

Table of Contents

CHAPTER 1. OVERALL FRAMEWORK TO GENERIC DRUG DEVELOPMENT AND PATENT LITIGATION

- § 1:1 Pathways to brand drug development
- § 1:2 Pathways to generic drug development
- § 1:3 Legal aspects of the generic drug development
pathway for judges and lawyers
- § 1:4 Caveats in the Hatch Waxman Act/Paragraph IV
litigation

CHAPTER 2. INTRODUCTION TO PATENTS

I. PATENT BASICS

- § 2:1 In general
- § 2:2 Basic patent application process
- § 2:3 Structural organization of a patent

II. PATENT CLAIMS

- § 2:4 Importance of patent claims
- § 2:5 Person of ordinary skill in the art (POSITA)
- § 2:6 Organizational structure of the claim
 - § 2:7 —Preamble
 - § 2:8 —Transition phrase
 - § 2:9 —Body of the claim
 - § 2:10 Conclusion

III. STATUTORY PROVISIONS INTRODUCTION

- § 2:11 Common statutory provisions of the patent law

CHAPTER 3. COMMON TYPES OF PHARMACEUTICAL PATENTS

- § 3:1 Base chemical/compound claims
- § 3:2 Salts, esters, and solvates

- § 3:3 Enantiomers
- § 3:4 —History of enantiomer patentability
- § 3:5 —Enantiomer patentability when racemate is known
- § 3:6 —Case study—Levofloxacin
- § 3:7 — —Levetiracetam
- § 3:8 — —Clopidogrel
- § 3:9 Polymorphs
- § 3:10 Claim Types in Polymorphs
- § 3:11 Polymorphs—Amorphous to crystal form conversion and implications
- § 3:12 Typical litigation issues in polymorphism
- § 3:13 Combinations of APIs
- § 3:14 Formulations
- § 3:15 Methods of use
- § 3:16 Method of manufacture or process claims
- § 3:17 Product-by-process claims
- § 3:18 —Embedding in a method claim
- § 3:19 Release profiles—Potential invalidity under single means claim theory

CHAPTER 4. FOUNDATIONS OF PATENT VALIDITY AND INVALIDITY

I. GENERALLY

- § 4:1 In general
- § 4:2 Claim construction breadth and invalidity: Broad constructions to invalidate or narrow constructions to avoid infringement

II. PRIOR ART

- § 4:3 Burdens of proof under Clear and Convincing Evidence—Prior art—Considered or not considered by examiner
- § 4:4 Burdens of proof—Prior art—Sources
- § 4:5 — —Fully presented and vetted
- § 4:6 — —Cited but not vetted
- § 4:7 — —Not cited

III. PRACTICING THE PRIOR ART

- § 4:8 Defense to infringement—Practicing the prior art

TABLE OF CONTENTS

- § 4:9 Practicing the prior art by replicating examples of the prior art—Inherent anticipation by replicating prior art examples

CHAPTER 5. SECTION 101’S SUBJECT MATTER & UTILITY

- § 5:1 Patentable subject matter generally
- § 5:2 Mayo 2-Part Test
- § 5:3 Printed Matter Doctrine
- § 5:4 Patentable Subject Matter—Printed Matter Doctrine 2-Part Test
- § 5:5 Patentable subject matter—Pharmaceutical Patents
- § 5:6 —USPTO guidelines for pharma patents
- § 5:7 —Pharmaceuticals and concepts related to data comparisons with mental steps or analogous human mental work
- § 5:8 —Pharmaceuticals and concepts relating to organizing or analyzing information
- § 5:9 Pharmaceutical patent utility
- § 5:10 Pharmaceutical patent utility and specific methods of use of compound
- § 5:11 Pharmaceutical patent utility and enablement
- § 5:12 Pharmaceutical patent utility and benefits of priority application dates
- § 5:13 Generic company litigation strategies for section 101 invalidity
- § 5:14 Patentable subject matter issues in pharmaceutical patents—Selected cases
- § 5:15 Summary of Section 101 cases involving diagnostics versus method claims
- § 5:16 Summary of diagnostic claims treatment under Section 101
- § 5:17 Summary of method of treatment claims under Section 101
- § 5:18 Summary of method of preparation claims under section 101

CHAPTER 6. NOVELTY AND LOSS OF RIGHTS UNDER SECTION 102

- § 6:1 Novelty and “new” inventions
- § 6:2 Novelty under the AIA
- § 6:3 “Old” Section 102(a)

- § 6:4 “Old” Section 102(b)
- § 6:5 —On-sale bar
- § 6:6 —Public use bar
- § 6:7 Public use by selling/testing samples via
technology transfer & licensing
- § 6:8 “Old” Section 102(c)
- § 6:9 “Old” Section 102(d)
- § 6:10 “Old” Section 102(e)—Utopian-world patent
issuance in the USPTO
- § 6:11 Section 102(e)—Understanding § 102(e) through
example and time lines
- § 6:12 “Old” Section 102(f)—Inventor is not the inventor
- § 6:13 “Old” Section 102(g)—Prior invention by another
- § 6:14 Section 102(g)—Contrasting section 102(g)(1)
versus 102(g)(2)
- § 6:15 Joint inventorship
- § 6:16 Conclusion
- § 6:17 Invalidating patent because invention is not new
- § 6:18 Element-by-element analysis, express and
inherent anticipation
- § 6:19 Anticipation by equivalency: broadening claim
scope through equivalency could lead to
anticipation
- § 6:20 Inherent anticipation
- § 6:21 —Necessarily present/natural result
- § 6:22 —Accidental anticipation
- § 6:23 —Recognition of the inherent element
- § 6:24 —Hypothetical
- § 6:25 — —*SmithKline v. Apotex* revisited

CHAPTER 7. OBVIOUSNESS UNDER SECTION 103

I. BACKGROUND TO OBVIOUSNESS

- § 7:1 Inventions more than trivial variations
- § 7:2 *Graham v. Deere* factors—Primary obviousness
factors
- § 7:3 Timing of obviousness inquiry
- § 7:4 Guarding against hindsight—Motivation,
suggestion, teaching (MST) to combine prior art
- § 7:5 —Combination of references—Flowing from the
prior art

