A Simple Solution to the Problem of “Product Hopping”

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ABSTRACT

Brand-name drug companies frequently switch from one version of a drug to another. Sometimes, the switch is made just to keep the generic off the market. Should this anticompetitive “product hopping” be allowed? Surprisingly, several courts have said yes. These courts have found that when the drug company leaves the original version on the market, consumers cannot be harmed since they have a “choice.” This position, however, is at odds with the realities of the pharmaceutical industry, in which doctors prescribe but do not pay for the drug and consumers (or their insurers) pay for but do not choose it.

In this piece, I explain why legislation addressing product hopping is the best option to address this anticompetitive behavior. I focus on the Affordable Prescriptions for Patients Act of 2021, bipartisan legislation that addresses the harms from product hopping while appropriately deferring to any reasonable justifications the drug company could offer. I explain how the legislation is conservative in several ways. I address the industry’s argument that product-hopping legislation harms innovation. And I conclude that legislation can play a crucial role in ensuring that consumers have access to affordable generic medicines.

ARTICLE

Brand-name drug companies frequently switch from one version of a drug to another.1 Many times, this is justified, with the new version offering meaningful benefits for patients as compared to the original. But sometimes, it is not. Sometimes, the switch is made just to keep the generic off the market.

Should antitrust law allow this anticompetitive “product hopping”? Surprisingly, several courts have said yes. Product hopping, however, causes significant harms to consumers. In this piece, I explain why legislation is the best option to address this practice.

Product hopping costs consumers billions of dollars, with the most exhaustive empirical study finding that $28 billion worth of drugs were subject to the activity.2 Consumers have overpaid $1.7 billion for Alzheimer’s-treating Namenda, $200 million for antidepressant Effexor, and $700 million per year for cholesterol-treating TriCor.3 In addition, according to legal complaints, consumers have overpaid $11.5 billion for heartburn-treating Nexium and $650 million annually for opioid-dependence drug Suboxone.4

Just to pick one example of product hopping, the plaintiffs in a case involving drugs treating heartburn alleged that AstraZeneca “launched a massive advertising and detailing campaign designed to persuade doctors and consumers that Nexium was a significant improvement over Prilosec.”5 This campaign was questionable given that (1) AstraZeneca “assured the FDA” that it was “not stating that Nexium is better” than the original; (2) its “own set of studies showed no statistically significant difference” in outcomes; and (3) a government administrator explained to doctors that “[y]ou should be embarrassed if you prescribe” the reformulated version.6 The plaintiffs also alleged that AstraZeneca conceded that, “of the dozens of potential actions that they considered to replace the anticipated lost Prilosec sales, launching and switching prescriptions to Nexium was the worst for consumers.”7

Courts sometimes understand that product hopping can violate antitrust law. This is particularly the case for “hard switches,” which occur when the drug company pulls the original drug off the market. For example, in Abbott Laboratories v. Teva Pharmaceuticals (TriCor), the Delaware district court denied a motion to dismiss on the grounds that the brand firm “allegedly prevented [] a choice by removing the old formulations from the market while introducing new formulations.”8 Similarly, in New York ex rel. Schneiderman v. Actavis PLC (Namenda), the U.S. Court of Appeals for the Second Circuit found that
Forest engaged in monopolization by combining the “withdrawal of a successful drug from the market” with the “introduction of a reformulated version of that drug,” as this forced patients to “switch to the new version.”

The court in Namenda explained that it was not concerned with “soft switches,” which occur when the brand firm keeps the original on the market. The court stated that if Forest had allowed the original version “to remain available until generic entry, doctors and Alzheimer’s patients could have decided whether the benefits of switching” to the reformulated version “would outweigh the benefits of adhering” to the original version “using [the] less-expensive generic” version.

While the conduct in Namenda centered on a hard switch, other courts, confronted only with soft switches, have refused to recognize any harms. For example, the D.C. district court in Walgreen Co. v. AstraZeneca Pharmaceuticals (Walgreens) concluded that “there is no allegation that AstraZeneca eliminated any consumer choices.” To the contrary, the court asserted that the firm “added choices,” that “determinations of which product among several is superior . . . are left to the marketplace,” and that “[n]ew products are not capable of affecting competitors’ market share unless consumers prefer the new product.

The Walgreens case was not the only one that failed to recognize the harm from soft switches. The Massachusetts district court in In re Solodyn Antitrust Litigation found that the plaintiffs “failed to allege plausibly that [the brand firm] limited consumer choice by offering [the drug] at new strengths in 2009 and 2010” because it continued selling the original strengths until 2011. Similarly, the same court in In re Asacol Antitrust Litigation found that “allegations of a soft switch through marketing efforts cannot substitute for the key product withdrawal that undergirds a product-hopping claim.”

