Preface

After completing our first book, *ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators*, now in its second edition, we immediately recognized a need for another book detailing the enormous undertaking employed by innovators and generic pharmaceutical companies, and their associated professionals, to develop drug products and patent portfolios before litigation begins. It is not a straight and easy path from initial drug concept to public use. The road is long, difficult, and expensive. It is an investment of tremendous resources and a path full of hazards for innovators and generics alike. As consumers, we want it that way, but we also do not.

We want tough patent laws and standards at the U.S. Patent & Trademark Office (PTO) to prevent effortless and inexhaustible patent monopolies. There must be balance, though. The hurdle to patent exclusivity cannot be so difficult as to stifle the invention it promotes. If it were, there would not be enough incentive to find the next miracle cure to make life better. The cutting edge, frontline of drug development is risky. It is also expensive. Patent exclusivity is the “carrot” that provides the opportunity for innovators to profit and recoup investment. Drug development must be meaningful. Generic pharmaceutical companies, however, drive prices down and create drug market efficiencies. They require accessibility. We, as consumers, want both—patent laws and PTO rules and regulations geared to innovation but designed “[t]o promote the Progress of Science and the useful Arts”\(^1\) for the benefit of all.

We also want tough standards at the Food and Drug Administration (FDA) to ensure the safety and efficacy of the drugs we consume. FDA rules and regulations must be exacting. Although this likely increases the costs borne by the innovator and passed on to consumers, we cannot have it any other way. It is our protection. A lapse in the system can have

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The initial introduction of a brand drug is thus expensive. We do not want this period, however, to last forever. It should have an end where market forces and competition can lower the costs of branded drugs and make FDA-approved drugs more obtainable. Accordingly, a patent monopoly for brand drugs is of limited duration, and generic pharmaceutical companies can obtain FDA approval for generic drugs at lower costs with an Abbreviated New Drug Application (ANDA) by utilizing the FDA groundwork laid by innovators in having their New Drug Application (NDA) approved.

The process of developing a drug for market and building a patent portfolio involves numerous complex decisions by innovators and generic pharmaceutical companies and many proceedings before the PTO and FDA. This work occurs before ANDA patent litigation and provides much of the foundation on which it rests. It is important to recognize the different alternatives and consequences these companies may have during this period, as they impact the course of ANDA and other patent litigation, as well as the success of the drug companies involved. Patenting innovative drugs and coordinating an NDA or ANDA drug portfolio strategy with a goal of achieving FDA approval requires a host of expert professionals with varying sets of skills. We attempt here to collect that knowledge and present it from the perspective of both the innovator and generic pharmaceutical company. We examine the different routes they take before the PTO and FDA to give context to the difficult choices they must make along the way. We also provide a perspective at the end of the book on how these same processes unfold in foreign countries for comparison.

As professionals, we want to build the best drug products and patent portfolios for our companies and our clients. We want the process understandable and simple. It is not often that way. The rewards, however, exist for those that persist. A single blockbuster drug can propel an innovator, save millions of lives, and foster an entire new market for generic competition. A portfolio of such drugs literally changes the world. This likely was not lost on Senators Orrin G. Hatch (R-Utah) and Henry A. Waxman (D-CA) when sponsoring The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. The act strikes a compromise in the pharmaceutical industry to balance market competition against patent exclusivity. It does so, in at least one way, by allowing an
abbreviated FDA review process for generic drugs and creating a right for innovators to initiate litigation before generic companies enter the market. These were the subjects of our first work. This book examines the steps innovator and generic pharmaceutical companies take before litigation to patent drugs and to bring them to market.

As with our first book, I hope you too will find this one a welcome addition.

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3. The success of any project depends largely on the assistance and talents of many others. First, I would like to thank each one of the authors for their contributions. My sincerest gratitude and thanks for their valuable time and expertise devoted to this book. Second, I wish to acknowledge the valuable support and assistance of Tasha Ford, Janet Barrowclough, and Barbara Mikolajczyk of Morris James LLP. I immensely appreciate their organizational talents, patience, and continual support in managing, compiling, and reviewing the manuscript for this book.