Ending Pay-for-Delay Patent Litigation Settlements in the Pharmaceutical Industry

1.3%-5.3%
of Spending on Small Molecule Drugs (0.06%-0.23% of Total Health Spending)

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Issue Summary: The U.S. depends on timely initiation of competition from multiple generic drug sellers to keep drug costs down. Generic entry has been subverted by collusive patent litigation settlements between brand and generic companies, colloquially referred to as "pay-for-delay" settlements. Colluders keep ahead of antitrust authorities by finding creative ways to delay generic entry and split profits. Most recently, brand firms have been paying generic firms with so-called "implicit no-authorized generic" (no-AG) agreements, which are terms that make it economically irrational for the brand firm to sell its own generic (or AG) to compete with the generic firm. Pay-for-delay settlements add $3-$12 billion in health care costs each year.

Policy Recommendation: We recommend Congress prohibit brand and generic firms from structuring patent infringement litigation settlements that transfer value to the generic firm in exchange for delaying or limiting generic competition. Because this practice has evolved to stay ahead of antitrust enforcement, the prohibition should specify that modern forms of pay-for-delay—including implicit no-AG arrangements—constitute a value transfer.

Potential Savings: A ban or similar policy that successfully stopped collusive patent litigation settlements could reduce U.S. spending on pharmaceuticals by $3-$12 billion per year. This represents 1.3%-5.3% of the $225 billion that was spent on small molecule drugs in 2024 and 0.06%-0.23% of the $5.3 trillion in total U.S. spending on health care.

Related Literature and Evidence:

Albert, Brad and Hannah Lamb. 2025. "Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities." Available at: https://www.ftc.gov/enforcement/competition-matters/2025/01/reverse-payments-cash-quantity-restrictions-other-possibilities.

Drake, Keith and Thomas McGuire. 2025. "Using Stock Price Movements to Estimate the Harm from Collusive Drug Patent Litigation Settlements." *Journal of Health Economics*, 103, 1-15.

Drake, Keith, Gered Dunne, Aime Mason, Thomas McGuire, and Amie Price. 2025. "Trends in Authorized Generic Drug Launches and Their Effects on Competition in Oral-Solid Drug Markets in the US, 2016-23." *Health Affairs*, 44(6), 745-753.

Drake, Keith and Thomas McGuire. 2024. "The Simple Math of Royalties and Drug Competition During the 180-day Generic Exclusivity Period." *Journal of Competition Law & Economics*, 20(1-2), 50-59.

Background

U.S. pharmaceutical policy encourages investments in research and development by protecting new brand drugs from competition for an initial period (Thomas 2016). It also aims to make drugs affordable by encouraging the eventual entry of cheaper generic copies of older brand drugs. The competition that ensues between multiple sellers of the same generic drug substantially reduces prices and spending on drugs.

Sellers attempt to protect a new brand drug from generic competition by continuously acquiring new patents. More patents are generally acquired for drugs with higher sales (Hemphill and Sampat 2025). For example, the seller of the blockbuster drug Hetlioz, used to treat sleep-wake disorder, acquired 33 different patents before generic entry. Many drug patents, especially those acquired late in a drug's life cycle, do not claim the active ingredient but instead claim peripheral features such as the extended-release mechanism or dosing schedule. These secondary patents are frequently found invalid or uninfringed when litigated in court (Hemphill and Sampat 2013).

To combat brand drug sellers' incentives to extend market life ad *infinitum*, pharmaceutical policy encourages generic drug sellers to challenge patents and enter before all of a drug's patents expire. In fact, most drugs with moderate-to-high sales are involved in patent infringement litigation around the secondary patents, and the outcome determines the timing of when generic competition begins.