TABLE OF CONTENTS

§ 7:6	—References—From nature of problem to be solved
§ 7:7	Secondary indicia of obviousness
§ 7:8	Unexpected results of the invention
§ 7:9	Long-felt need for the invention
§ 7:10	Failure of others to make the invention
§ 7:11	Copying by others—Benign factor in obviousness
§ 7:12	—Active ingredient
§ 7:13	—Formulation
§ 7:14	Licensing by others
§ 7:15	Commercial success—Generic drug infringement cases
§ 7:16	Skepticism by others and proof of nonobviousness
§ 7:17	Third-party praise and awards
§ 7:18	Chemical similarity—Chemical homology, isomerism, and structural similarity
§ 7:19	—Structural obviousness of chemical compounds
§ 7:20	—Isomers and obviousness
§ 7:21	Conclusion

II. OBVIOUSNESS & INVALIDITY

§ 7:22	Invalidity defense
§ 7:23	USPTO guidelines
§ 7:24	Combining prior art elements according to known methods to yield predictable results
§ 7:25	—Simple substitution of one known element for another to obtain predictable results
§ 7:26	Known techniques to improve similar devices, methods, or products
§ 7:27	Applying known technique to yield predictable results
§ 7:28	“Obvious to try”—Choosing from finite number of items
§ 7:29	—Role of common sense
§ 7:30	—Applicability to enantiomers, salt selection, and extended release (ER) formulations
§ 7:31	Market forces and design considerations
§ 7:32	Teaching, suggestion, or motivation in the prior art
§ 7:33	Person of ordinary skill in the art (POSITA)
§ 7:34	—The ordinary skilled artisan is not the inventor
§ 7:35	Structural obviousness—Breaking compound patents and the lead compound analysis

- § 7:36 — —Structural obviousness and lead compound analysis—Case study on pioglitazone
- § 7:37 —Lansoprazole versus rabeprazole
- § 7:38 —Attacking of analogue of compound
- § 7:39 The new lead formulation test—Copying lead compound test
- § 7:40 Reasonable expectation of success in obviousness

CHAPTER 8. SECTION 112’S BEST MODE

A. STATUTORY PROVISIONS: SPECIFICATION

- § 8:1 Role of the specification
- § 8:2 Section 112(a) (Pre-AIA Section 112, first paragraph)
- § 8:3 —Best mode requirement
- § 8:4 Patent invalidity theories under Section 112—Best mode requirement
- § 8:5 Invalidity based on best mode no longer allowed under AIA
- § 8:6 Using inequitable conduct to challenge best mode violations when invalidity is not allowed
- § 8:7 Best mode in claim construction

CHAPTER 9. SECTION 112’S ENABLEMENT

- § 9:1 Role of the specification
- § 9:2 Section 112(a) (Pre-AIA Section 112, first paragraph)
- § 9:3 —Enablement requirement basics
- § 9:4 —Quick Summary
- § 9:5 Patent invalidity theories under Section 112
- § 9:6 —Lack of enablement
- § 9:7 — —Gap filling enablement with common knowledge and inadvertent obviousness
- § 9:8 — —Undue experimentation
- § 9:9 — —“How to make”
- § 9:10 — —“How to use”
- § 9:11 — —In vitro to in vivo teaching
- § 9:12 — —Effective amounts
- § 9:13 Contrasting enablement and best mode

TABLE OF CONTENTS

CHAPTER 10. SECTION 112'S WRITTEN DESCRIPTION

- § 10:1 Role of the specification
- § 10:2 Section 112(a) (Pre-AIA Section 112, first paragraph)
- § 10:3 Written description
- § 10:4 Patent invalidity theories under Section 112: written description invalidity
- § 10:5 Written description—Ranges in the specification
- § 10:6 Broad claim constructions can lead to written description invalidity
- § 10:7 Written description invalidity and mechanics of written description challenge
- § 10:8 Negative limitations in claims and specification support
- § 10:9 Written description—Breaking chains of priority to invalidate later patents
- § 10:10 Written description when specification catalogs lists of elements and claim plucks out elements

CHAPTER 11. SECTION 112'S INDEFINITENESS

- § 11:1 Section 112(b) (Pre-AIA Section 112, second paragraph): claim precision and boundaries
- § 11:2 Section 112, second paragraph: claim precision, indefiniteness, and boundaries
- § 11:3 Indefiniteness: failure of ability to measure and testing
- § 11:4 Indefiniteness and what the inventor regards as the invention
- § 11:5 Indefiniteness and rebuttable presumption in claim amendments to avoid ambiguity
- § 11:6 Indefiniteness and means plus function claim language

CHAPTER 12. SECTION 112'S DEPENDENT AND MEANS PLUS FUNCTION CLAIMS

- § 12:1 Section 112(c)-(d) (Pre-AIA Section 112, third and fourth paragraph): Dependent claims
- § 12:2 Dependent claim infringement and invalidity
- § 12:3 Section 112(f) (Pre-AIA Section 112, sixth paragraph): means plus function claims

CHAPTER 13. GENUS AND SPECIES

- § 13:1 What is a genus and species
- § 13:2 Anticipation of genus and species patents
- § 13:3 Obviousness of genus and species
- § 13:4 Written description support for genus in view of disclosure of species
- § 13:5 Case study—Genus and species: Zyprexa® (Olanzapine)

