Preventing Pharmaceutical Companies from Exploiting Anti-Competitive Loopholes
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Competition is key to keeping drug prices low and affordable for American citizens. A functional health system depends on the ability of generic drug companies to create products that can quickly enter the market. However, because competition drives down prices, it reduces the incentives for pharmaceutical companies to innovate new products, a risky process that is often estimated to cost around $2.7 billion per drug.[1]

Since 1984, the balance between promoting innovation and encouraging competition has been struck by the Hatch-Waxman Act. On the whole, it's been a success. But pharmaceutical companies are increasingly finding new ways to game the system and take advantage of loopholes that haven't been closed. Most of the fixes to these problems are straightforward, but they require an understanding of the Hatch-Waxman Act and the complicated ways that pharmaceutical companies can exploit it.

The Hatch-Waxman Act and the Current Regulatory Framework

The Hatch-Waxman Act was passed to increase innovation in the pharmaceutical industry and encourage generic competition, both of which were being slowed by onerous regulatory approval procedures that were applied indiscriminately. The act helped compensate innovating companies for the increasingly expensive FDA-required clinical trials by granting them the ability to extend their patents—usually granted for 20 years—by a portion of the time lost to regulatory review.[2]

At the same time, Hatch-Waxman allowed generic companies to file abbreviated new drug applications (ANDAs) which were only required to prove bioequivalence to an existing drug patent in order to pass regulatory review, and which could make use of the clinical trial data produced by the original patent holder.[3] Moreover, the first company to file an ANDA would be granted a 180-day period of market exclusivity alongside the original patent holder, making it profitable to bring generics to market.

All things considered, this system has worked reasonably well. In 1984, only 19% of drug prescriptions were for generics; today, over 80% of drug prescriptions are filled using generics, and the existence of the generic market saved Americans $265 billion in 2017, including $123

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[1] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs," *Journal of Health Economics* 47 (May 2016): 20-33.
[2] Wendy H. Schacht and John R. Thomas, "CRS Report for Congress: The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents," Congressional Research Service, April 30, 2004.
[3] Ibid. The initial patent filer is required by the FDA to oversee clinical trials in three phases to demonstrate both safety and efficacy, a process that can cost billions of dollars. Before Hatch-Waxman, all drugs had to undergo the same process—a cost so high it basically killed investment in relatively unprofitable generics.

billion in savings to Medicare and Medicaid.[4] [5] Yet although branded drugs accounted for only 17% of prescriptions in 2017, they made up 79% of total pharmaceutical costs.[6] Some degree of patent protection is necessary to encourage innovation, but these figures indicate that there is an enormous cost to Americans when generics are excluded from the market for too long.

Pharmaceutical companies, however, have exploited a number of loopholes in the Hatch-Waxman Act to artificially extend their patents. These anti-competitive behaviors fall under two categories: using legal loopholes to delay generic entry into the market, or producing functionally identical products to artificially extend the life of the patents themselves.

Delaying Generic Entry

One of the easiest tactics available to pharmaceutical companies is to simply create generic versions of their own branded drugs, called "authorized generics." Because authorized generics do not need to go through ANDA approval process, they can be timed to enter the market at the same time as the first ANDA-approved generic, undermining the incentive of the 180-day exclusivity period. In 2011, the FTC found that a full third of all authorized generics were timed to be released just after the first generic competitor entered the market, a tactic that discourages investment in generic drugs.[7]

The FDA is also required by law to consider "citizen petitions" that raise scientific or safety concerns with a generic drug, and to delay ANDA approval when those concerns are well-grounded. Unsurprisingly, this is a system that pharmaceutical companies abuse: even though 93% of all petitions are denied or denied in part, drug manufacturers often file them because even a denial can delay generic entry by up to 150 days, the time allotted to the FDA to respond.[8]

Other branded drug manufacturers have deliberately misused the FDA's Risk Evaluation and Mitigation Strategy (REMS) to avoid providing drug samples to generic developers. REMS

