



ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators

Kenneth L. Dorsney

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Examining the intersection between the statutory and regulatory scheme governing approval of generic pharmaceuticals and U.S. patent law in the context of Paragraph IV ANDA litigation, ANDA Litigation focuses both on the current and developing law as well as the strategies and tactics employed by the litigants. This is a ready roadmap to practice in the area – an especially valuable resource as the Hatch-Waxman Act with its amendments is a hybrid of two already complex areas of the law—U. S. patent law and FDA regulatory law—makes patent litigation in this area especially complicated and hotly contested. It begins with an explanation of the act, its implementation, and litigation under the act, including responses to the complaint, discovery, the work of experts, and patent claim construction and summary judgment. Additional practice-focused information examines issues such as preparing the case for trial, the work of trial, managing the litigation process, post-trial issues and appeals, remedies, settlement, antitrust implications, and regulation and litigation of pharmaceuticals outside the U.S.

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