Generic Pharmaceutical Patent and FDA Law

2014 Edition

Shashank Upadhye

THOMSON REUTERS
WESTLAW

Generic Pharmaceutical Patent and FDA Law

2014 Edition

Issued in April 2014

Shashank Upadhye

THOMSON REUTERS™

For Customer Assistance Call 1-800-328-4880

Mat #41451749

ISBN: 978-0-314-62956-2

About the Author

Shashank Upadhye, B.Sc., B.A., J.D., LL.M., is currently a partner in the Chicago office of Seyfarth Shaw, LLP, a global 800+ attorney law firm. He practices in its Intellectual Property & Litigation practice group. He was formerly the Vice President & Global Head of Intellectual Property for Apotex, Inc., a global generic drug company based in Toronto, Ontario, Canada. Prior to Apotex, he was in Princeton, NJ, as the VP - Head of Intellectual Property for Sandoz, Inc., a Novartis company, where he led its IP and regulatory law group. Prior to Sandoz, he was the VP - Intellectual Property at Eon Labs, Inc., in Long Island, NY, prior to its acquisition by Sandoz, Inc. He practiced law with various law firms in Boston and Chicago, specializing in brand side and generic side patent law.

Shashank graduated with his B.Sc. in Biochemistry and then his B.A. in Business Administration from Brock University, St. Catharines, Ontario. He then graduated with his J.D. degree from the New England School of Law, Boston, Massachusetts, and with his LL.M. degree specializing in intellectual property from John Marshall Law School, Chicago, Illinois.

His expertise extends to counseling companies at the confluence of intellectual property and health regulatory laws, specifically in designing patent strategies and developing regulatory strategies that bring generic drugs to market, or by assisting brand companies in developing strategic portfolios of rights to protect their branded drugs. Shashank is a prolific author and speaker in the area of brand and generic drug laws. As usual with any legal text, the views expressed herein remain those of the author personally and are not in any way attributable to any client or employer, past, present, or future.

Shashank welcomes comments on this Book and can always be reached at: supadhye@hotmail.com.

Dedication

This book is dedicated to my wife, Shilpa, and to my children, Sarina and Sacheen, because without their support and encouragement this book would not exist. I am eternally grateful and lucky to have such an understanding family when I spent countless nights and weekends researching and writing this book.

Acknowledgment

This book would not have been possible without the support and encouragement of Shilpa, Sarina, and Sacheen, who urged Shashank to write and then complete the book. Shashank also acknowledges his colleagues, law firms, and his employers for teaching him the impact of intellectual property on the commercialization of generic drugs and how intellectual property is aligned with other corporate functions to make that happen. Shashank also thanks Thomson Reuters/West and his editors for producing this book. Although many thanks are owed to others, any mistakes, omissions, or errors are Shashank's alone.

Preface—About this Book

This book represents the culmination of several years of studying the intersection of patent and FDA law. The statutes implementing the patent and FDA laws are extremely complex, and two decades of litigation have flushed out many but not all of the pertinent issues. The distinguishing feature of this book is that it is intensely practice-focused and gives extensive depth of discussion to important issues and nuances. The book is not a piece of academic scholarship that simply synthesizes cases for easy research but is divorced from the actual practical considerations of drug development and litigation. The book starts with the principles of patent law and patent infringement and then adds the principles of FDA regulatory law. The remainder of the book provides the extensive details and the issues surrounding each and every aspect of generic drug development, approval, and litigation.

Due to the complexity of the laws governing drug development and marketing, this book is written in a style that presents the important legal issues in a clear manner initially but then builds upon the issue by adding successive layers of complexity. Examples and graphic illustrations are used to clarify complicated points. Cases and statues are cited, where possible, in their entirety to provide the actual language cited.

This book is intended for multiple audiences. First, despite its focus on generic drugs, brand-focused companies and law firms will find this book very useful because it describes the issues facing generic drug companies. Second, judges and law clerks will find this useful because the issues related to managing generic drug patent infringement are complex and judges and clerks will benefit from the presentation of the issues and the legal precedence supporting them. Case citations generally include the precise language quotation. Third, obviously, generic drug companies and law firms will benefit from the precise details explained herein.

Finally, finance managers such as hedge-fund and investment managers will benefit from the explanations and case studies presented.

It is important for the reader to recognize and understand that this book does not represent the views of any particular company, employer, or client, past or present. Moreover, no reader should attempt to pluck out isolated statements from this book as any pronouncement of law or fact or as an industry-accepted practice. In addition, it is recognized that nothing in this book is applicable to any specific situation or scenario unless so identified, as a myriad of facts or circumstances may apply to any given situation. Nothing in the book, specifically in its practice tips, imposes obligations on any company, unless otherwise required by law.

