Preface

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No intellectual property rights impact society more forcefully than patents on pharmaceuticals. Yet effective advocacy and accurate policy discussion alike have been hampered by a surprising shortfall of materials explaining the nexus between the law of patents and the food and drug law. This work endeavors to meet this need. My goal has been to provide, in a single volume, a reasonably thorough introduction and analysis of pharmaceutical patent law for practitioners, policy makers, jurists, students, and interested onlookers alike.

Publication of this third edition of *Pharmaceutical Patent Law* has afforded me the opportunity to correct errors in the earlier texts, improve upon existing explanations, and incorporate important details that I have previously overlooked. I was also able to address the considerable number of new developments that has arisen since the second edition of this treatise was published in 2010. I intend to continue my practice of providing annual supplements to the book to address developments in days yet to come.

Any book on pharmaceutical patents will, now and for the foreseeable future, remain a work in progress. Even as the ink is drying on the pages of this text, legislative, judicial, administrative, and marketplace developments continue to advance at a rapid pace. Future supplements will continue to track the activities of Congress, the judiciary, the Patent and Trademark Office, the Food and Drug Administration, and the Federal Trade Commission, along with other actors whose pronouncements combine to shape this discipline.

In completing this work, I have been assisted by many colleagues. I owe a debt of gratitude to Barbara Ryan, Lucas Herrmann, Jason Yeung, and the pharmaceutical research staff at Deutsche Bank Securities who first introduced me to the field. I am also grateful for the efforts of Wendy Schacht, Specialist in Science and Technology at the Congressional Research Service, who got me thinking about the policy dimensions of pharmaceutical patent law. I also thank Martin Adelman, Robert Armitage, E. Anthony Figg, David Forman, Steven Lee, Steven Lieberman, Otto Licks, Nancy Linck, Joseph Straus, Paul Tauchner, and Hal Wegner, each an extraordinarily

capable attorney who, at crucial moments, helped me place another piece in the puzzle that is the Hatch-Waxman Act. The guidance and forbearance of my editor, Jim Fattibene, along with his colleagues at BNA, was greatly appreciated. I additionally wish to express my gratitude to my coauthor on several other projects, Roger Schechter of the George Washington University Law School, who taught me to appreciate quality writing within this genre. I am also thankful that the Georgetown University Law Center generously provided me with a sabbatical in order to complete this work, and I very much appreciate the efforts of Kate Cassidy, David Johnstone, and Jing Wang, each of whom contributed valuable editorial and research assistance.

Despite the efforts of each of these individuals to point me in the right direction, I may well have veered off course in the pages that follow. As a result, the views expressed herein should by no means be attributed to any of these individuals or their institutions, and all errors remain my responsibility alone.

The legal issues concerning the proprietary protection of pharmaceuticals are unusually compelling. Nowhere else in intellectual property law are questions of statutory construction so bewilderingly complex. Yet the legal semantics only thinly disguise both the pressing need of society to develop new treatments for our most debilitating and deadly diseases and the grim realities of social access to medicines. My hope is that readers of this text will share the author's sense of the importance of this legal milieu; be better able to comprehend its subtleties; and be encouraged, in the interest of public health, to advocate sensible rules to govern the practice of pharmaceutical patent law in the future.

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