Most patent infringement litigation ends with a settlement that sets a date for generic entry at some point before patent expiration. Settlements are not inherently problematic. The issue is that the parties

have clear incentives to collude to extend the brand drug seller's monopoly and split the profits by, in effect, paying the generic drug seller not to compete (Shapiro 2003). By collusion, we mean an agreement between would-be competitors to coordinate rather than compete—here, to keep the lower-priced generic off the market and share the resulting monopoly profits. This class of drug patent litigation settlements is called "pay-for-delay." This form of collusion is the profit-maximizing outcome for the drug sellers (including both the brand and generic firms), but it harms drug purchasers who, without generic competition, continue paying high brand-drug prices. Such agreements can be illegal under existing antitrust law. In *FTC v. Actavis* (2013), the Supreme Court held that a reverse-payment settlement can violate the antitrust laws and must be judged under the "rule of reason"—a case-by-case inquiry in which the FTC or a private plaintiff must show that a large, otherwise-unexplained payment from the brand to the generic firm produced anticompetitive effects. The Court declined, however, to treat these settlements as presumptively unlawful. As a result, each case turns on fact-intensive litigation over whether a given settlement term functions as a payment for delay. Creative forms of profit splitting have kept the companies one step ahead of antitrust enforcement.

Evidence Base

Modern Forms of Pay-for-Delay

Collusive patent litigation settlements have plagued competition in the pharmaceutical industry for decades. The FTC and private plaintiffs have brought dozens of lawsuits alleging that specific agreements violated antitrust laws (Carrier and Bank 2024). The FTC has no dedicated statutory authority to ban pay-for-delay outright; under the *Actavis* framework, it must challenge each settlement after the fact, one at a time, and bear the burden of proving that a given term amounts to a payment for delay. This case-by-case approach is slow and resource-intensive, and it has struggled to keep pace with the settlements themselves. In the agency's one fully litigated appellate victory, *Impax Laboratories* v. FTC (5th Cir. 2021), the court affirmed that a brand firm's promise not to launch its authorized generic (an explicit "no-AG agreement") can itself constitute an unlawful reverse payment, but that result came more than a decade after the settlement was signed. Despite these efforts, the practice continues as some drug sellers have simply switched to increasingly complex forms of payment to buy delay in generic entry. So-called *implicit* no-AG agreements are the most common form of payment used in recent years (Albert and Lamb 2025; Drake and McGuire 2025).

A no-AG agreement works as follows. When a generic company is the first to file a patent challenge of a brand drug's patent(s), federal law rewards it with eligibility for a 180-day exclusivity period. The Food and Drug Administration (FDA) will not approve any other generic company's version of the drug until after the exclusivity period has expired. However, the *brand* drug manufacturer can still sell its own generic copy of the drug during the 180-day period under its original FDA approval of the brand drug. This is

called an AG. In a no-AG agreement, the brand firm refrains from selling its AG during those 180 days, reducing the number of initial generic products from two to just one. This more than doubles the generic firm's sales and profits because it does not have to split the generic market with the AG, and it can sell at a higher price.

No-AG agreements have evolved in response to antitrust scrutiny. The use of *explicit* promises by the brand not to sell an AG seems to have ended after several antitrust challenges. However, some recent settlements have included *implicit* no-AG agreements. Implicit no-AG agreements technically allow the brand to sell an AG but provide incentives for it to be withheld, burying the payment in complex licensing terms that make its existence harder to prove in court. The outcome is the same with an explicit or implicit no-AG agreement: one initial generic drug seller and high generic drug prices.

For example, one type of implicit no-AG agreement involves the generic firm paying the brand firm an unusually high royalty that deters the brand firm from selling its AG (Drake and McGuire 2024). Another type involves the generic firm agreeing to limit the volume of its sales so that the brand firm has no need to launch an AG to retain sales (Albert and Lamb 2025). Although these terms superficially appear to reduce the generic firm's profits, well-crafted royalty payments and volume limits leave the generic firm better off because it does not have to compete against the AG.

The Harm Caused by Pay-for-Delay

We recently coauthored a paper examining how often generic markets opened with just one initial entrant instead of the expected two (Drake, Dunne, Mason, McGuire, Price 2025). Among brand drugs with at least $500 million in annual sales before generic entry, an AG appeared in only 37.3% of the corresponding initial generic markets in 2016-2023—less than half the roughly 80% rate the FTC found for 2003-2008, an era in which no-AG agreements were less common. AG entry was less likely after a patent litigation settlement. The prior norm of AG entry was especially rare in the most recent years of our study (2021-2023).