RELATED PRODUCTS

Anthology

Copyright Law Anthology
edited by Rodney A. Smolla

Entertainment, Publishing, and the Arts Handbook
edited by Karen B. Tripp

First Amendment Law Handbook
edited by Rodney A. Smolla

Intellectual Property Law Review
edited by Karen B. Tripp

Patent Law Review
edited by Karen B. Tripp

Antitrust

Intellectual Property and Antitrust Law
William C. Holmes

Computer and Related Law

Computer and Information Law Digest
Kurtis A. Kemper

Computer Software Agreements: Forms and Commentary
John H. Ridley, Peter C. Quittmeyer, and John Matuszeski

Computer Software: Protection, Liability, Law, and Forms
L.J. Kutten

Information Law
Raymond T. Nimmer

Information Security and Privacy: A Practical Guide to Federal, State and International Law
Andrew Serwin

Internet Law and Practice
International Contributors

Law and Business of Computer Software 2nd Edition
Katheryn A. Andresen

Law of Computer Technology

Generic Pharmaceutical Patent and FDA Law

Raymond T. Nimmer

State Computer Law
Virginia V. Shue and James V. Vergari

Copyright

Copyright Law Anthology
edited by Rodney A. Smolla

Copyright Law in Business and Practice
John W. Hazard Jr.

Copyright Litigation Handbook
Raymond J. Dowd

Copyright Registration Practice
James E. Hawes and Bernard C. Dietz

The Law of Copyright
Howard B. Abrams

Patry on Copyright
William F. Patry

Patry on Fair Use
William F. Patry

Entertainment & Sports

Art, Artifact & Architecture Law
Jessica Darraby

Cable Television and Other Nonbroadcast Video
Robert Brenner, Monroe Price, and Michael Myerson

Entertainment Law
Robert Fremlin and Michael Landau

Entertainment Law; Legal Concepts And Business Practices
Robert Lind et al.

Film and Multimedia and the Law
James Sammataro

Fundamentals of Sports Law
Walter Champion

Law of Defamation
Rodney A. Smolla

Law of Professional & Amateur Sports
Gary Uberstine

Lindey on Entertainment, Publishing, and the Arts

Alexander Lindey and Michael Landau

Media, Advertising & Entertainment Law Throughout the World
Andrew B. Ulmer & MULTILAW International Contributors

Rights and Liabilities of Publishers, Broadcasters, and Reporters
Len Niehoff and Slade Metcalf; updated by Rodney A. Smolla

The Rights of Publicity and Privacy, 2d
J. Thomas McCarthy

Smolla and Nimmer on Freedom of Speech
Rodney A. Smolla

General Titles

Assets & Finance: Audits and Valuation of Intellectual Property
Lisa M. Brownlee

Assets & Finance: Insurance Coverage for Intellectual Property and Cyber Claims
Tod I. Zuckerman, Robert D. Chesler & Christopher Keegan

Assets and Finance: Intellectual Property in Mergers and Acquisitions
David Klein

Calculating Intellectual Property Damages
Richard B. Troxel and William O. Kerr

Franchise and Distribution Law and Practice
W. Michael Garner

Intellectual Property: Due Diligence in Corporate Transactions
Lisa M. Brownlee

Intellectual Property in Commerce
Prof. Thomas M. Ward

Intellectual Property in Mergers and Acquisitions
David Klein

Intellectual Property Law for Business Lawyers
Kinney & Lange, P.A.

IP Strategy: Complete Intellectual Property Planning, Access and Protection
Howard C. Anawalt

Licensing

Eckstrom's Licensing in Foreign and Domestic Operations: The Forms and Substance of Licensing
Robert Goldscheider

Eckstrom's Licensing in Foreign and Domestic Operations:

Joint Ventures
Terence F. MacLaren

Eckstrom's Licensing in Foreign and Domestic Operations: Text
David M. Epstein

Forms and Agreements on Intellectual Property and International Licensing
David de Vall and Peter McL. Colley

The Law of Merchandising and Character Licensing: Merchandising Law and Practice
Gregory J. Battersby and Charles W. Grimes

Licensing and the Art of Technology Management
Robert Goldscheider

Licensing Law Handbook
Melvin F. Jager

Modern Licensing Law
Raymond T. Nimmer and Jeff C. Dodd

Multimedia and Technology Licensing Agreements
Gregory J. Battersby and Charles W. Grimes

Patents

Annotated Patent Digest
Robert A. Matthews, Jr.

