

One Minute Memo®



Innovation in Hatch-Waxman and ANDA Litigation

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The Hatch-Waxman Act was enacted in 1984 to address two main congressional goals: (1) to encourage innovation in pharmaceutical research and development; and (2) to help generic drugs reach the market more quickly. Through amendments to both the patent and the food and drug laws, the Act established several practices intended to provide brand-name firms with incentives to innovate while facilitating the marketing of generic pharmaceuticals. Whether or not it was envisioned at the time, the use of generic drugs in the US has seen a tremendous increase since the enactment of the Act. From about 13% (of all prescriptions) in 1984, use of generic drugs grew to 50% by the late 1990s and currently constitute well over 80% of all prescriptions in the US.

Among other things, the Act included elaborate provisions governing the mechanisms through which a potential generic manufacturer may obtain marketing approval for a drug that has been patented by another party. It also put in place an expedited approval processes for generic drugs. In doing so, the Act launched a new type of litigation, “Hatch-Waxman” or “ANDA” litigation. The evolution of the US generic drug industry has been shaped, in part, as a result of such litigation proceedings that unfolded many questions critical to understanding the generic approval process.

Although generic drug usage is over 80% of all prescriptions in the US, as of 2015 the sale of generics were only a quarter as large as those of patented drugs. In the past several years, the number of ANDA litigations has significantly increased. As an active member of the legal community within the ANDA space, we took a look at the latest developments in the field and now share our observations. In the article titled “[Hatch-Waxman And Biosimilars Litigation: 2017 Year-in-Review](#),” we provide a brief overview of the Hatch-Waxman Act, a summary of the recently released FDA Draft Guidance, a general timeline of Hatch-Waxman and Biosimilars litigation, and summaries of some of the related decisions issued by the U.S. Supreme Court and Court of Appeals for the Federal Circuit in the year 2017. If you would like to order a hard copy of the Year in Review, please see our [blog post](#).

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