Foreword

Well-deserved congratulations to the authors of this new text on ANDA litigation. While there are excellent materials available about patent law generally, this book speaks specifically to the peculiar nature of ANDA cases. As is mentioned in the preface that follows, the Hatch-Waxman Act, which is the wellspring of ANDA litigation, represents an effort to balance important societal interests in protecting the intellectual property rights of pharmaceutical companies while making advanced drugs widely available. The particular mechanisms of the law make it unique and can shift what judges and lawyers usually expect in a lawsuit.

For example, in most patent cases, as in other litigation, it is ordinarily the plaintiff patentee who seeks an early trial date and as rapid a course as possible through pretrial proceedings, while defendants often are happy to see the case take a slower route to conclusion. In an ANDA case, by contrast, the plaintiff patentee may well be content for pretrial proceedings to move more slowly, knowing that the defendant generic drug manufacturer is laboring under an automatic stay of FDA approval for the generic drug, a stay that kicks in when an ANDA suit is filed and may last until a judgment is rendered against the patentee. A lawyer or judge might be surprised when first encountering a leisurely plaintiff in an ANDA case, but they will find in Chapter 4 of this text a succinct explanation of the timing motivations. This highlights an especially admirable quality of the book: its balance. The authors have endeavored, with good success, to address issues from the perspectives of both the brand-name drug patentees and the generic drug manufacturers, thus enabling readers to understand the conflicting strategies that frame specific disputes.

Each chapter ably addresses important topics, so that the book as a whole is comprehensive and should prove valuable to judges and practitioners. Among other things, readers will find a detailed description

of the regulatory scheme behind the filing of an Abbreviated New Drug Application (Chapter 1), a discussion of remedies (Chapter 16), and an overview of how antitrust principles may come into play (Chapter 18). Without naming all of the topics covered, suffice it to say that a wide array of ANDA-specific questions can be answered by turning to these pages.

I commend Ken Dorsney and the team of authors he has assembled for tackling this very important subject matter, as I commend the book to all interested parties.

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