CHAPTER 14. CLAIMING PRIORITY PROVISIONALS CONTINUATIONS AND DIVISIONALS

- § 14:1 Concept of claiming priority or benefit to earlier filing date
- § 14:2 Provisional patent applications
- § 14:3 Priority and earliest filing dates
- § 14:4 Section 119: claiming foreign priority dates to U.S. provisional applications
- § 14:5 Section 119(e): provisional application prior art date under pre-AIA 102(e) and AIA 102(a)(2)
- § 14:6 Section 119: claiming foreign priority—Claim for priority must include a specific reference to earlier filed foreign application
- § 14:7 Mechanics of claiming priority and benefits to earlier filing dates
- § 14:8 Section 119: claiming foreign priority—Tool for evaluating prior art effect
- § 14:9 —Prior Art and section 119(a) before and after the AIA
- § 14:10 Claiming the benefit of earlier-filed applications under Section 120 & 121
- § 14:11 Continuation applications for a different invention using the same specification
- § 14:12 Claim for benefit of earlier filing date under section 120 must include a specific reference to earlier filed application
- § 14:13 Divisional applications for examiner-mandated restrictions to different inventions
- § 14:14 Divisional applications and safe harbor provision of section 121 for divisional applications
- § 14:15 Continuation-in-part applications—Introducing new matter
- § 14:16 Rolling provisionals allow for chains of priority

TABLE OF CONTENTS

- § 14:17 Importance of adequate disclosure to support
later filed applications

CHAPTER 15. CLAIM CONSTRUCTION IN PATENT INFRINGEMENT

- § 15:1 Generally
§ 15:2 Basic infringement test
§ 15:3 Claim construction generally
§ 15:4 Evidence considered in claim construction
§ 15:5 —Intrinsic evidence must be considered first and
mandatory evidence
§ 15:6 —Extrinsic evidence can be considered and
permissive evidence
§ 15:7 —Dictionaries and treatises as sources of
evidence of claim meaning
§ 15:8 Customary claim construction rules
§ 15:9 Tools for the generic company
§ 15:10 Specification clearly defines claim term
§ 15:11 Claim term is *implicitly* defined by consistent
use throughout specification
§ 15:12 Pattern of examples in specification deduces
claim meaning
§ 15:13 Embodiment is the invention
§ 15:14 Specification disavows particular meaning
§ 15:15 Specification *explicitly disclaims* definition
§ 15:16 Limiting the claim scope because consistent with
invention's purpose
§ 15:17 Specification contains *implicit disclaimer* of
definition
§ 15:18 Specifications and underclaiming—Claiming less
than you could have
§ 15:19 Prosecution history as intrinsic evidence—
Mandatory or permissive evidence
§ 15:20 Using Inter Partes Review (IPR) and Post-Grant
Review (PGR)
§ 15:21 Prosecution history contains narrow definition
when ordinary meaning is unclear
§ 15:22 Claim term is narrowed because of disclaimer of
ordinary meaning in prosecution history
§ 15:23 Using prosecution history of parent application
in subsequent applications
§ 15:24 Choosing narrow claim scope when competing
scopes exist

- § 15:25 Claim differentiation and interpreting claims of different scope
- § 15:26 Inexact modifiers or relative terminology
- § 15:27 Illustration regarding scope of “about”
- § 15:28 Timing of claim construction in view of issued patent
- § 15:29 Special Topic in Claim Construction for Chemical Compounds, Enantiomers, & Racemates
- § 15:30 Preambles in Claim Construction
- § 15:31 Using Trademark Doctrinal Law On Surveys to Assist in Claim Construction

CHAPTER 16. LITERAL INFRINGEMENT

- § 16:1 Generally
- § 16:2 Litigating more than one claim construction at trial: Federal Circuit review of record
- § 16:3 Special case: inherent infringement under single crystal theory
- § 16:4 —Impact of *SmithKline v. Apotex* on infringement
- § 16:5 Proving literal infringement
- § 16:6 Literal infringement as based on the generic drug application
- § 16:7 The ANDA specification controls the infringement inquiry
- § 16:8 Current ANDA infringement for future modifications to ANDA

CHAPTER 17. DOCTRINE OF EQUIVALENTS INFRINGEMENT

- § 17:1 Doctrine of equivalents (DOE) infringement
- § 17:2 Tests for DOE
- § 17:3 —General limitations on the doctrine of equivalents
- § 17:4 —Insubstantial differences test for equivalency infringement
- § 17:5 —Function way result test
- § 17:6 —Element-by-element analysis
- § 17:7 Expanding scope of equivalents to ensnare prior art—Ensnarement Test
- § 17:8 Subject matter disclosed but not claimed—“Dedication to the public” rule

TABLE OF CONTENTS

§ 17:9	Doctrine of Prosecution History Estoppel (PHE)
§ 17:10	—Amendment-based estoppel
§ 17:11	— —Rebutting the presumption of estoppel
§ 17:12	— —Festo IX: Federal circuit summary of equivalency factors
§ 17:13	— —Festo Test Part 7: Rebutting prosecution history estoppel
§ 17:14	— —Festo Test Part 7(i): Foreseeable changes
§ 17:15	— —Foreseeability of drafting claim to equivalent: Is it new matter?
§ 17:16	— —Festo Test Part 7(ii): Tangential relationship
§ 17:17	— —Festo test part 7(iii): Some other unexplained reason
§ 17:18	—Argument-based estoppel
§ 17:19	—Related applications may evoke estoppel
§ 17:20	—Scope
§ 17:21	—Prior art preclusions—Hypothetical claim analysis
§ 17:22	Doctrine of prosecution history estoppel (PHE)— Detailed structure test: An alternate to the insubstantial differences and function way result tests
§ 17:23	Case studies: <i>SmithKline Beecham</i> and Equivalency—Sustained release bupropion
§ 17:24	—Conclusion
§ 17:25	DOE as applied to the word “about”

CHAPTER 18. INDIRECT INFRINGEMENT THROUGH INDUCEMENT AND CONTRIBUTORY INFRINGEMENT

§ 18:1	Contributory and inducement infringement generally
§ 18:2	Patent infringement—Inducement under 35 U.S.C.A. § 271(b)
§ 18:3	Inducement requires subjective, not objective intent
§ 18:4	The RLD label when taken as a whole—non- infringing uses
§ 18:5	Pleading and proving specific intent
§ 18:6	Strategies to mitigate or thwart inducement to infringe claims

- § 18:7 —Opinions of counsel of invalidity to thwart specific intent to induce infringement
- § 18:8 Patent infringement—Inducement under 35 U.S.C.A. § 271(b)—Summary
- § 18:9 Inducement to infringe a patent claiming an unapproved FDA use—pointing to other section of label to prove inducement
- § 18:10 Contributory patent infringement under 35 U.S.C.A. § 271(c)
- § 18:11 —Knowing component is especially made
- § 18:12 —Substantial, noninfringing uses
- § 18:13 —Materiality

