.2 Tests for Equivalence .............................................. 10-13
§ 10:3.3 Limitations on the Doctrine of Equivalents ........... 10-14
[A] Prosecution History Estoppel ........................................ 10-15
[A][1] Estoppel by a Claim Amendment Made for
Substantial Reason Related to Patentability .............. 10-15
[A][1][a] Presumption of General Disclaimer of
Equivalents; Rebutting the Presumption ......... 10-15
[A][1][a][i] Unforeseeability of Equivalent .............. 10-16
[A][1][a][ii] Amendment Bears “No More than a
Tangential Relation” to Equivalent .............. 10-18
[A][1][a][iii] Some Other Reason ...................... 10-18
[A][2] Estopped by Argument Made During
Prosecution ................................................................. 10-19
[B] Dedication of Described, but Unclaimed
Subject Matter: Johnson & Johnston .............. 10-19
[C] Specific Exclusion: Dolly v. Spalding .......... 10-21
Chapter 11  Experimental Use Defense to Patent Infringement

Leora Ben-Ami, Christopher Jagoe & Peter Fratangelo

§ 11:1  Introduction ................................................................. 11-1
§ 11:2  Historical Development .................................................. 11-2
§ 11:3  Cases .............................................................................. 11-3
  § 11:3.1  Roche Products, Inc. v. Bolar Pharmaceutical Co. .......11-3
  § 11:3.2  Deuterium Corp. v. United States ................................. 11-4
  § 11:3.3  Embrex, Inc. v. Service Engineering Corp. ................ 11-7
  § 11:3.4  Madey v. Duke University ........................................ 11-8
§ 11:4  Other Views.................................................................. 11-10

Chapter 12  Government Funded Research:
Bayh-Dole and Other Acts

Richard G. Greco

§ 12:1  Policy Behind Enactment of Bayh-Dole.......................... 12-2
  § 12:1.1  Ownership of Government Funded Inventions
             Prior to Bayh-Dole.......................................................... 12-3
  § 12:1.2  The Motive for Change ............................................. 12-3
Table of Contents

§ 12:1.3 Reagan Policy Extension of Bayh-Dole to All Contracting Parties................................................... 12-4

§ 12:2 Overview of the Bayh-Dole Act ...................................... 12-4

§ 12:2.1 “Funding Agreements” ............................................. 12-4

§ 12:2.2 Potential Requirement for Written Agreement .......... 12-5

§ 12:2.3 Private Party Right to Acquire Inventions Made Under Funding Agreement ................................ 12-6

§ 12:2.4 Requirements for Acquiring Private Ownership of an Invention Pursuant to Funding Agreement..... 12-7

[A] Notice of the Invention ............................................ 12-7

[A][1] Timing.................................................................. 12-7

[A][2] Scope of Disclosure .............................................. 12-8


[B] Election to Retain Rights to the Invention.................. 12-9

[C] Consequences of Failure to Provide Timely or Sufficient Notice or Election ...................................... 12-10

[C][1] Insufficient Disclosure: Campbell Plastics .......... 12-10

[C][2] Failure to Comply with Bayh-Dole Act As a Defense: T.M. Patents ............................................ 12-11

[C][3] Good Practices.................................................... 12-12

[D] Filing Patent Applications ...................................... 12-12

§ 12:2.5 Special Funding Agreement Requirements for Non-Profit Corporations..................................... 12-13

§ 12:3 Retained Government Rights in Inventions Funded Under a Bayh-Dole Agreement................................. 12-13

§ 12:3.1 Non-Exclusive Government License ....................... 12-14

[A] Statutory Provision.................................................... 12-14

[B] Potential Impact on Patented Drugs ......................... 12-14

§ 12:3.2 March-In Rights: Federal Power to Use Privately Owned Bayh-Dole Act Patents to Make Inventions Publicly Available ......................................................... 12-15

[A] Statutory Provision.................................................... 12-15

[B] Failure to Satisfy U.S. Manufacturing Requirements Could Trigger Use of March-In Rights ............. 12-16

