Strategic Patenting: Evidence from the Biopharmaceutical Industry

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Biological drugs account for just two percent of prescriptions filled in the U.S. but fifty percent of prescription-drug spending. To explore the role patents play in explaining high biologics prices, we build the first comprehensive database of patents associated with all FDA-approved biologics. We document robust evidence consistent with two patenting strategies that may block biosimilar competition: thicketing and evergreening, whereby firms supplement primary patents with a dense web of later-expiring patents on secondary drug features—e.g., drug formulations. Whether such strategies actually forestall biosimilar entry is ambiguous for a range of reasons. While it is difficult to construct a counterfactual to explore how much sooner competitors will enter absent such practices, we do demonstrate that the threat of biosimilar entry causes biologics manufacturers to build denser patent portfolios in the first place. For these purposes, we explore responses to a 2009 Act that created an abbreviated pathway for biosimilars to receive FDA approval. Finally, we simulate the degree to which the thickness of patent portfolios and the nominal patent lives of biologics are impacted (under certain assumptions) by various policy proposals currently under consideration.