Beyond the Pharmaceutical Patent Arms Race

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Over forty years after the Hatch-Waxman Act created a patent-based framework for balancing pharmaceutical innovation with competition, the system it established needs reform. We use data on pharmaceutical research and development over this four-decade period to argue that the current equilibrium is accurately characterized as an arms race of strategic legal activity. Brand-name firms amass increasingly large patent portfolios for each new drug. Generic firms challenge these patents in a perpetual cycle of litigation. Though the number of patents per drug has increased sharply over time, the average drug's market exclusivity—time without generic competition—has remained remarkably stable. This growth in the potential length and scope of intellectual property protection appears to offer few benefits for patients: We find no evidence that growing portfolios are linked to higher-quality drugs or rising research costs, or that variation in exclusivity aligns incentives with any social policy goals. Instead, the current system encourages only widespread uncertainty—for patients, physicians, and firms—and a growing, wasteful litigation enterprise.

We argue that this costly stalemate is the consequence of a set of factors peculiar to the pharmaceutical sector—namely, its bespoke regulatory design, and a fundamental mismatch between the timelines of patent law doctrine and the timelines of new drug approval—which make infeasible any resolution within the bounds of the patent system itself. A solution is, however, entirely within reach.

Drawing inspiration from a series of legislative proposals with consistently bipartisan support, we propose a workable system for replacing pharmaceutical patent exclusivity with a new form of regulatory exclusivity administered by the Food and Drug Administration. We build an economic model that sheds light on calibrating this system to ensure that the drugs that deliver the greatest benefit to patients are also the most profitable to develop. Perhaps most importantly, this proposal aligns the interests of not only industry stakeholders but also patients, in a way that makes reform politically feasible. We identify, as well, a set of other policy levers that would deemphasize the role of pharmaceutical patents. Though the pharmaceutical industry is often held up as the "poster child" for the patent system, this Article argues that removing the pharmaceutical industry from the patent system would be a victory for patients, for the industry, and for the patent system itself.