



The Battle Between Big Pharma and Generics Heats Up in 2018

The Hatch-Waxman Act (1984) made it easier for generic drugs to enter the market by relieving a manufacturer from having to conduct clinical tests to prove the safety and efficacy of the generic. Instead, the manufacturer need only submit an Abbreviated New Drug Application (ANDA) proving the bioequivalence of the generic to the original branded drug by showing the rate of absorption and bioavailability of the generic is the same as the branded drug. The Act also exempts generic manufacturers from patent infringement claims for conducting testing and other conduct necessary to prepare the ANDA filing. These rules have resulted in nearly all branded drugs facing generic copycats.



Brent Johnson

The Act also created rules of engagement for branded pharma to enforce patents. Under the Act, a patent holder publicly lists all drug-related patents and respective expiration dates. When a generic submits an ANDA, it certifies the absence of patent infringement, or that any applicable branded patent is invalid. The branded company then has 45 days to initiate an infringement action, the filing of which stays FDA approval of the generic ANDA product for 30 months.

The American Invents Act of 2014 created a second, faster track for challenging branded drug patents other than in federal court. The inter partes review (IPR) allows a challenge to be made before the Patent Trial and Appeal Board within nine months after the branded patent issues, with a ruling 12 to 18 months thereafter. A generic company

prevailing in an IPR could then rely on the other companies' efficacy studies to enter the market bypassing the ANDA procedures. In contrast, under the Hatch-Waxman Act, the federal proceeding may take between 25 and 32 months to get to trial, and can only be initiated after a generic files an ANDA application with the FDA.



Michael Katz

In June 2018, Senator Hatch proposed an amendment called the "Hatch-Waxman Integrity Act of 2018" "to prevent companies from using IPR to put added litigation pressure on innovators above and beyond what Hatch-Waxman already provides." The proposed amendment would force a generic company to choose between an IPR challenge and the ANDA/biosimilar approval process. A party opting for the former would be required to develop its own safety and efficacy studies.

Congress must decide whether to afford protection to branded pharma not available to other technology industries. The Hatch-Waxman Integrity Act would do just that. All this is unfolding against the backdrop of the diminishing investment of U.S. companies in patents more generally. Prognostications about outcome and effect are difficult. The authors predicts another article in 2019.

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