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[4] Ann M. Thayer, "30 Years of Generics," *Chemical and Engineering News*, September 29, 2014, https://cen.acs.org/articles/92/i39/30-Years-Generics.html.
[5] "2018 Generic Drug and Access Savings Report," Association for Accessible Medicines, accessed July 14, 2019, https://accessiblemeds.org/resources/blog/2018-generic-drug-acces-and-savings-report.
[6] Alex Kacik, "Branded-drug price hikes dwarf higher utilization of lower-cost generics," Modern Healthcare, November 16, 2018, https://www.modernhealthcare.com/article/20181116/NEWS/181119947/branded-drug-price-hikes-dwarf-higher-utilization-of-lower-cost-generics.
[7] "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," Federal Trade Commission, August 2011, https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.
[8] "Ninth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2016," Food and Drug Administration, January 8, 2018, https://www.fda.gov/media/112351/download.

gives some drug manufacturers discretion over who they sell their products to, on the grounds that risky medications should not be provided to individuals that they may end up harming. But some drug companies have claimed—falsely—that REMS prohibits them from making their drugs available to companies looking to develop generic alternatives.[9]

Perhaps the most harmful strategy used by branded manufacturers is the "pay-for-delay" settlement. Under the Hatch-Waxman Act, ANDA filers must certify either that all relevant patents will expire by the time they take their product to market, or that the relevant patents are invalid. If they choose the latter option, known as paragraph IV certification, the original patent holder can countersue, a move that immediately triggers a 30-month freeze on the ANDA approval process and locks out other generic companies.[10] These litigation procedures frequently result in settlements near the 30-month deadline where the original patents are left untouched and generic companies are functionally bribed to keep their drugs off the market.

Pay-for-delay agreements are incredibly expensive: the FTC estimates that they cost Americans $3.5 billion every year in higher drug prices.[11] They are also anti-competitive and allow branded drug companies to essentially collude with the first ANDA filer in order to control a market for up to 30 months.

Product Hopping and Patent Extensions

The other major method that pharmaceutical companies use to artificially prop up their monopolies is called "forced switching" or "product hopping." This looks innocuous on the surface: a company simply develops a new version of an old drug that—because it has a different dosage or some other new feature—is subject to a new patent. But then the branded company spends money aggressively hounding physicians to switch to the new version, possibly even removing profitable old drugs from the market before their patents expire.

In a perfect market, this would only pose a slight problem: because the new patents don't prohibit generics based on the old version, ANDAs would still be filed and consumers could switch to those functionally equivalent drugs as soon as they entered the market. In reality, only 10-20% of consumers actually do this.[12] A large part of the reason why is the fact that many state laws allow pharmacists to substitute generic drugs only if they match a prescription's dosage amounts and

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[9] Thomas M. Burton, "FDA Calls Out Drug Makers That Improperly Block Generic Competition," *Wall Street Journal*, May 17, 2018, https://www.wsj.com/articles/fda-to-call-out-drug-makers-that-improperly-block-generic-competition-1526563613.

[10] Meredith H. Boerschlein and Shana K. Cyr, "Intricacies of the 30-Month Stay in Pharmaceutical Patent Cases," *American Pharmaceutical Review*, March 25, 2018, https://www.americanpharmaceuticalreview.com/Featured-Articles/348913-Intricacies-of-the-30-Month-Stay-in-Pharmaceutical-Patent-Cases/.

[11] "Pay for Delay," Federal Trade Commission, accessed July 15, 2019, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay.

[12] Jonathan Lapook, "Forced switch? Drug cos. develop maneuvers to hinder generic competition," *CBS News*, August 28, 2014, https://www.cbsnews.com/news/drug-companies-dvelop-maneuvers-to-hinder-generic-competition/.

other characteristics, even if these features are unrelated to drug efficacy.[13] So once physicians begin prescribing the new drug, the branded manufacturer has effectively extended their monopoly by the lifespan of the new patent.

These practices are wildly costly. Product hopping used by Abbott Laboratories for just one product—fenofibrate, an anti-cholesterol medication—has been estimated to cost the U.S. healthcare system $700 million per year.[14] When Actavis switched from producing Namenda to Namenda XR in 2015—a slow-release version of the same Alzheimer's medication—it cost Medicare $288 million in the first year alone.[15]

What is truly incredible is the ways companies have found to combine many of the above tactics. In negotiating paragraph IV settlements, branded companies may threaten to launch authorized generics or file citizen petitions as negotiating tactics.[16] At the same time, even engaging in paragraph IV litigation at all can give branded drug owners time to safely oversee a forced product switch, ensuring that they can maintain a full monopoly on a product even as their old patents run out.[17]

