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Patent Law: How Big Pharma Delays Generic Entry

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The introduction of generic competitors is tough on a brand-name drug company, which must face the loss of its monopoly status and the resulting severe drop in price. The design of the patent system, however, dictates that a patent holder's right to exclude others from the market must end with the expiration of the patent.

Brands and Generics

Today, 88% of all prescriptions in the U.S. are filled using generic medication. A generic drug normally enters at a 20% discount from the branded medication, and the price falls quickly from that point. Eventually, most generics are priced at an 80% to 85% discount from their name-brand equivalents. The FDA estimates that consumers saved over $217 billion in 2012 alone through the use of generics, with total savings of $1.68 trillion from 2005 to 2014.

One might call the generic revolution a miracle, but it certainly did not occur naturally or serendipitously. The underlying mechanism behind it is particularly complex. Generic drug entry is covered by the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. Before the Act, generic entry into the market was slow. Passed in 1984, Hatch-Waxman created a pathway to generic entry meant to incentivize the speedy introduction of generic drugs to market by allowing generic drug manufacturers to (1) begin the approval process so that they are ready to launch as soon as the patent expires, and (2) rely on safety and efficacy testing performed for the branded drug. Hatch-Waxman also contains incentives to encourage generic companies to challenge patents that are invalid or should not be applied to a particular drug.

Generic-Delay Tactics

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1. Summarized and excerpted from Robin C. Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499 (2016).

The actual miracle, however, is not the dramatic rise of generics. Rather, the miracle is that the benefits of Hatch-Waxman have largely held up despite its complexity and the persistent attempts at undercutting its aims. Complexity breeds opportunity, and Hatch-Waxman has created a veritable playground of opportunities that pharmaceutical companies have used to hold off generic competition. This is understandable. The temptation to avoid the impact of Hatch-Waxman can be overpowering when even a few months of additional monopoly profits can be worth hundreds of millions of dollars or more. This encourages companies to expend tremendous energy blocking generic entry by any means possible, with some companies using ever more clever and complicated strategies. As a result, many pharmaceutical firms no longer compete solely on the basis of innovation, but also on their ability to manipulate policy mechanisms and pathways to extend monopoly and duopoly terms. These manipulations can be categorized into three "generations" to illustrate the evolution of generic-delay tactics over time.

In Generation 1.0, delay generally takes the form of "pay-for-delay" settlements, in which a potential generic manufacturer is simply paid by the brand-name drug maker to refrain from entering the market until a stipulated date. These settlements were commonplace for many years, but the Supreme Court's 2013 ruling in *FTC v. Actavis* opened the door to antitrust scrutiny. A recent state court decision and a large FTC settlement may signal the end of basic pay-for-delay.

Next has come the rise of a new generation of pay-for-delay tactics—"Generation 2.0." Beginning long before *Actavis*, these strategies generally involve the transfer of benefits from the branded firm to a generic manufacturer, but not through a simple cash settlement. Generation 2.0 agreements include patterns of multiple side deals, where two companies settle a number of Hatch-Waxman disputes at once, resulting in a net benefit for the generic firm but without any large, conspicuous payment. Other instruments include overvalued agreements in which the generic delays entry but is paid handsomely to promote, manufacture, or otherwise assist the brand-name company with the sale of its drug. Finally, Generation 2.0 includes what are called "boy scout clauses"—agreements to behave honorably that actually mask anticompetitive collusion. These side deals are now themselves facing antitrust scrutiny in the courts.

"Generation 3.0" tactics, so far, have been deployed largely under the radar. These tactics no longer focus on delay agreements with generic competitors but rather on using administrative processes, regulatory schemes with connections to Hatch-Waxman, and drug modifications to obstruct generics from getting to market. Many of these strategies have little justification beyond obstruction of generics, and some recent fact patterns are falling further outside the boundaries of common sense. These include using so-called "citizen petitions" to slow down generic entry, refusing to provide samples that generics need for demonstrating bioequivalence, refusing to cooperate with generics on safety labels, product-hopping, and other blocking tactics. Some of these strategies have been part of recent schemes to restrict generic substitution while simultaneously raising prices of the brand-name drug, leading to a swell of public outrage in fall 2015 and the return of pharmaceuticals as a key policy topic.

Reform

Shining a spotlight on these problematic behaviors and the techniques used to mask them leads to ideas for reforming the generic-entry pathway. These ideas borrow from systems theory—looking from the perspective of how different systems interact to create opportunities and incentives to correct suboptimal behaviors. Moreover, to move the system away from hide-and-seek games, standards-based legislation and regulation should be adopted. Most important, to avoid "death by tinkering"—that is, adjusting doctrines a little here and a little there without comprehensive logic until the entire area collapses under its own weight—a more comprehensive overhaul of different intersecting regimes should be pursued. Hatch-Waxman was indeed a brilliant legislative innovation, heralding nothing short of a miracle in the reduction of drug costs. Now, it is time to consider the next generation of the regime so those miracles are not swept away.