CHAPTER 19. INEQUITABLE CONDUCT AND PATENT UNENFORCEABILITY

- § 19:1 Inequitable conduct—Fraud on the Patent Office
- § 19:2 —How Long Does A Duty Last?
- § 19:3 Types of inequitable conduct test—Common situations
- § 19:4 Penalties for inequitable conduct
- § 19:5 —Unenforceability—Later patents through infectious unenforceability
- § 19:6 — —Awarding attorney’s fees and costs
- § 19:7 — —Fraud-based damages (Walker Process fraud)
- § 19:8 — —Private enforcement of fraud
- § 19:9 Curing inequitable conduct
- § 19:10 Asserting inequitable conduct—Not a game of “gotcha”
- § 19:11 — —Pleading inequitable conduct under heightened pleading standards
- § 19:12 Materiality threshold—Current and past tests for materiality
- § 19:13 —Materiality of patent and FDA materials
- § 19:14 —Current and past tests for materiality—Information does not have to be claimed
- § 19:15 — —Failure to comply with section 112(1)
- § 19:16 —Information does not have to verbatim
- § 19:17 — —False statements
- § 19:18 — —Failure to disclose relationship of affiant to applicant
- § 19:19 — —Data is presumed material
- § 19:20 —Failure to update information—petitions to make special

TABLE OF CONTENTS

§ 19:21	—Failure to provide unfavorable test results
§ 19:22	— —Accurate description of test conditions
§ 19:23	— —Claim for priority
§ 19:24	— —Issues examiner focuses on
§ 19:25	— —Affirmative misrepresentations
§ 19:26	Intent to deceive
§ 19:27	—Stressing importance of submitted prior art
§ 19:28	—Gross negligence
§ 19:29	—“Totality” can include gross negligence
§ 19:30	—Mere denial is never enough to overcome inference of intent
§ 19:31	—Searching for prior art
§ 19:32	—Patterns of misrepresentations or omissions— Single actions
§ 19:33	—Cultivated ignorance—Obtaining translations of foreign language documents
§ 19:34	—“Burying” critical reference
§ 19:35	—Failure to disclose prior art and foreign office actions from foreign searches
§ 19:36	—False or misleading affidavits
§ 19:37	—Failure to name proper inventors
§ 19:38	Materiality threshold—Pitfalls for patent applicants and corrective measures and practice tips
§ 19:39	Recap of cases post- <i>Therasense</i>
§ 19:40	Litigation misconduct as patent unenforceability
§ 19:41	Duty of candor and good faith during PTE applications
§ 19:42	Duty of candor and good faith during post issue PTAB trials
§ 19:43	Duty of candor during maintenance fee payments
§ 19:44	Conclusion

CHAPTER 20. EQUITABLE DEFENSES TO PATENT INFRINGEMENT

§ 20:1	Introduction
§ 20:2	Issue preclusion, collateral estoppel/claim preclusion, and res judicata
§ 20:3	Laches
§ 20:4	—What’s left of laches after Supreme Court SCA Hygiene
§ 20:5	—Quick comparison of laches and equitable estoppel

- § 20:6 —Factors
- § 20:7 —Laches and presumptions
- § 20:8 Equitable estoppel—Factors
- § 20:9 —Presumptions
- § 20:10 Prosecution laches
- § 20:11 —Recent developments
- § 20:12 Other defenses under 35 U.S.C.A. § 282
- § 20:13 Implied license
- § 20:14 —By sales of products
- § 20:15 —By litigation settlement

CHAPTER 21. PATENT INFRINGEMENT SAFE-HARBOR EXEMPTIONS

- § 21:1 Introduction
- § 21:2 Genesis of safe harbor exemption—*Roche v. Bolar*
- § 21:3 Hatch Waxman Act/safe harbor exemption—
Scope of exemption
- § 21:4 “Information” development and “information”
submission to FDA
- § 21:5 Reasonable scope of exemption
- § 21:6 —Medical devices and other ostensibly unrelated
activities
- § 21:7 —Effect of Congressional action on scope of
exemption
- § 21:8 —Chain of exemption
- § 21:9 — —Generic drug development
- § 21:10 — —Ancillary activities
- § 21:11 Recourse for patent holders
- § 21:12 Common law research exemption and de
minimis infringement
- § 21:13 Safe harbor exemption is not limited to just
generic drug development
- § 21:14 Safe harbor exemption and stock-piling
inventory

CHAPTER 22. BASICS OF BRAND DRUG APPROVAL PROCESS AND ORANGE BOOK LISTINGS

- § 22:1 Introduction
- § 22:2 Brand drug approval
- § 22:3 Investigational new drug application (IND)—
Beginning clinical trials

TABLE OF CONTENTS

§ 22:4	—Contents
§ 22:5	New drug application (NDA)
§ 22:6	—Drug master files (DMF)
§ 22:7	Types of new drugs in NDA
§ 22:8	Internal FDA machinations
§ 22:9	Patent information and the Orange Book
§ 22:10	—Listable and nonlistable patents
§ 22:11	—Patent listing as clerical not substantive
§ 22:12	—Delisting patents
§ 22:13	Orange book—Delisting patents under OB Transparency Act
§ 22:14	Patent information and the Orange Book— Forcible listing of unlisted patents
§ 22:15	When patents may be listed; reissue patents
§ 22:16	Who may list which patents
§ 22:17	Medical device patents, antibiotic, and REMS patents
§ 22:18	Polymorph patent listing
§ 22:19	Blinds and clinical testing
§ 22:20	—Clinical trial phases
§ 22:21	—Clinical trial phases- Public use patent invalidity
§ 22:22	“Paper NDAs”—New Drug Applications/section 505(b)(2) applications
§ 22:23	NDA approval and approval dates
§ 22:24	Publishing exclusivities in the Orange Book