Solutions

A full solution to these problems would involve an overhaul of the federal patenting system for pharmaceutical drugs to award patents on the basis of added value, not mere newness. As long as the patent system continues to reward companies for simply changing a formula, large elements of this system will need to remain in place. Paragraph IV certifications, for instance, are overwhelming filed against secondary or tertiary patents, so although they make pay-for-delay settlements possible, they also provide an important check against patent abuse.[18]

Yet many of these loopholes could be closed rather straightforwardly. The FDA has repeatedly informed the industry that REMS does not prohibit pharmaceutical companies from making their drugs available to generic companies, and has noted that 92% of citizen petitions are submitted

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[13] The New York Times Editorial Board, "Sneaky Ways to Raise Drug Profits," *The New York Times*, June 8, 2015, https://www.nytimes.com/2015/06/08/opinion/sneaky-ways-to-raise-drug-profits.html.

[14] NS Downing, JS Ross, CA Jackevicius, and HM Krumholz, "Avoidance of generic competition by Abbott Laboratories' fenofibrate franchise," *Archives of Internal Medicine* 172, no. 9 (May 2012): 724-730, https://www.ncbi.nlm.nih.gov/pubmed/22493409.

[15] Ed Silverman, "Actavis and its Forced Switch Could Cost Medicare $288M This Year: Study," *The Wall Street Journal*, May 7, 2015, https://blogs.wsj.com/pharmalot/2015/07/actavis-and-its-forced-switch-could-cost-medicare-288m-this-year-study/.

[16] "Authorized Generic Drugs," FTC.

[17] Michael A. Carrier, "A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping," *Florida Law Review* 62 (April 2010), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1587818.

[18] Aaron S. Kesselheim, Lindsey Murtagh, and Michelle M. Mello, "'Pay for Delay' Settlements of Disputes over Pharmaceutical Patents," *The New England Journal of Medicine* 365 (October 2011): 1439-1445, https://www.nejm.org/doi/full/10.1056/NEJMhle1102235.

by branded drug manufacturers.[19] [20] Although the FDA is aware of this problem and can identify offenders, the companies face no costs for their actions and therefore choose not to change their behavior. Empowering the FDA or the FTC to issue fines for these types of anti-competitive behaviors would be a huge step in the right direction.

Even greater benefits can be gained from simply adjusting some of the most absurd parts of the current law. The current system automatically awards 180-day generic exclusivity to the first company to *file* an ANDA, not the first company to successfully complete development of a generic and have an application approved. This, combined with the 30-month automatic litigation period triggered by paragraph IV certification, makes pay-for-delay schemes possible.

One way to fix this problem is to pass sweeping legislation making all settlements reached under paragraph IV litigation presumptively illegal. This is the thrust of a current bill co-sponsored by Amy Klobuchar and Chuck Grassley.[21] But a more straightforward solution is to simply grant the 180-day exclusivity period to the first company to successfully have an ANDA approved. Even when paragraph IV litigation is triggered, this change would allow other generics to begin entering the market long before the 30-month litigation period elapses, thereby removing the incentive to pursue pay-for-delay schemes in the first place.

Finally, on the state level, restrictive regulations that allow pharmacists to fill prescriptions with generic drugs only in cases of exact equivalence and not *effective* equivalence should be repealed. These regulations, intended to protect consumer safety, ultimately protect the anti-competitive practice of forced switching.

Pharmaceutical companies have found a host of ways to cheat the current regulatory framework and artificially extend their patent protections. Closing these loopholes requires a similarly varied number of policy solutions. But barring significant changes to the patent system, major progress can be made with a handful of simple reforms to restore competition to pharmaceutical markets.

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[19] Don McCormick, "FDA targets abuse of rules to delay entry of generic drugs," BioSpace, June 1, 2018, https://www.biospace.com/article/fda-targets-abuse-of-rules-to-delay-entry-of-generic-drugs/.

[20] Erin Fox, "How Pharma Companies Game the System to Keep Drugs Expensive," *Harvard Business Review*, April 6, 2017.

[21] See "S.64 - Preserve Access to Affordable Generics and Biosimilars Act," Congress.gov, https://www.congress.gov/bill/116th-congress/senate-bill/64/text.