Biotechnology and the Law
Iver P. Cooper

Designs and Utility Models Throughout the World
International Contributors

Federal Circuit Patent Case Digests
Kevin L. Russell

Generic Pharmaceutical Patent and FDA Law
Shashank Upadhye

Guide to European Patents
Andrew Rudge

Intellectual Property Litigation Guide: Patents & Trade Secrets
Gregory E. Upchurch

Inter Partes Reexamination 2d
Matthew A. Smith

Japanese Patent Litigation
Abe, Ikubo, & Katayama

Manual of Patent Examining Procedure, 8th
from the U.S. Department of Commerce, Patent & Trademark Office

Medical Device Patents
Lawrence M. Sung

Moy's Walker on Patents
R. Carl Moy

Nanotechnology Law
John C. Monica Jr.

Patent Application Practice
James E. Hawes

Patent Applications Handbook
Stephen A. Becker

Patent Claims, 3d
Ernest Bainbridge Lipscomb III

Patent Damages Law and Practice
John Skenyon, Christopher Marchese, and John Land

Patent Jury Instruction Handbook
Robert A. Matthews, Jr.

Patent Law Basics
John G. Mills III, Donald C. Reiley III, and Robert C. Highley

Patent Law Fundamentals
John G. Mills III, Donald C. Reiley III, and Robert C. Highley

Patent Law Handbook
Lawrence M. Sung and Jeff E. Schwartz

Patent Law: Legal and Economic Principles
John W. Schlicher

Patent Law Practice Forms
Barry Kramer and Allen D. Brufsky

Patents Throughout the World
International Contributors

Practitioner's Manual of Patent Examining Procedure
Cheryl H. Agris

Practitioner's Patent Guidelines
Cheryl H. Agris

Pre-Litigation Patent Enforcement
Don W. Martens and John B. Sganga, Jr.

Trademarks

McCarthy on Trademarks CD-ROM

McCarthy on Trademarks and Unfair Competition
J. Thomas McCarthy

Practitioner's Trademark Manual of Examining Procedure, 6th Ed.
annotated by James E. Hawes and Amanda V. Dwight

Trade Dress Protection
William E. Levin

Trademark Law Practice Forms
Barry Kramer and Allen D. Brufsky

Trademark Manual of Examining Procedure
United States Patent and Trademark Office

Trademark Practice Throughout the World
Mary M. Squyres

Trademark Registration Practice
James E. Hawes and Amanda V. Dwight

Trademark Trial and Appeal Board Practice and Procedure
Gary D. Krugman

Trademarks Throughout the World 5th Edition
Anne-Laure Covin, Edward Fennessy, and International Contributors

Trade Secrets

Trade Secrets Law
Melvin F. Jager

Trade Secrets Throughout the World
Melvin F. Jager and International Contributors

Unfair Competition

Callmann on Unfair Competition, Trademarks and Monopolies
Louis Altman

Federal Unfair Competition: Lanham Act § 43(a)
Charles E. McKenney and George F. Long III

Protecting Intellectual Property Rights Across Borders
Timothy P. Trainer and Vicki E. Allums

Unfair Competition and the ITC: Actions Before the International Trade Commission Under Section 337 of the Tariff Act of 1930
Donald Knox Duvall, Philip J. McCabe and John W. Bateman

Thomson Reuters® thanks you for subscribing to this product.

Related Products

Should you have any questions regarding this product please contact Customer Service at 1-800-328-4880 or by fax at 1-800-340-9378. If you would like to inquire about related publications or place an order, please contact us at 1–800–344–5009.

Thomson Reuters
610 Opperman Drive
Eagan, MN 55123

legalsolutions.thomsonreuters.com

Table of Contents

CHAPTER 1. BASICS OF PATENT LAW

I. INTRODUCTION

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

II. PATENT CLAIMS

§ 1:4 Importance of patent claims
§ 1:5 Person of ordinary skill in the art
§ 1:6 Organizational structure of the claim—Preamble
§ 1:7 Transition phrase
§ 1:8 Organizational structure of the claim—Body of the claim
§ 1:9 Common types of pharmaceutical claims—Base chemical/compound claims
§ 1:10 —Salts, esters, and solvates
§ 1:11 —Enantiomers
§ 1:12 —Polymorphs
§ 1:13 —Amorphous to crystal form conversion and implications
§ 1:14 —Combinations of APIs
§ 1:15 —Formulations
§ 1:16 —Methods of use
§ 1:17 —Method of manufacture or process claims
§ 1:18 —Product-by-process claims
§ 1:19 —Release profiles
§ 1:20 Conclusion

III. STATUTORY PROVISIONS

A. IN GENERAL

§ 1:21 Common statutory provisions of the patent law