CHAPTER 23. BRAND SIDE EXCLUSIVITIES

§ 23:1	Filing and approval exclusivities
§ 23:2	New Chemical Entity (NCE) exclusivity [five-year]
§ 23:3	NCE exclusivity and DEA scheduling
§ 23:4	NCE exclusivity for fixed combination products
§ 23:5	Extension of five year NCE exclusivity to 10 year NCE (and three year exclusivity) under qualified infectious disease products program
§ 23:6	Contrasting New Molecules for NCE Status versus New Molecules for Patent Term Extension (PTE) Purposes
§ 23:7	New Chemical Entity (NCE) exclusivity [five-year]—When to file ANDAs with Paragraph IV certifications

- § 23:8 —Extensions of the 30-month stay to Year 7.5
for NCE-based lawsuits
- § 23:9 —Delisting patents from Orange Book right
before NCE-1 date to thwart generic filings
- § 23:10 New product/clinical information/supplemental
exclusivity [three-year]
- § 23:11 —Requirements for the new clinical information
exclusivity
- § 23:12 —Requirements—Working example for generic
approval of less than all indications
- § 23:13 —Difference between NCE and three-year
exclusivity
- § 23:14 Three-year exclusivity for enantiomers
- § 23:15 Orphan drug exclusivity [seven-year exclusivity]
- § 23:16 Pediatric exclusivity [six months]
- § 23:17 —Effect
- § 23:18 —Tracking
- § 23:19 —Effect on ANDA filings
- § 23:20 —Effect on the 30-month stay
- § 23:21 — —Working examples of pediatric exclusivity
- § 23:22 — —Working examples—*Ranbaxy v. FDA and
Pfizer*; fluconazole
- § 23:23 — — —*Alza v. Mylan / Mylan v. FDA*; fentanyl
patch
- § 23:24 —Effects on the 30-month stay—Working
examples—*Pfizer v. Apotex*; amlodipine
- § 23:25 —Pediatric exclusivity and combination products
- § 23:26 Patent infringement implications
- § 23:27 Key points about pediatric exclusivity

CHAPTER 24. “PAPER NDA” AND SECTION 505(B)(2) APPLICATIONS

- § 24:1 Section 505(b)(2) application—General principles
- § 24:2 Contrasting 505(b)(2) applications with
Abbreviated New Drug Applications (ANDA)
- § 24:3 Similarities between 505(b)(2) application and
ANDA
- § 24:4 General types of applications
- § 24:5 Information needed to support the application
- § 24:6 Strategic uses
- § 24:7 —Use of a 505(b)(2) application to circumvent the
180-day exclusivity
- § 24:8 Challenges to the 505(b)(2)’s reference listed drug

TABLE OF CONTENTS

§ 24:9 Conclusion

CHAPTER 25. ABBREVIATED NEW DRUG APPLICATION (ANDA) APPROVAL PROCESS

- § 25:1 Reference Listed Drug (RLD)
- § 25:2 Suitability petitions to refer to different RLDs
- § 25:3 Abbreviated New Drug Application (ANDA)
- § 25:4 ANDA submissions standards & impact of refusal to receive (RTR)
- § 25:5 Challenging the refusal to receive (RTR) decision: no private right of action to enforce the FDCA
- § 25:6 Abbreviated New Drug Application (ANDA)—Differences between the NDA and ANDA
- § 25:7 —Last minute RLD label changes to thwart generic competition
- § 25:8 —Bioequivalency of generic drug
- § 25:9 Access to the RLD when RLD is protected by REMS
- § 25:10 Inner workings of the FDA
- § 25:11 Labeling review
- § 25:12 Chemistry and Manufacturing Controls (CMC)
- § 25:13 Biopharmaceutical review and bioavailability
- § 25:14 Classification system for biopharmaceutical properties
- § 25:15 —Patents claiming pharmacokinetics
- § 25:16 Microbiology review
- § 25:17 Clinical review
- § 25:18 CGMP review
- § 25:19 Deficiency letters
- § 25:20 —Major deficiency
- § 25:21 —Minor deficiency letter
- § 25:22 — —Telephone amendment
- § 25:23 Approval matrix
- § 25:24 Final approval versus tentative approval
- § 25:25 Tentative approval—Reasons for getting it
- § 25:26 Patent attorney involvement in answering deficiency letters
- § 25:27 Showing bioequivalency of generic versions
- § 25:28 Bioavailability defined
- § 25:29 Bioequivalency defined

GENERIC PHARMACEUTICAL PATENT AND FDA LAW

- § 25:30 Measuring bioequivalence of traditional solid oral dosage forms—Immediate and extended release forms
- § 25:31 —Extended release (ER) forms
- § 25:32 Extended release types—Diffusion control system
- § 25:33 —Dissolution control system
- § 25:34 —Erosion control system
- § 25:35 —Osmotic pump system
- § 25:36 —Ion-exchange resin system
- § 25:37 Proving bioequivalency—Failed biostudies as evidence of non-obviousness
- § 25:38 —In vitro dissolution studies
- § 25:39 —Dissolution testing and standardized testing protocols
- § 25:40 —Particle size and dissolution testing
- § 25:41 In vitro bioequivalency (BE) testing—Reasons for BE testing and biowaivers
- § 25:42 Biostudies in human subjects—Pilot and pivotal biostudies
- § 25:43 —Fasting and fed biostudies
- § 25:44 — —Food effect patents are not patentable
- § 25:45 Impurity specifications
- § 25:46 Impurity levels as defined by a regulatory authority
- § 25:47 Avoiding impurity patent claims may jeopardize regulatory approval
- § 25:48 Metered and powder dose inhalers
- § 25:49 Dry powder dose inhalers (DPI)
- § 25:50 Nasal sprays and inhaled solutions, sprays
- § 25:51 Samples and patent issues in samples
- § 25:52 Changes to the Abbreviated New Drug Application
- § 25:53 —Major changes
- § 25:54 —Moderate changes—Changes being effected in 30 days (CBE-30)
- § 25:55 —Minor change—Minimal impact change documented in annual report
- § 25:56 Changes to the ANDA and patent issues
- § 25:57 Review of ANDA approval process
- § 25:58 Designing around RLD patents to obtain non-infringing generic versions and excipient changes permitted

