

Generic Pharmaceutical Patent and FDA Law

2014 Edition

Shashank Upadhye

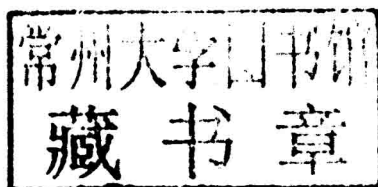
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About the Author

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 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.

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