Abstract

Firms in the pharmaceutical industry typically rely on a period of market exclusivity derived from patent protection and data exclusivity to recoup their investments in R&D. The invalidation of patent rights during drug development renders data exclusivity the sole source of protection and shifts the period of market exclusivity at the project-level. Invalidation therefore constitutes a natural experiment that allows us to causally identify how the duration of market exclusivity affects firms’ incentives to innovate. Our analysis is based on a novel data set that links the development histories of drug candidates with underlying patent data. We identify causal effects relying on the participation of the initial patent examiner in the opposition proceedings as an instrument for the potentially endogenous patent invalidation. Our findings from instrumental variables regressions highlight that shorter durations of market exclusivity reduce the likelihood of successful drug commercialization. This main effect is largely driven by patent invalidations during early stages of the drug development process and by large originators. We discuss the policy implications of these results.
Patents, Data Exclusivity, and the Development of New Drugs

Fabian Gaessler\textsuperscript{a} \quad Stefan Wagner\textsuperscript{b}

\textsuperscript{a} Max Planck Institute for Innovation and Competition, Munich
\textsuperscript{b} ESMT European School of Management and Technology, Berlin

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Firms in the pharmaceutical industry typically rely on a period of market exclusivity derived from patent protection and data exclusivity to recoup their investments in R&D. The invalidation of patent rights during drug development renders data exclusivity the sole source of protection and shifts the period of market exclusivity on the project level. Invalidation therefore constitutes a natural experiment that allows us to identify how the duration of market exclusivity affects firms’ incentives to innovate. Our analysis is based on a novel data set that links the development histories of drug candidates with underlying patent data. We identify causal effects relying on an instrument for the potentially endogenous patent invalidation. Our findings highlight that shorter durations of market exclusivity reduce the likelihood of successful drug commercialization.

Keywords: patents, drugs, data exclusivity, clinical trials.

JEL Classification: K41, L24, L65, O31, O32, O34