TABLE OF CONTENTS

- § 25:59 Changing excipients in non-solid oral dosage forms and filing 505(b)(2) applications to avoid patent infringement
- § 25:60 ANDA submission filing date and refusing to accept the ANDA for Filing; Effect of a refusal to receive on ANDA filing date
- § 25:61 Issues relating to the size/shape/color of generic products

CHAPTER 26. MECHANICS OF ORANGE BOOK PATENT CERTIFICATIONS AND NOTICE LETTERS

- § 26:1 Introduction
- § 26:2 Patent certifications and Orange Book listing
- § 26:3 When to file ANDA?
- § 26:4 —The difference between Data Exclusivity and Market Exclusivity
- § 26:5 When to file ANDA when no orange book patent exists during NCE 5 year exclusivity?
- § 26:6 Patent certifications and Orange Book listing—Paragraph I, II, III, or IV certifications
- § 26:7 —Patent certifications to “pop up” and “late listed” patents
- § 26:8 —ANDA certifications when the current RLD itself referred to a previous RLD
- § 26:9 —Impact on ANDA approval
- § 26:10 —Hypothetical patent certifications—Case study on Viagra
- § 26:11 Section viii statements: omitting patented methods of use
- § 26:12 Section (viii) statements: omitting patented methods of use—Use codes, patent infringement, and carve outs
- § 26:13 —Working example on Section viii statements—Sertraline
- § 26:14 —One and only indication
- § 26:15 —Carving out indications to unlisted patents
- § 26:16 —Request listing of currently unlisted method of use patent
- § 26:17 —Using suitability petitions to allow carve out
- § 26:18 Combining Paragraph I certification in lieu of Section viii statement
- § 26:19 Paragraph IV certification and notice letter requirements

- § 26:20 —Paragraph IV certification to just one claim of just one patent
- § 26:21 —Identifying the patents in the notice letter
- § 26:22 —Content and sufficiency of the notice letter
- § 26:23 —How much detail is necessary
- § 26:24 —Details on claims that are not normally listable
- § 26:25 —Form of letter and detailed statement
- § 26:26 —Appending letter to a complaint
- § 26:27 —Predicates to antitrust injury
- § 26:28 —How to send the notice letter
- § 26:29 —Where to send the notice letter
- § 26:30 —When to send the notice letter
- § 26:31 —Sending Paragraph IV Notice Letters before ANDA is officially submitted/received
- § 26:32 —Updating the FDA on notice letters
- § 26:33 Reissue patents: new patents or rollovers of old patents that require new patent certifications
- § 26:34 —Summary
- § 26:35 Offer for Confidential Access (OCA)
- § 26:36 —Where invalidity is alleged
- § 26:37 —Issues with the Offer for Confidential Access (OCA)
- § 26:38 Tracking Paragraph IV certifications on the FDA Web site
- § 26:39 Updating the Paragraph IV certification and notice letter when changes occur to ANDA formulation
- § 26:40 Filing split Section viii carve-outs and Paragraph IV certifications in a single patent
- § 26:41 Sending a Paragraph IV notice letter is not a waiver of privilege
- § 26:42 Amendments to the pending ANDA trigger obligations to update certifications
- § 26:43 Adding Paragraph IV certification in pending ANDA

CHAPTER 27. THE 30-MONTH INJUNCTION/STAY

I. GENERALLY

- § 27:1 Introduction

TABLE OF CONTENTS

- § 27:2 Creating the 30-month stay and counting days
- § 27:3 The “frozen” Orange Book and patents that qualify for 30-month stays
- § 27:4 Who notifies the FDA of the lawsuit

II. TERMINATION OF THE 30-MONTH STAY

- § 27:5 How the 30-month stay is normally terminated
- § 27:6 Court decision to terminate a stay
- § 27:7 Generic company wins at trial level
- § 27:8 Generic company wins on appeal
- § 27:9 Patentee delays

III. LENGTHENING, SHORTENING, OR REINSTATING THE STAY

- § 27:10 Extending stay because court made no decision
- § 27:11 Reinstating if wrongfully terminated
- § 27:12 Lengthening or shortening due to lack of cooperation
- § 27:13 Cases extending the 30-month stay
- § 27:14 Generic Company Request to Elongate 30-month stay to avoid forfeiture because the generic company “filed too early”
- § 27:15 Cases shortening the 30-month stay
- § 27:16 Cases where the stay was not altered despite request to alter

IV. EFFECT OF DELAYS

- § 27:17 Missing the 45-day window—Can suit still be brought?

V. EARNING NEW 30-MONTH STAYS

- § 27:18 Generally
- § 27:19 Repetitive 30-month stays under the old rules
- § 27:20 Earning 30-month stays under the December 2003 rules
- § 27:21 Effect of “pop-up” (newly issued) patents
- § 27:22 Reformulation may cause new 30-month stay
- § 27:23 Working examples of the 30-month stay

VI. STAGGERED EXPIRATIONS

- § 27:24 Multiple applicants 30-month stay; staggered stay expiries

- § 27:25 Stay of court decision pending appeal to maintain 30-month stay intact: case study in oxaliplatin
- § 27:26 Extending the 30-month stay to year 7.5 after New Chemical Entity (NCE) exclusivity
- § 27:27 Impact of pending Inter Partes Reviews (IPR) on 30-month stays

