

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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