Anticompetitive Behaviors

AV HEALTH CARE POLICY BRIEF

Brand-name drug and biologic manufacturers engage in anticompetitive behaviors to keep lower-cost alternatives off the market. The abuse of tactics such as pay-for-delay patent settlements, product hopping, and citizen petitions allows manufacturers to perpetuate significant profit by extending monopoly protections and preventing patient access to more affordable drugs.

ISSUE: PAY-FOR-DELAY AND PATENT THICKETS

"Pay-for-delay" blocks competition and can be very difficult for the Federal Trade Commission (FTC) to prosecute. These anticompetitive settlement agreements involve brand-name drug manufacturers paying generic competitors to delay launching cheaper alternatives. Even if fines and enforcement actions are taken by the FTC, the sales from extra weeks or months of monopoly power are highly profitable, which incentivizes brand manufacturers to pursue these settlement agreements. From 2010 to 2017, the number of settlements between brand-name and generic companies doubled, with the majority resulting in generic entry delay or restrictions.[1] While that trend has slowed, the FTC has noted that pay-for-delay deals have evolved to include other strategies such as caps on the amount a generic company can sell at launch,[i] and incentives for generic manufacturers to introduce first in foreign markets to delay U.S. launch.[2,3]

Patent thickets consist of patents for the active ingredient in addition to secondary patents on manufacturing processes, methods of use, delivery devices, and other aspects of a product. Because of the uncertainty and litigation cost for manufacturers to challenge each patent — especially for biosimilars — some opt to settle with the originator manufacturers instead. For example, in 2016 AbbVie secured an additional 6 years of patent exclusivity from settlements with biosimilar manufacturers for its blockbuster drug Humira.[4] As a result of these settlements, Humira biosimilars have only been launched on the U.S. market since 2023, whereas they have been available in Europe since 2018 with discounts of nearly 80%.[5] It has been estimated that this delay resulted in $2.2 billion in lost savings to Medicare.[6]

SOLUTIONS:

- *The Preserve Access to Affordable Generics and Biosimilars Act.* In 2024, the Congressional Budget Office found the bill would reduce federal budget deficits by about $1.65 billion over 10 years.[7] This bipartisan bill was reintroduced in the 119th Congress and would:
  - Limit anticompetitive agreements that prevent or delay the introduction of lower-cost generic or biosimilar products.
  - Require that manufacturers prove an agreement is not anticompetitive rather than asking the FTC to prove an agreement is anticompetitive.
- *The Eliminating Thickets to Increase Competition (ETHIC) Act.* This bipartisan bill was introduced in the 119th Congress and would limit the number of patents that brand-name manufacturers can assert to one patent per family when suing for infringement.
- *The Medication Affordability and Patent Integrity Act.* This bipartisan bill was introduced in the 119th Congress and would require pharmaceutical companies to share consistent information between the Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (PTO), stopping companies from exploiting agency discrepancies to secure additional patents.
- Congress should:
  - Direct FDA to delist invalid patents from the Orange Book.
  - Require manufacturers of biologics to disclose patent rights in their biologics license application, including process patents.[8]

i A no-authorized generic commitment is used to induce a generic firm to delay entry of its product to the market. In this case a brand-name firm, as part of a patent litigation settlement, agrees that it will not launch its own generic alternative when the first generic begins to compete, since the introduction of the branded generic would cut into the revenues of the competing generic product.

