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NEWS

Hatch-Waxman Practice in the Supreme Court of the United States

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Litigation Partner Chuck Klein contributed a chapter in the second edition of the American Bar Association's ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators. The book examines the connection between the statutory and regulatory scheme governing approval of generic pharmaceuticals and U.S. patent law, as well as providing an in-depth resource from both name-brand drug patentees and generic drug manufacturers.

The chapter is titled "Hatch-Waxman Practice in the Supreme Court of the United States." Following is an excerpt from the book:

> As the U.S. judiciary's ultimate arbiter of "what the law is," the Supreme Court has addressed issues involving the Hatch-Waxman Amendments to the Food, Drug, and Cosmetics Act (FDCA) on six occasions. Two of these cases involved the scope of the FDCA's experimental-use exception to patent infringement; one involved the act's counterclaim provision, which authorizes the courts to require brand-name drug makers to correct inaccurate patent information filed with the Food and Drug Administration (FDA); two involved "preemption" issues involving the effect of Hatch-Waxman's requirements on conflicting state tort law; and one involved the potential antitrust implications of cases settled under the Hatch-Waxman framework. The Supreme Court also will occasionally use pharmaceutical cases to delve into general patent law issues, as in 2015's *Teva v. Sandoz* decision. This chapter summarizes these cases.

The book is available for purchase here.

View the full chapter here.

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