[C] Petitions to Exercise March-In Rights .................... 12-17

[C][1] Product Still in Trials: In re CellPro ...................... 12-17

[C][2] High Prices: In re Norvir® and In re Xalatan® ........ 12-18

[D] Failure of Prior Government Efforts to Support Research As a Means to Regulate Drug Prices .... 12-19


§ 12:3.3 Additional Contractually Imposed Restrictions ...... 12-20
Chapter 13  Antitrust, FTC, and State Competition Law

Stephen J. Elliott

§ 13:1 Introduction ......................................................... 13-3
§ 13:2 Sherman Act Claims .................................................. 13-4
§ 13:2.1 Elements of a Section 1 Claim ................................ 13-4
[A] Concerted Conduct .................................................. 13-4
[B] Unreasonable Restraint of Trade .................................. 13-5
[C] Patent License Agreements ......................................... 13-7
[C][1] Analysis of Specific Agreement Terms ...................... 13-8
[C][1][a] Royalty Rates .................................................. 13-8
[C][1][b] Extending License Beyond Patent Term .................. 13-9
[C][1][c] Resale Price Maintenance .................................... 13-9
[C][1][d] Extending License Beyond Patent Subject Matter ....... 13-10
[C][1][e] Field of Use and Territory Restrictions ................. 13-10
[C][1][f] No-Challenge Provisions ...................................... 13-10
[D] Patent Litigation Settlement Agreements ...................... 13-11
[D][1] Importance of Settlement Agreements ...................... 13-11
[D][2] Importance of Patent Monopoly ............................... 13-12
[D][3] FTC/DOJ Reporting Requirement ...................... 13-12
[D][4][b] Post-Actavis Reverse Payment Cases .................... 13-15
[D][4][b][i] Applying the Rule of Reason Under Actavis .......... 13-16
[D][4][b][ii] Defining a Large and Unexplained Payment .......... 13-16
[D][4][b][iii] Lawful Agreements ........................................ 13-18
[D][4][b][iv] The Relevance of Patent Validity ....................... 13-19
§ 13:2.2 Elements of a Section 2 Claim ............................ 13-20
[A] Relevant Market Definition .................................... 13-21
[B] Predatory Conduct Involving Patents ......................... 13-23
Table of Contents

[B][1][a] More Is Required to Prove a Walker-Process Claim than to Prove Inequitable Conduct........13-24
[B][1][b] Case Upholding Finding of Walker-Process Violation.............................................. 13-25
[B][1][c] Case Reversing Finding of Walker-Process Violation.............................................. 13-26
[B][2] Sham Patent Litigation......................................................... 13-26
[B][2][a] The Noerr-Pennington Doctrine ..................... 13-26
[B][2][b] The Professional Real Estate Exception for Sham Litigation.............................. 13-27
[B][2][b][i] Grounds for Rejecting Sham Litigation Claims.............................................. 13-28
[B][2][b][ii] Cases Addressing Sham Litigation Claims Based on Pharmaceutical Patent Litigation......................................................... 13-29
[B][2][c] Application of Professional Real Estate to a Series of Related Cases............... 13-31
[B][3] Orange Book Listings .......................................................... 13-32
[B][3][a] Application of Noerr-Pennington ..................... 13-32
[B][3][b] Standard for Listing.................................................. 13-34

§ 13:2.3 Antitrust Injury Requirement.......................... 13-38
[A] Elements of Antitrust Injury............................................. 13-39
[B] Orange Book Listings.................................................. 13-40

§ 13:2.4 Antitrust Standing Requirement ....................... 13-40
[A] Factors Relevant to Standing............................................. 13-41
[B] Overcharges.................................................................. 13-42
[C] Suppliers..................................................................... 13-42
[D] Associations and Advocacy Organizations .................. 13-43

§ 13:3 Related State-Law Causes of Action ...................... 13-44

§ 13:3.1 State-Law Antitrust and Unfair Competition Claims............................................. 13-44
[A] Indirect Purchaser Claims............................................. 13-44
[B][2] Agreement to Drop Invalidity Challenge................ 13-47
[B][3] Claims Based on Settlement Agreements.............. 13-47
[C] Statutory Requirements.................................................. 13-48
[C][1] Choice of Law.......................................................... 13-48
[C][2] Noerr-Pennington Applies to State Law Claims...................................................... 13-49

xlvii
Chapter 14  Biologic and Biosimilar Drug Products

David K. Barr

§ 14:1  Introduction ......................................................... 14-2