CHAPTER 28. THE PARAGRAPH IV BASED 180-DAY EXCLUSIVITY

- § 28:1 Introduction
- § 28:2 Creating the 180-day exclusivity
- § 28:3 Against whom the 180-day exclusivity applies
- § 28:4 FDA's patent-by-patent approach to patent certifications in pre-MMA Dec. 2003
- § 28:5 Product-by-product approach to exclusivity
- § 28:6 180-day exclusivity naturally expires with the underlying patent
- § 28:7 Triggering the 180-day exclusivity clock
- § 28:8 —Under pre-December 2003 MMA rules
- § 28:9 —Under the post-MMA rules
- § 28:10 —Court Decision To Trigger Exclusivity Is Now Part of the Forfeiture Scheme
- § 28:11 Tracking the 180-day exclusivity
- § 28:12 Reissue patents and new 180-day exclusivities
- § 28:13 Authorized generics
- § 28:14 —Curbing by Medicaid Best Price Law
- § 28:15 Waiver or relinquishment of the 180-day exclusivity
- § 28:16 Relinquishment and waiver for joint exclusivity holders or multiple first applicants
- § 28:17 Waiver or relinquishment of the 180-day exclusivity—Mechanics of selective waiver and total relinquishment
- § 28:18 Strategy to file with split paragraph III/IV to convert to paragraph IV later to still share co-exclusivity
- § 28:19 The 180-exclusivity can exist for a “pop-up” patent: effect on ANDA filers
- § 28:20 Effect of Pediatric Exclusivity and Ability To Obtain Almost 12-Months Exclusivity

TABLE OF CONTENTS

CHAPTER 29. FORFEITURE OF THE 180-DAY EXCLUSIVITY

§ 29:1	Introduction
§ 29:2	Forfeiture provisions
§ 29:3	—Failure to market
§ 29:4	Failure to market under little (aa); 30 months to approval, 75 days to market
§ 29:5	Failure to market under little (bb)
§ 29:6	—Court decision litigant needs to have tentative approval to trigger
§ 29:7	—Does the court litigant triggering little (bb) have to be the same ANDA applicant that has tentative approval?
§ 29:8	—What kind of court decision is needed to trigger under little (bb)?
§ 29:9	Estoppel effect of judgment and parties vacating judgment to avoid estoppel
§ 29:10	New America Invents Act Procedures should not create, by itself, a little (bb) event
§ 29:11	Rationale for little (bb)'s patent position versus little (aa)'s regulatory position
§ 29:12	Effect of patentee delisting Orange Book patents to create date-certain forfeiture event under little (bb)/Big (CC)—Case study: Dorzolomide + Timolol (Cosopt®)
§ 29:13	Effect of patentee delisting of Orange Book patents to create date-certain forfeiture event under little (bb)/Big (CC)—Case study: acarbose (Precose®)
§ 29:14	Effect of patentee delisting of Orange Book patents to create date certain forfeiture event under little (bb)/Big (CC)—Case study: Losartan (Cozaar®)
§ 29:15	Failure to market: no delisting and no litigation—Case study: Granisetron (Kytril)
§ 29:16	Coercive agreements; settling lawsuits but maintaining paragraph IV to avoid forfeit
§ 29:17	—Case study: Ramipril (Altace)
§ 29:18	Withdrawal of application
§ 29:19	Amendment of certification
§ 29:20	Failure to obtain tentative approval in 30 months
§ 29:21	Failure to obtain tentative approval in 30 months & Impact of GMP Compliance

GENERIC PHARMACEUTICAL PATENT AND FDA LAW

- § 29:22 Concurrent qualification and forfeiture due to failure to obtain tentative approval in 30-months: Adding a new para. IV certification can cause immediate forfeiture
- § 29:23 The statutory (non-statutory) basis for calculating the 30-months to obtain tentative approval may belie or support the FDA's interpretation
- § 29:24 New FDASIA law of 09 July 2012 statutorily overrules FDA interpretation that led to simultaneous grant of exclusivity and forfeiture
- § 29:25 New FDASIA law extends 30-month period to obtain tentative approval to avoid forfeiture
- § 29:26 Failure to obtain tentative approval in 30 months—Is “within 30 months” really in 30 months or is it day one of the 31st month? Computation of time
- § 29:27 Computation of time for obtaining approval “within 30 months” and policy considerations
- § 29:28 Failure to obtain tentative approval in 30 months—Case study: Irinotecan (Campostar) and famotidine Chewable (Pepcid Complete)
- § 29:29 Failure to obtain tentative approval—Tentative approval, changed conditions, and citizen petitions
- § 29:30 Failure to obtain tentative approval in 30-months: instances where no forfeiture occurred because of changed circumstances
- § 29:31 ANDA review backlog at FDA increases mean ANDA approval time possibly causing forfeitures
- § 29:32 No-rolling exclusivity
- § 29:33 Expiration of patents
- § 29:34 —Multiple patents confer exclusivity
- § 29:35 Forfeiting applicant does not go to the back of the bus nor do back seaters come forward—Case study of nateglinide (Starlix®)
- § 29:36 Forfeitures in general policy terms; vested property right
- § 29:37 Forfeitures for filing the ANDA “too early”
- § 29:38 Forfeiture of the 180-day exclusivity: Intentional forfeiture

TABLE OF CONTENTS

CHAPTER 30. 180 DAY MARKET EXCLUSIVITY UNDER COMPETITIVE GENERIC THERAPY (CGT) INITIATIVE

- § 30:1 About the Competitive Generic Therapies (CGT) initiative
- § 30:2 Qualifying for the CGT
- § 30:3 Inadequate generic competition
- § 30:4 Securing CGT 180-day exclusivity and losing it
- § 30:5 General commentary on the new CGT
- § 30:6 Should FDA wait 75-Days to see if CGT ANDA sponsor launches before approving other ANDA's?
- § 30:7 Relevant statutory provisions of the CGT 180-Day exclusivity and forfeiture

CHAPTER 31. PREISSUE SUBMISSIONS AND POST-ISSUANCE IPR WITH IMPACTS ON COURT LITIGATION

- § 31:1 Cleaning up patent quality before or after a patent issues
- § 31:2 Preissue submissions to interject into a pending application
- § 31:3 Post-issuance procedures to invalidate a patent
- § 31:4 Post Grant Review (PGR) and Inter Partes Review (IPR)
- § 31:5 Potential impacts of IPR's on parallel patent litigation
- § 31:6 —Timing of IPR/Appeals & Standing to Appeal
- § 31:7 —Denial of IPR petition and subjective effect of perceptual estoppel
- § 31:8 —Using denied IPR petition as roadmap to correct or summary judgment of no invalidity
- § 31:9 —Instituted IPR to deny TRO/Preliminary Injunction (PI)
- § 31:10 —Petitioner losing at PTAB
- § 31:11 —Patentee losing at PTAB
- § 31:12 —To cause forfeiture of 180-Day exclusivity by getting a “court decision” for failure to market