- Ensure that the Purple Book includes more complete data on FDA-licensed biological products, such as patents and exclusivities from the time of licensure going forward.[9]
- Direct FDA to publish timely updates to the Purple Book.[10]
- Create a unified registry for drug and biological products that increases patent transparency and promotes timely approval of generics and biosimilars.[11]

ISSUE: PRODUCT HOPPING

In anticipation of generic competition, a brand manufacturer makes small, patent-protected changes to their original product that provide no significant clinical benefit — such as changing from a tablet to a capsule — but offer the manufacturer longer market exclusivity. They then work to direct consumers away from the original product formulation towards the new, patent-protected version. This tactic is costly for consumers and the federal government, with one study showing that five recent product hops have cost the U.S. $4.7 billion annually.[12]

For example, in 2025, Merck began shifting patients from the original intravenous (IV) form of its top-selling cancer drug, Keytruda, to a new subcutaneous injection version, Keytruda Qlex. This has been done in advance of the expiration of Merck's primary patents for Keytruda in 2028. This strategy protects the company's brand exclusivity and blocks cheaper biosimilar competition until 2033.[13,14]

Inhalers for asthma and chronic obstructive pulmonary disease (COPD) have been historically subject to "device hopping." A study of patents and regulatory exclusivities for inhalers approved by FDA from 1986 to 2020 found that out of 62 approved inhalers, 53 were brand-name products with a median protection period of 16 years.[15] Of these inhalers, only one included an ingredient with a new mechanism of action and more than half of the patents were for devices, rather than active ingredients. This extended the median exclusivity period to twenty-eight years for brand-name follow-on products. This underscores the need for reform, as our current regulatory system rewards incremental changes to existing products.

SOLUTIONS:

- *The Drug Competition Enhancement Act*. This bipartisan bill was introduced in the 119th Congress and would prohibit product hopping, providing the FTC with methods for enforcement.
- Congress should strengthen the ability to challenge patent validity under the PTO, including keeping the Inter Partes Review (IPR) process in place.

ISSUE: SHAM CITIZEN PETITIONS

The FDA implemented the citizen petition process in the 1970s to allow the public to voice concerns regarding safety or efficacy as a drug is being considered for approval. However, there is widespread, strategic misuse of citizen petitions by drug companies striving to hold off competition. Specifically, nearly half of the petitions filed by brand-name drug manufacturers that could have delayed generic entry from 2000 to 2012 were filed within a year and a half of the FDA approving a generic competitor, with roughly 40% filed a year or less before generic approval.[16] Between 2016 and 2019, brand-name drug companies were behind about 86% of all citizen petitions, with most failing to raise legitimate safety concerns.[17]

For example, to maintain its monopoly, ViroPharma waged a campaign of citizen petition filings and lawsuits to delay the generic entry of its antibiotic Vancocin. Between 2006 and 2012, knowing that FDA would not move forward with generic approval until all pending citizen petitions were resolved, ViroPharma submitted 43 petitions and filed 3 lawsuits against FDA.[18] These citizen petitions claimed that competitors were not using adequate study designs to test their products. ViroPharma failed to provide any clinical data to support this argument, and the petitions were rejected, but the company persisted with repeated citizen petitions of the same unsupported argument to delay generic entry.

Citizen petitions cost very little to file and pose no consequences for the filing party. Even in instances where citizen petition cases by pharmaceutical manufacturers are ultimately denied, each day of postponed competition could earn the company millions of dollars.

SOLUTIONS:

- *The Stop STALLING Act*. In 2024, the Congressional Budget Office found the bill would reduce federal budget deficits by $401 million over 10 years.[19] The bill was reintroduced in the 119th Congress and would:
  - Penalize brand-name drugmakers from filing "sham" or baseless citizen petitions to FDA with the intent that the FDA's review of the petition would delay the approval of a generic competitor.
- *The STOP GAMES Act* and the *Ensuring Timely Access to Generics Act*. These bipartisan bills were introduced in the 119th Congress. They would give FDA clear authority to deny citizen petitions at any point if the agency determines they were submitted with the primary purpose of delaying drug approvals.
- Congress should improve transparency and reduce the potential for abuse of citizen petitions by requiring FDA to report more information about petition-related delays and its review process, as well as require petitions to be filed within one year of a generic application and ensure petition reviews do not delay the generic approval process.[20, 21]

ENDNOTES

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