Generic Pharmaceutical Patent
and FDA Law

2020 Edition

Issued in July 2020

Shashank Upadhye
Introduction to the 2020 Edition

Generic Pharmaceutical Patent and FDA Law covers Food and Drug Administration (FDA) approval of generic drugs and the interaction of patents and FDA law. A practitioner’s guide, it walks the reader through the stages of drug approval, identifying the critical issues in the process and advising the client about the issues and areas of concern or exploitation. It also discusses the areas that impact the interaction of patents and Food and Drug Administration law, including litigation.

Changes in this update includes:

- new section on the genus-species distinction in the written description defense [see § 4:12];
- new sections covering § 101 cases involving diagnostics versus method claims [see §§ 5:16-5:18];
- a new chapter on issues relating to the size/shape/color of generic products [see Chapter 35];
- a new chapter on pharmaceutical compounding [see Chapter 36];
- a new chapter on over the counter drugs [see Chapter 37].

The Publisher
July, 2020
About the Author

Shashank Upadhye, B.Sc., B.A., J.D., LL.M., is a found-
ing partner in the Chicago office of Upadhye Cwik, LLP. The
boutique firm specializes in I.P. law with a focus on patents,
trademarks, trade secrets, and related FDA matters.

He is the former chief in-house counsel at three leading
pharmaceutical companies; namely as Vice President &
Global Head of Intellectual Property for Apotex, Inc., a global
generic drug company based in Toronto, Ontario, Canada; as
Vice President – I.P & Regulatory for Sandoz (a Novartis
company) in Princeton NJ and Munich Germany; and Eon
Labs, Inc. in Long Island, NY. In each of the companies, he
led the legal/IP and regulatory law functions.

He is known for spearheading innovative business and
legal strategies to protect an existing drug’s patent – or chal-
lenge those of a competitor.

Shashank is widely regarded as one of the leading Hatch-
Waxman “Paragraph IV” attorneys in the country. Small to
mid-market players turn to him to overturn brand patents
in Paragraph IV litigations, aimed at bringing generic ver-
sions of medicines swiftly and effectively to the marketplace.
Fortune 500 pharmaceutical companies trust him to protect
their brand from such challenges. For all of his clients,
Shashank provides strategic guidance from the initial prod-
uct idea, through product design, R&D, clinical trials, FDA
approval, and product launch. He has an unwavering goal to
help bring products to the market, and help keep them there.

Shashank is a trusted advisor at every step of the drug
product lifecycle, including product selection, research and
development, product application, product launch, and ongo-
ing marketing and sales. His long track record in-house
makes him adept in both the intricacies of drug laws and the
demands of corporate and transactional work. He is as effec-
tive with complex litigation strategies in “failure to warn” or
defective FDA label cases as he is with strategic business
advice and public policy counseling on pending legislation or
dealing with agencies.
He also maintains a robust practice with drug repositioning and life cycle management. He helps pharmaceutical clients with the 505(b)(2) NDA process, with an emphasis on creating savvy business and legal strategies around intellectual property, FDA, and supply chain.

Shashank also helped pioneer the legal framework around biosimilars under the new 351(k) application process. We have experience in stem cells, nucleic acids, antibodies (chimeric and humanized), vaccines, and other biotechnologies. We help companies navigate the BPCIA regime, in counseling to litigation.

Shashank has a robust counseling and compliance practice where he advises clients on matters relating to drug approval, drug marketing, supply chain management, and marketing and data exclusivity issues. He also assists clients with FDA enforcement defense and counseling, including:
- Good Manufacturing Practices (GMP) violations
- 180-Day marketing exclusivity and forfeiture
- label/label carve-outs and advertising review
- guidance and compendial reviews for impact on drug marketing
- Citizen Petition drafting or responses

A Canadian by birth and upbringing, 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. He practiced law with various law firms in Boston and Chicago, specializing in brand side and generic side patent law.

He is a USA Hockey® Level 3 certified ice hockey coach and a PADI® certified Master Scuba Diver; someday, he plans to invent (and patent) a way to play underwater hockey. He is also very active as a Scoutmaster for the Boy Scouts of America.

He can be contacted at: shashank@ipfdalaw.com or 312-327-3326 (office).
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 me to write and then complete the book. I also acknowledge my colleagues, law firms, and my employers for teaching me 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. I also thank Thomson Reuters/West and my editors for producing this book. Although many thanks are owed to others, any mistakes, omissions, or errors are mine 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. Rather, 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 statutes 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.
THOMSON REUTERS
WESTLAW™

MOST PREFERRED ONLINE LEGAL RESEARCH SERVICE

Thomson Reuters Westlaw has been voted the #1 Best Online Legal Research vendor year-after-year by industry professionals. That's because we continually invest more than any other online legal research provider in our people and technology where it matters most. As a result, you find exactly what you need quickly and confidently.