§ 14:2  Biological Drug Product Defined ............................... 14-3

§ 14:3  FDA Approval of “Follow-On Biologics” Before the
        BPCIA ................................................................. 14-4

§ 14:4  The BPCIA ............................................................... 14-5

§ 14:4.1 “Biosimilar” Drug Products .................................... 14-5

§ 14:4.2 “Interchangeable” Biosimilar Drug Products ............... 14-6

§ 14:4.3 FDA Guidances on Biosimilar Drugs ....................... 14-7

§ 14:4.4 BPCIA Exclusivity Provisions ................................ 14-8

[A] Reference Product Exclusivity .................................... 14-8

[A][1] Pediatric Exclusivity ................................................ 14-8

[A][2] Orphan Drug Exclusivity ......................................... 14-9

[B] Exclusivity for the First Interchangeable
    Biological Product .................................................... 14-9

§ 13:3.2  Unjust Enrichment .............................................. 13-50

[A] Elements of State Law Unjust Enrichment
    Claim ................................................................. 13-50

§ 13:4  Damages ............................................................... 13-52

§ 13:4.1  Antitrust Damages .............................................. 13-52

[A] Overcharges to Purchasers ...................................... 13-53

[B] Indirect Purchasers .............................................. 13-53

[C] Claims by Competitors ........................................ 13-54

[D] Period for Calculating Damages ........................... 13-54

§ 13:4.2  Disgorgement Remedy for Unjust Enrichment ......... 13-55

§ 13:5  Class Actions ......................................................... 13-55

§ 13:5.1  Rule 23(a) ......................................................... 13-55

[A] Numerosity ......................................................... 13-55

[B] Commonality ....................................................... 13-56

[C] Typicality .......................................................... 13-56

[D] Adequacy ............................................................ 13-57

[D][1] Conflict of Interest ........................................... 13-57

[D][2] Vigor ............................................................... 13-59

§ 13:5.2  Rule 23(b) ......................................................... 13-59

[A] Inconsistency ....................................................... 13-59

[B] Type of Relief ..................................................... 13-59

[C] Predominance and Superiority ............................... 13-59

[C][1] Predominance .................................................. 13-59

[C][2] Superiority ....................................................... 13-61

§ 13:5.3  The Class Action Fairness Act of 2005 ................. 13-61
Table of Contents

§ 14:4.5 The “Purple Book” .................................................. 14-10
§ 14:4.6 BPCIA’s Patent Dispute Resolution Provisions ........ 14-11
  [A] Confidential Access to the Biosimilar Application and Manufacturing Information .... 14-11
  [C] Patent Resolution Negotiations ........................................ 14-14
  [D] Patent Infringement Actions Based on Filing of a Biosimilar Application ........ 14-14
  [E] Remedies for Infringement .................................. 14-16
  [F] Later Issued or Exclusively Licensed Patents .......... 14-18
  [H] Limitation on Declaratory Judgment Actions ... 14-19

§ 14:5 Litigation Under the BPCIA ........................................ 14-20
§ 14:5.1 Sandoz v. Amgen {Enbrel®} ........................................... 14-20
§ 14:5.2 Celltrion v. Kennedy Trust and Hospira v. Janssen (Remicade®) ........................................ 14-22
§ 14:5.3 Amgen v. Sandoz {Neupogen®} .................................. 14-23
  [A] The District Court Decision .................................. 14-24
  [B] The Federal Circuit Decision .................................. 14-26
  [C] The Supreme Court Decision .................................. 14-31
§ 14:5.4 Amgen v. Sandoz {Neulasta®} ......................... 14-34
§ 14:5.5 Amgen v. Hospira {Epogen®} ............................. 14-34
§ 14:6 Conclusion ................................................................. 14-35

Appendix A Glossary of Biotechnology Terminology from Case Law ........................................ App. A-1

Appendix B Primer on Basic Biotechnology Concepts ........................................ App. B-1

Appendix C The Science of Biosimilars ................................ App. C-1

Table of Authorities ............................................................... T-1

Index ....................................................................................... I-1
Preface

Patents are a focal point in the development, manufacture, and marketing of pharmaceutical and biotechnological products. The scope of patent protection for these products has profound effects upon pharmaceutical and biotech research, and the development of new therapeutic products.