CHAPTER 32. PATENT INFRINGEMENT DAMAGES AND REMEDIES

- § 32:1 Introduction

GENERIC PHARMACEUTICAL PATENT AND FDA LAW

- § 32:2 Potential remedies for patent infringement
- § 32:3 Impact of the loss on the ANDA approval status and redating the ANDA approval date
- § 32:4 Redating the ANDA approval date is not permissible if the infringing activities were under sections 271(a), (b), and (c)
- § 32:5 Impact of the loss on the ANDA approval status and redating the ANDA approval date—ANDAs for old antibiotics should not have redated approval dates
- § 32:6 Injunctive relief to stop future infringement or prevent at-risk launch
- § 32:7 —Other factors to consider in whether to grant a launch-prevention injunction
- § 32:8 Awarding an injunction against future infringement when generic company loses
- § 32:9 Product recall of generic products in the marketplace
- § 32:10 Money damages for patent infringement
- § 32:11 Patent damages for post-publication of patent to patent issuance under provisional rights under Section 154(d)
- § 32:12 Money damages for patent infringement—Money damages, reasonable royalty or lost profits
- § 32:13 —Reasonable royalty
- § 32:14 — —Hypothetical negotiations
- § 32:15 — —Factors to consider in setting the royalty: Georgia Pacific test
- § 32:16 — —Factors in relation to generic drug infringement
- § 32:17 —Effect on permanent injunction
- § 32:18 —Lost profits
- § 32:19 —Lost profits and market reconstruction
- § 32:20 — —No lost profits when substitutes exist
- § 32:21 — —No lost profits when substitutes and authorized generics exist
- § 32:22 —Calculating lost profits and bringing expenses into the calculus
- § 32:23 — —Expense deductions
- § 32:24 Monetary Damages Are Not Permitted During Pediatric Exclusivity
- § 32:25 Enhanced damages and willful infringement
- § 32:26 —Willful infringement and factors to consider
- § 32:27 —Legal opinions and willful infringement

TABLE OF CONTENTS

- § 32:28 The America Invents Act of 2011 Creates 35 U.S.C.A. § 298 on the advice of counsel
- § 32:29 Willful infringement if patent is in reexamination
- § 32:30 Enhanced damages and willful infringement—Willful infringement for filing an ANDA
- § 32:31 —Willfulness and the need to specify facts in the pleading
- § 32:32 Exceptional cases and attorney's fees
- § 32:33 —When can attorney's fees be awarded
- § 32:34 —Steps in awarding attorney's fees
- § 32:35 —Who is a prevailing party
- § 32:36 —Attorney's fees amounts
- § 32:37 —Case study: Pioglitazone and attorney's fees awarded to patentee
- § 32:38 Case study: omeprazole OTC, awarding attorney's fees to generic company for brand company frivolous litigation

CHAPTER 33. DECLARATORY JUDGMENT

- § 33:1 Introduction: purpose of the Declaratory Judgment Act (DJA)
- § 33:2 When DJs are used in pharmaceutical patent cases
- § 33:3 Traditional declaratory judgment standards
- § 33:4 Post-MedImmune declaratory judgment standards
- § 33:5 Post-*MedImmune* declaratory judgment standards—*Famciclovir* case and factors allowing a declaratory judgment action
- § 33:6 Declaratory judgments to trigger exclusivity
- § 33:7 —Is tentative approval needed before filing a DJ?
- § 33:8 —Orange Book listing alone could confer DJ jurisdiction
- § 33:9 — —Patents listed but statutorily disclaimed may or may not confer jurisdiction
- § 33:10 Covenants not to sue; removing fear of suit
- § 33:11 —Covenants divesting court's jurisdiction
- § 33:12 Declaratory judgment updates
- § 33:13 —DJ's and offers for confidential access
- § 33:14 —Is enforcement of an offer for confidential access an improper private right of action

- § 33:15 Declaratory judgment in counterclaims based on
section viii patents

CHAPTER 34. CITIZEN PETITIONS

- § 34:1 What is a citizen petition
§ 34:2 Form of the citizen petition
§ 34:3 Time period for FDA to respond
§ 34:4 What is an FDA response?
§ 34:5 Potential antitrust penalties for sham citizen
petitions
§ 34:6 Implications of citizen petition denial and ANDA
approvals
§ 34:7 Citizen petitions by generic companies
§ 34:8 Citizen petitions based on confidential
information from ANDA; protective order
prohibited uses

CHAPTER 35. ISSUES RELATING TO THE SIZE/SHAPE/COLOR OF GENERIC PRODUCTS

- § 35:1 Size, shape, and color of generic products
§ 35:2 Functionality of generic drug product as defense
to trademark infringement
§ 35:3 Cases involving generic drug product size, shape,
or color

CHAPTER 36. PHARMACEUTICAL COMPOUNDING AND INTELLECTUAL PROPERTY ISSUES

- § 36:1 Introduction to drug product compounding
§ 36:2 FDA authority over compounded drug products
§ 36:3 Patent infringement issues in compounding
§ 36:4 False advertising issues in compounding
§ 36:5 Animal drugs are subject to compounding
problems too

CHAPTER 37. OVER THE COUNTER (OTC) DRUGS

- § 37:1 Overview of prescription versus over the counter
(OTC) drugs
§ 37:2 OTC drugs and the orange book

TABLE OF CONTENTS

§ 37:3	ANDA filing against OTC NDA drug product
§ 37:4	Prescription to OTC switches
§ 37:5	ANDA commercial issues in the Rx to OTC switch
§ 37:6	ANDA considerations for 180-day exclusivity in Rx to OTC switch

APPENDICES

Appendix A.	355
Appendix A-1.	Annotations to 21 U.S.C. 355f
Appendix B.	Annotations to 35 U.S.C.
Appendix C.	Selected Sections of 35 U.S.C.

Glossary

Table of Cases

Index