- Build the strongest argument with the most comprehensive collection of legal content
- Deliver better results confidently with WestSearch®, the only search engine designed specifically for the law
- Rely on the most current version of the law with proprietary editorial enhancements
- Access your legal research anytime, anywhere with the free Westlaw apps

LEARN MORE: legal.thomsonreuters.com
SIGN ON: westlaw.com
24/7 REFERENCE ATTORNEYS: 1-800-REF-ATTY (733-2889)
This title is one of many now available on your tablet as an eBook.

Take your research mobile. Powered by the Thomson Reuters ProView™ app, our eBooks deliver the same trusted content as your print resources, but in a compact, on-the-go format.

ProView eBooks are designed for the way you work. You can add your own notes and highlights to the text, and all of your annotations will transfer electronically to every new edition of your eBook.

You can also instantly verify primary authority with built-in links to WestlawNext® and KeyCite®, so you can be confident that you’re accessing the most current and accurate information.

To find out more about ProView eBooks and available discounts, call 1-800-328-9352.
RELATED PRODUCTS

Antitrust

Antitrust Adviser
Irving Scher and Scott Martin

Antitrust and American Business Abroad
Spencer Waller and Andre Fiebig

Antitrust Law Handbook
William C. Holmes and Melissa H. Mangiaracina

Antitrust Law Sourcebook
William C. Holmes and Melissa H. Mangiaracina

Designing an Effective Antitrust Compliance Program
William M. Hannay

Intellectual Property and Antitrust Law
William C. Holmes

International Trade and U.S. Antitrust Law
Spencer Waller and Jeffrey L. Kessler, Updated by Susannah Torpey

Materials on Antitrust Compliance
David Steiner

Computer and Related Law

Cloud Computing Legal Deskbook
edited by Gregory Barbee

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

Cybercrime and Security
Pauline C. Reich

Data Security and Privacy Law
Ronald N. Weikers

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

Internet Law and Practice
Joseph Fazio and International Contributors

Internet Marketing and Consumer Protection
Andrew B. Serwin

Law of Computer Technology
Raymond T. Nimmer

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

Thomas on Data Breach
Liisa M. Thomas

Copyright

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

Copyright Throughout the World
edited by Silke von Lewinski

The Law of Copyright
Howard B. Abrams and Tyler T. Ochoa

Patry on Copyright
William F. Patry

Patry on Fair Use
William F. Patry

Entertainment & Sports

Art, Artifact, Architecture & Museum Law
Alexandra Darraby

Cable Television and Other Nonbroadcast Video
Daniel Brenner, Monroe Price, and Michael Meyerson

Entertainment and Intellectual Property
Mark S. Lee

Entertainment Law
Robert Fremlin and Michael Landau
RELATED PRODUCTS

Entertainment Law: Legal Concepts and Business Practices
Robert Lind et al.

edited by Karen B. Tripp

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
MULTILAW International Contributors

Rights and Liabilities in Media Content: Internet, Broadcast, and Print
Rodney A. Smolla

The Rights of Publicity and Privacy
J. Thomas McCarthy and Roger E. Schechter

Smolla and Nimmer on Freedom of Speech
Rodney A. Smolla

General Titles

Assets & Finance: Intellectual Property in Mergers and Acquisitions
Christopher Turoski

Calculating Intellectual Property Damages
Gregory Smith and Cleve Tyler

Callmann on Unfair Competition, Trademarks and Monopolies
Louis Altman and Malla Pollack

Customs Enforcement of Intellectual Property Rights
Timothy P. Trainer and Vicki E. Allums

First Amendment Law Handbook
edited by Rodney A. Smolla

Franchise and Distribution Law and Practice
W. Michael Garner

Guide to Biosimilars Litigation and Regulation in the U.S.
Goodwin
GENERIC PHARMACEUTICAL PATENT AND FDA LAW

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

Intellectual Property in Commerce
Thomas M. Ward and Stephen M. McJohn

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

Intellectual Property Law Review
edited by Karen B. Tripp

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

Potato Chips to Computer Chips: The War on Fake Stuff
Timothy P. Trainer

World Intellectual Property Rights and Remedies
Center for International Legal Studies

Licensing

Eckstrom’s Licensing in Foreign and Domestic Operations: The Forms and Substance of Licensing
Robert Goldscheider and Melvin F. Jager

Eckstrom’s Licensing in Foreign and Domestic Operations: Joint Ventures
Terence F. MacLaren and Ralph H. Folsom

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 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

Edward D. Manzo
RELATED PRODUCTS

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

First to File Patent Drafting: A Practitioner's Guide
Harold C. Wegner

Generic Pharmaceutical Patent and FDA Law
Shashank Upadhye

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

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

Moy's Walker on Patents
R. Carl Moy

Patent Application Practice
James E. Hawes and Frederic M. Douglas

Stephen A. Becker, Bernard P. Codd, and Babak Akhlaghi

Patent Claim Construction in the Federal Circui
Kevin E. Noonan, Adam G. Kelly and Edward D. Manzo

Patent Claims
Ernest Bainbridge Lipscomb III

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

Patent-Eligibility
Harold C. Wegner

Patent Jury Instruction Handbook
Edward D. Manzo

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