a new drug. The simplifying step is that the generic application can make use of a branded drug company's preexisting clinical trial data that prove the safety and efficacy of the drug.[6] This saves the generic applicant the years of work and great expense necessary to conduct new clinical trials.

As discussed in the Introduction, the Hatch-Waxman Act expressly allows the activity necessary to prepare a generic drug application to take place prior to the expiration of the patent on the original drug. Without such a provision, generic hopefuls had to wait until the patent expired before they could begin activity such as obtaining samples of the drug, developing their product, and engaging in the bioequivalence testing required by the FDA. As a result, brand-name companies could enjoy a monopoly well beyond the patent term because no generic could possibly be ready to enter when the patent expired.[7] Under Hatch-Waxman, these activities are exempt from an assertion of patent infringement when used for development of a generic application.[8] The exemption allows generics to file an application well before expiration of the patent, so that they can be ready for entry when the patent expires at the latest, rather than having to wait for patent expiration and only then begin the approval process.

The entire process of drug approval has changed substantially in the last 50 years. Before 1962, FDA drug approval requirements were incredibly lax by modern standards – drugs could simply be sold 60 days after information was filed with the FDA, as long as the FDA did not object.[9] This process changed as a result of the thalidomide crisis in Europe in 1961, when thousands of babies were born with partially formed limbs and other severe birth defects after mothers were given the drug for nausea during pregnancy. In response, the U.S. Congress passed the Kefauver-Harris Amendments, which, among other changes, required manufacturers to prove the safety and efficacy of a drug before marketing approval could take place.[10] While the amendments revolutionized attitudes toward drug safety and scientific rigor, they created a bind for generic drug makers wishing to follow the brand-name drug onto the market. In the 1984 case of *Roche v. Bolar*, for example, the United States Court of Appeals for the Federal Circuit, a U.S. appeals court that often hears cases related to patents and other intellectual property, found that prospective generic manufacturers could not use patent-protected brand-name information for

[6] *See* Wendy H. Schacht & John R. Thomas, Cong. Res. Serv., Report R41114, The Hatch-Waxman Act: A Quarter Century Later, at 1 (2011).

[7] *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863–64 (Fed. Cir. 1984) ("The [brand-name companies] gain for themselves, it is asserted, a *de facto* monopoly of upwards of 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires.").

[8] 35 U.S.C. § 271(e)(1) (2012).

[9] *See 50 Years: The Kefauver-Harris Amendments*, U.S. Food & Drug Admin., www.fda.gov/Drugs/NewsEvents/ucm320924.htm (last updated February 26, 2016).

[10] *Ibid.*