Preface

The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, in reference to the act's two congressional sponsors, Senator Orrin G. Hatch (R-Utah) and Henry A. Waxman (D-CA), reflects a compromise in the pharmaceutical industry in an effort to balance patent exclusivity against market competition. The act was passed into law in 1984. It introduced amendments to the Federal Food, Drug and Cosmetic Act and the Patent Act of 1984. The amendments included provisions for an abbreviated process for the Food and Drug Administration's (FDA) approval of generic versions of patented pharmaceuticals by the filing of an Abbreviated New Drug Application (ANDA) and a right to initiate patent litigation against an ANDA applicant submitting an ANDA with the FDA having a paragraph IV certification. Paragraph IV ANDA (or Hatch-Waxman) patent litigation was thus born. Branded and generic pharmaceutical companies have employed the law ever since in a constant struggle to shape the landscape of the governing patent and regulatory regime and the marketplace for FDA-approved patented and generic drugs.

The resulting effect of the Hatch-Waxman Act on the law controlling the pharmaceutical market and its participants remains unsettled. As a hybrid of two already complex areas of law, U.S. patent and FDA regulatory law, Hatch-Waxman patent litigation was complex from the start. The Hatch-Waxman Act, as with any statutory text, is only the starting point. Hatch-Waxman patent litigation has evolved substantially over the past 25 years, and continues to evolve as the controlling statutes and regulations are amended and interpreted further. During this period, branded and generic pharmaceutical companies have struggled, and continue to struggle, to strengthen their respective positions by shaping the patent and regulatory law landscape governing the use and approval of generic drugs. A constant throughout the struggle is the ultimate value and

significant impact of the litigation on the participants. The economic value at issue in Hatch-Waxman cases commonly exceeds hundreds of millions of dollars per case. Not surprisingly, the litigations are hotly contested.

Navigating patent and regulatory law in litigation, while simultaneously executing a business strategy, requires a broad range of expertise and involves potentially conflicting considerations. Some of the issues that arise in ANDA patent litigation are common to patent litigation generally. Many more, however, derive uniquely from the Hatch-Waxman Act and the regulations associated with FDA approval of a patented or generic pharmaceutical drug. Combining the elements, successfully, requires considerable expertise. This book details the process at the intersection between the statutory and regulatory scheme governing approval of pharmaceutical drugs and U.S. patent law in the context of ANDA patent litigation. Specific emphasis is placed on presenting the issues, the strategies, and the tactics employed by the litigants from the perspective of both branded and generic pharmaceutical companies.

For novice litigators in the field, we strived to create a ready roadmap for the course ahead. For experienced, and possibly battle-worn and weary, litigators, the goal was a book for use as a new weapon in the arsenal, to match wits against, to compare tactics and strategy, or to function as a handy time-saver. For the pharmaceutical companies, the federal courts and other governing bodies (the arbiters in this litigation), and even the consumers, the work represents an insiders' guide to the process as a means of offering understanding and perspective. To this end, the book covers ANDA patent litigation from the moments immediately before inception through appeal to the U.S. Court of Appeals for the Federal Circuit. Along the way, and throughout the discussion, insight and guidance are offered to aid the reader confronted with the particular issue at hand.

The early chapters detail the governing statutory and regulatory scheme that is the Hatch-Waxman Act, the factors leading to its adoption, that is, the impetus for the reform that was needed, and how it was implemented. An overview of the drug-approval process is presented, and the required notice and prelitigation considerations are described. The timeline of the litigation, its logistics, and scheduling are also presented here, along with the initiation of the litigation from consideration of the proper parties, venue and jurisdiction, and infringement to the availability of juries. The middle of the book explores deeper into the actual litigation. The available responses to the complaint, pre-answer motions, the answer and potential counterclaims, and nonlitigation alternatives are provided. Discovery, its planning, conduct, and objectives, and differences encountered in this form of patent litigation also are addressed. The

work of experts, from pretrial proceedings through trial, is explored here, too. Patent claim construction and summary judgment, their complexities and strategies for use, are then discussed. Chapters 16 through 18 take a moments detour from the litigation to present remedies, settlement, and antitrust implications. Litigation resumes in Chapters 19 through 21 with the work required to prepare a case for trial, the work of trial, and post-trial considerations. Chapters 22 and 23 are devoted to appeals to the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court, respectively. Chapter 24 provides advice on managing the litigation. Chapter 25 looks abroad to regulation and litigation of pharmaceuticals in foreign countries. The chapters are designed to provide a complete discussion of the particular chapter topic and, thus, some principles are reiterated to provide contextual support.

The stakes in ANDA patent litigation are indeed high. On one hand, patent rights and patent exclusivity are balanced. On the other, societal objectives and a recognition that patents are a limited grant from the federal government are weighted. The patent clause of the U.S. Constitution was designed, simply enough, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[1] It is silent on the issues encountered in ANDA patent litigation beyond that. The Hatch-Waxman Act is merely an attempt to fill the void. This book attempts to bridge the gap in the context of patent litigation.

I hope you, too, will find it a welcome addition.

Kenneth L. Dorsney
Wilmington, DE[2]

1. U.S. CONST. § 8, cl. 8.

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