For over twenty-five years, we and our colleagues have advised pharmaceutical and biotechnology companies on patent issues and represented them in patent litigations involving major drugs, diagnostic products, and medical devices. From our work with these companies, we saw the need for a practical guide to help both lawyers and non-lawyers navigate through these complex issues. To this end, our group has produced *Pharmaceutical and Biotech Patent Law*.

Traditional patent law treatises cover patent law as a general topic without focusing on the law’s impact on specific areas of technology. Over the past several decades, however, the courts and the U.S. Congress have made many significant changes to U.S. patent law that uniquely affect the pharmaceutical and biotech industries. Both political and technological forces have driven these changes. Specific provisions of the Patent Statute, such as the Hatch-Waxman Act, have been enacted to adjust the balance between pioneering and generic drug companies. An entire chapter of the book has been devoted to this topic, which is often overlooked in other patent treatises and relegated to non-patent books on FDA regulation. Congress also amended the U.S. Patent Statute to harmonize United States law with foreign patent law. The book discusses these changes in the context of pharmaceutical and biotech issues. There has also been a tremendous growth in patent litigation involving the pharmaceutical sciences. New and developing areas of technology, such as molecular biology, have generated an ever-growing body of case law specific to these areas. This body of pharmaceutical and biotech law, we believe, deserves separate treatment apart from the general discussion of patent law.

We organized the book to present patent law issues that arise from the earliest stages of drug discovery through final regulatory approval, marketing, and enforcement, and arranged the chapters in that order. To make this book accessible to the non-lawyer, we have kept lengthy discussions of case law to a minimum. Instead, we emphasize fundamental holdings and principles organized by substantive topics, rather than by individual cases. Where necessary, we provide a more
expansive treatment for the most important decisions. However, to provide rapid access to relevant cases for practitioners, we have made an effort to provide citations to significant decisions in footnotes.

One particularly unique feature of the book is a chapter on different types of pharmaceutical patents. Rather than limiting the book’s organization to general topics such as anticipation and obviousness, we created individual sections organized based on the types of pharmaceutical and biotech patents, much as the industry informally categorizes its patents. Thus we have sections that focus on the case law and issues surrounding chemical compound patents, pharmaceutical formulations, methods of treatment, and numerous other categories. Although the book remains a text on the law, not science, of pharmaceutical and biotech patents, we included general discussions of the science throughout the text when needed to provide context. We also provided an appendix that gives an overview of relevant scientific concepts, and a glossary that gives definitions for scientific terminology taken from court decisions to provide the reader with an understanding of how the courts view and apply these concepts. We included a chapter on antitrust and unfair competition issues which have arisen with increasing regularity in pharmaceutical and biotech patent litigations, and therefore have an impact on all aspects of patent procurement, licensing, and enforcement.

Although it is not the purpose of this volume to replace the many fine general treatises on patent law, a concise background on general patent law principles is also provided to give context to the issues that relate more specifically to the pharmaceutical and biotech industries.

We hope our book proves to be a valuable guide to this important and fascinating area of law.

David K. Barr
Daniel L. Reisner
Editors
Acknowledgments

Joel Katcoff provided invaluable assistance in editing chapter 8, The Hatch-Waxman Act, and section 5:9, Inequitable Conduct. In addition, the following Kaye Scholer lawyers assisted in the preparation of this book, including legal research, cite checking, and provision of content: Tatiana Alyonycheva, John S. Cahalan, Hanna G. Cohen, Brett D. Dockwell, Amir R. Ghavi, Andrew J. Gropper, Silvia Jordan, Regina Kent, Matthew D. Kohel, Matthew McFarlane, Edward J. Mullins, Oded Pincas, Dilpreet K. Rai, Joshua S. Reisberg, Brandon N. Sklar, and Marc Zubick. Assistance with illustrations was provided by Kaye Scholer graphics specialists Eldin Johnston and Bradley Brown.