The Walgreens, Solodyn, and Asacol courts erroneously discerned consumer choice in a setting in which it was lacking. The pharmaceutical industry is unique in being characterized by a “price disconnect.” There is no single entity that decides whether a new version of a product is worth more than the old: doctors prescribe the drug but do not pay for it, while consumers (or their insurers) pay for it but do not choose it. As a result, and unlike in other industries, no single entity makes the price-quality determination.

Given that courts have not recognized the harm from soft switches, what can be done? In a word: legislation. In the 117th Congress, the legislation has considered S. 1435, the Affordable Prescriptions for Patients Act of 2021. The legislation has 15 cosponsors (9 Democrat, 5 Republican, and 1 Independent), and in July 2021 the Senate Judiciary Committee approved it. An earlier version passed out of this Committee in 2019 by a 22-0 vote.

This legislation would address the harms from product hopping while appropriately deferring to any reasonable justifications the drug company could offer. By providing a cause of action under Section 5 of the FTC Act, the legislation gives only the FTC authority to file suit. Liability also is limited to the period in which the generic is about to enter the market — a so-called “generic window.”

The legislation addresses hard switches in which the company (1) withdraws its drug (or destroys inventory) and impedes competition and (2) sells a follow-on drug. It also addresses soft switches in which the firm (1) unfairly disadvantages the original and impedes competition and (2) sells a follow-on drug.

The drug company benefits from exclusions from liability for “truthful, non-misleading promotional marketing” and “ceasing promotional marketing.” It also can offer justifications based on showing that it (1) would have taken the actions regardless of the effect on competition and (2) had safety or supply-disruption reasons for the reformulation (for hard switches) or “had legitimate pro-competitive reasons, apart from the financial effects of reduced competition” (for soft switches).

These forms of analysis reflect a conservative framework in antitrust law known as the “no economic sense” test, which imposes liability only if the sole reason for the conduct is to harm competitors.

The FTC can rebut evidence a manufacturer offers or establish that (1) the procompetitive benefits do not outweigh the anticompetitive effects, (2) the conduct is not reasonably necessary to achieve the justifications, or (3) the justifications could be achieved through less anticompetitive means.

In short, the legislation is conservative, applying narrowly while not hindering innovation, in several ways. It limits the scope of the parties that can file suit and the timing of the reformulations that can be challenged. In addition, it erects a robust threshold for showing an anticompetitive product hop and provides an expansive set of exclusions and justifications that the drug company can offer.

The pharmaceutical industry often laments that any antitrust legislation would harm innovation. Not surprisingly, it has done so in this setting, claiming that product-hopping legislation “would fundamentally upend the biopharmaceutical innovation ecosystem, creating a presumption of violation for almost any post-approval innovation.”

But no empirical or other evidence has ever shown that applying antitrust law to product hopping would deter innovation. In fact, antitrust enforcement is necessary to address situations in which the brand firm delays introducing
In conclusion, product hopping causes significant harm. Courts have failed to recognize the competitive effects of soft switches, erroneously contending that patients have a “choice” in these settings. Legislation giving the FTC the power to challenge anticompetitive product hopping is the best option to ensure that this conduct does not evade scrutiny and would help ensure that consumers have access to affordable generic medicines.

ABOUT THE AUTHOR

Michael A. Carrier is Distinguished Professor at Rutgers Law School, where he specializes in antitrust and IP law. He has written more than 130 book chapters and articles, has been quoted more than 2000 times in the media, has been cited in courts including the U.S. Supreme Court, and has testified before the FDA, FTC, National Academies, Senate Judiciary Committee, House Judiciary Committee, and House Energy & Commerce Committee.

REFERENCES AND FOOTNOTES

2. Id.
3. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 661 (2d Cir. 2015) (Namenda); Explainer: Evergreening and How Big Pharma Keeps Drug Prices High, The Conversation, Nov. 5, 2014 (Effexor); Kevin Drum, How To Keep Healthcare Costs High In One Easy Lesson, Mother Jones, Apr. 18, 2012 (TriCor).
6. Id. ¶¶ 93-94.
7. Id. ¶ 47.
9. 787 F.3d 638, 659 (2d Cir. 2015).
10. Id. at 655.
12. Id.
20. Id. § 27(b)(2).
21. Id. § 27(b)(3).
22. See Carrier & Shadowen, at 210-16.
23. Id. § 27(b)(4).
26. See Michael A. Carrier & Steve D. Shadowen, Product Hopping: A New Framework, 92 Notre Dame L. Rev. 167, 202 (2016) (providing examples from (1) the TriCor case, in which the brand firm delayed seeking a new indication for its original product even though “[t]he data necessary . . . was available much earlier”; (2) “Warner-Lambert’s admission of criminal liability for promoting off-label uses of seizure-treating Neurontin,” which involved its “conce[ssion] that a ‘principal reason[] for not seeking FDA approval for those uses was that it wanted to reserve them for a later promotional campaign for its reformulated product’”); and (3) the Namenda case, in which “Forest waited until generic competition for twice-daily Namenda was imminent before introducing the once-daily version” even though it “had obtained FDA approval to market the once-daily version three years earlier”).