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Patent Portfolios and Generic Drug Challenges

The Hatch-Waxman Act regulates competition between brand-name and generic drugs in the United States. We examine a feature of the Act that has generated significant controversy, yet received little systematic attention. "Paragraph IV" challenges are a mechanism for generic drug makers to challenge the patents of brand-name drug makers as a means to secure early market entry.

We begin with a set of descriptive results about brand-name patent portfolios and Paragraph IV challenges. Over time, patenting has increased, measured by the number of patents per drug and the length of the nominal patent term. During the same period, Paragraph IV challenges have increased as a share of drugs within an approval cohort. Drugs are also challenged sooner, relative to brand-name approval.

Our econometric analysis shows that brand-name sales have a positive effect upon the likelihood of generic challenge and number of challengers, consistent with the view that patents that later prove to be valuable receive greater ex post scrutiny. The likelihood of Paragraph IV challenges also varies by patent type. Conditional on sales and other drug characteristics, drugs with weaker patents face a significantly higher likelihood of challenges. And while the number of patents issued early in the lifecycle of a drug is not associated with an increase in challenges—indeed, in some specifications, the contrary is true—more late-listed patents are associated with more challenges.