Foreword

All pharmaceutical companies, whether they are an innovator or a generic, must navigate the same complex legal and regulatory framework to bring a product to market and fend off competition. The nuances involved in making decisions along the way can be hard to grasp and can involve a multitude of different pathways. Any practitioner would be remiss in not having a guide to a key pathway—ANDA litigations. This book, Pre-ANDA Litigation: Strategies and Tactics for Developing a Drug Product and Patent Portfolio, is an in-depth resource for learning about and planning for ANDA litigations and all the different avenues that the pharmaceutical litigants could follow.

From the perspective of an innovator company, which has made the investment in research and development, clinical testing, and regulatory filings, patents are vital to protect these new drug products, both to recoup that initial investment and for future investments leading to the next medical breakthrough. For the innovator and patent owner, the patentee must be aware of the risk to those intellectual property rights and be prepared for any patent challenge. The statutory presumption of validity will never be enough. The risks to the market for the innovator product from patent litigation, which could result from the patent being invalidated or rendered unenforceable, need to be well understood by the innovator company. Generic companies will challenge patents, and it is not just a question of which patents will be challenged—most patents will be challenged given the incentives created by the Hatch-Waxman Act—but also when the generic companies could be ready to file an ANDA and begin a patent challenge. It should be a working assumption for the patent professional that any patent covering an innovative drug product will be the subject of a challenge by one or more generic companies as soon as permitted under the exclusivity rules. Whether that challenge is to the validity or enforceability of the patent or is based on an alleged noninfringement defense
that may require claim construction, it is imperative that the innovator be prepared. Patent litigations and strategies are complex and will require the patent professional to be able to explain complex technical and legal issues to lay persons, both within the organization and to judges and juries. Having a resource that will help formulate a strategy before patent litigation begins is invaluable.

From the perspective of a generic company, one must understand the innovator’s thought processes as well as many other factors in order to get a generic drug to market in a way that will maximize revenue. The generic drug planning process begins many years before the drug may be on the market. A generic drug manufacturer, when preparing a Paragraph IV challenge, must consider, inter alia, the strength of its patent challenge and the possible responses from the innovator. A generic company must also plan for battling not only innovators but also other generic companies. Then, as time moves on from the initial planning stage to any ensuing litigation or actual market launch, many events may occur (e.g., many manufacturers filed ANDAs, patents are added to the Orange Book, countersuit by another generic, launches at risk) that may cause a generic to shift directions. The generic manufacturer must be able to break down the drug planning and litigation processes into key decision points so that the manufacturer can decide to move forward or adjust its strategy accordingly. This resource will allow generic manufacturers to locate those points and make informed decisions.

The key for any pharmaceutical ANDA litigant wanting to increase market share, whether as an innovator or a generic, is to plan early and to be ready to alter plans as new events occur. This book, *Pre-ANDA Litigation: Strategies and Tactics for Developing a Drug Product and Patent Portfolio*, will aid us all as we look for the best avenue to follow.

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