In another paper, we quantified the harm from collusive patent litigation settlements on drug purchasers (Drake and McGuire 2025). When a settlement delays generic entry by more than investors anticipated, the brand firm's future expected profits rise, and its stock price jumps to reflect those gains. We used these sudden changes in firms' value to estimate how new profit flows affected drug purchasers. The logic is that the brand firm's extra profit is money that purchasers would have otherwise saved once cheaper generic copies arrived. Based on data for 64 settlements reached during 2014-2023 (including 17 potentially collusive settlements), we estimated that the collusive settlements increased purchaser spending by $3.1-$3.2 billion per year in terms of 2024 dollars. Factoring up our estimate to account for collusive settlements outside our data implies the increase in spending may be closer to $12 billion per year.

Policy Recommendation

We recommend Congress prohibit brand and generic firms from structuring patent infringement litigation settlements that transfer value to the generic firm in exchange for delaying or limiting generic competition. As mentioned above, the industry has a long history of evolving towards increasingly complex forms of payment in response to antitrust scrutiny. The FTC categorizes implicit no-AG agreements as "possible compensation" (Albert and Lamb 2025), and drug companies would likely argue that implicit no-AG clauses do not constitute a value transfer to the generic firm. Thus, any policy that simply bans transfers of value may not suffice to stop implicit no-AG agreements. To avoid this, the prohibition should be framed around the substance of the exchange rather than any enumerated list of practices: a settlement should be treated as presumptively anticompetitive whenever the generic (or biosimilar) filer receives anything of value and, in exchange, agrees to limit or forgo its own entry. Because this standard turns on the receipt of value and an agreement to limit competition—not on the specific mechanism used to convey that value—it reaches not only today's implicit no-AG agreements but whatever new structures may emerge as firms adapt to enforcement. To remove any doubt that current tactics are covered, the prohibition should further specify that modern forms of pay-for-delay, including implicit no-AG arrangements, constitute a transfer of value within the meaning of this standard.

Potential Savings

Based on our estimates described above, a ban or similar policy that successfully stopped collusive patent litigation settlements could reduce U.S. spending on drugs by $3-$12 billion per year. This represents 1.3%-5.3% of the $225 billion that was spent on small molecule drugs in 2024 (Aitken 2025) and 0.06%-0.23% of the $5.3 trillion in total U.S. spending on health care (Hartman et al. 2026). These figures do not include spending on biologics, which account for a growing share of the spending on medicines and may also be affected by collusive patent litigation settlements.

Existing Policy Proposals

In 2006, Senator Herb Kohl introduced the Preserve Access to Affordable Generics Act, which would ban brand drug firms from providing "anything of value" to generic firms in drug patent litigation settlements with the exception of a license to market the generic product prior to patent expiration (S. 3582, 109th Congress 2006). The purpose of the bill was to force the brand and generic firms to compromise on a generic entry date based on the merits of the challenged patents and not engage in shenanigans to delay generic competition.

The original bill has been reintroduced by Senators Amy Klobuchar and Chuck Grassley and modified in subsequent iterations, including a broadening to cover biosimilars. Their 2025 version would give the FTC more power to bring antitrust lawsuits by declaring that settlements "shall be presumed to be anticompetitive" if the generic firm receives anything of value (S. 1096, 119th Congress 2025). This bill would codify the presumption the Court declined to adopt in *Actavis*: a settlement would be presumed anticompetitive if the generic (or biosimilar) filer receives anything of value and agrees to limit or forgo its entry, rebuttable only if the parties show its procompetitive benefits outweigh its harms. This would shift the burden onto the settling firms rather than requiring the FTC to prove anticompetitive effects case by case. The House has advanced companion bills in prior Congresses, most notably the Nadler-Collins bill (H.R. 2375) that cleared the House Judiciary Committee unanimously in 2019, though no version has been enacted. S. 1096 was reported out of the Senate Judiciary Committee in April 2025.

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