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PRODUCT HOPPING: A NEW FRAMEWORK

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Abstract

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping," which occurs when a brand-name pharmaceutical company switches from one version of a drug to another. These switches, benign in appearance but not necessarily in effect, can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it occurs in uniquely complicated markets characterized by doctors who choose the product but don't pay for it, and consumers who buy the product but don't choose it.

It is thus unsurprising that courts have offered inconsistent approaches to product hopping. They have paid varying levels of attention to the regulatory structure, offered a simplistic analysis of consumer choice, adopted an underinclusive antitrust standard based on coercion, and focused on whether the brand firm removed the original drug from the market.

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. This rigorous and balanced framework is the first to incorporate the economic characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer (1) reformulates the product in a way that makes the generic non-substitutable and (2) encourages doctors to write prescriptions for the reformulated product rather than the original. The test also offers two safe harbors, which are more deferential than current caselaw, to ensure that the vast majority of reformulations will not be subject to antitrust scrutiny.

The analysis then examines whether a brand's product hop passes the "no-economic-sense" test. In other words, would the reformulation make economic sense for the brand if it did not have the effect of impairing generic competition? Merely introducing new products would pass the test. Encouraging doctors to write prescriptions for the reformulated rather than the original product—"cannibalizing" the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense other than through its impairment of generic competi-

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tion offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, practicalities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve and standardize the antitrust analysis of product hopping.

INTRODUCTION

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping." A brand-name pharmaceutical company switches from one version of a drug (say, capsule) to another (say, tablet). The concern with this conduct is that some of these switches can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it involves uniquely complicated markets characterized by buyers (insurance companies, patients) who are different from the decisionmakers (physicians).

It thus should not be a surprise that courts have offered inconsistent approaches to product hopping. Some have emphasized the regulatory structure while others have ignored it. Some have offered a simplistic analysis of consumer choice, while others have adopted an underinclusive test based on coercion. Nearly all have focused on whether the brand firm removed the original drug from the market (a "hard switch") or left it on the market (a "soft switch").

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. The framework, which is balanced and rigorous, is the first to incorporate the characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer:

(1) reformulates the product in a way that makes the generic non-substitutable; and

(2) encourages doctors to write prescriptions for the reformulated product rather than the original.

This definition excludes many product reformulations, such as those in which the brand manufacturer does not "cannibalize"[1] sales of the original

1 "Cannibalize" is an industry term loosely defined as the brand manufacturer's marketing against its own original product to encourage doctors to switch their prescriptions to the reformulated product. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 44–45 (2009).

product. It also avoids targeting brand reformulations designed to improve the product by competing with other brands or growing the market, reserving its focus for the switching of the market in order to stifle generic competition.

Where the brand's conduct does not satisfy both elements of a product hop, it is not subject to antitrust scrutiny. And when the conduct does meet both elements, our framework offers two stages of analysis. First, we propose two safe harbors that are more deferential than current caselaw and that ensure that the vast majority of reformulations will not face antitrust review.

And second, for reformulations that are product hops and are outside the safe harbors, the framework examines whether the hop passes the "no-economic-sense" test. In other words, would the product hop make economic sense for the brand if the hop did not have the effect of impairing generic competition? Merely introducing new products would pass the test (indeed, would not even constitute a product hop). Encouraging doctors to write prescriptions for the reformulated rather than the original product—cannibalizing the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense—other than through its impairment of generic competition—offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. In fact, our framework offers manufacturers three opportunities to sidestep antitrust liability: (1) avoid our definition of "product hop"; (2) be covered by one of the safe harbors; or (3) undertake conduct that makes economic sense. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, realities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve the antitrust analysis of product hopping.

Part I offers a background on product hopping. Section A categorizes various types of reformulations. Sections B and C address the relevant regulations: the Hatch-Waxman Act and state substitution laws. Section D then focuses on the crucial element of timing, explaining how generic entry before a brand reformulates a drug dramatically reduces price.

Part II highlights the market failure that is unique to the pharmaceutical industry. Section A describes the "price disconnect" that distinguishes prescription drugs from other products and that separates the consumer's price/quality determination that is unified in other markets. Section B analyzes drug patents, emphasizing the limited role of the patent system and, in particular, the lack of a requirement of a medical improvement over earlier versions. Part C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico, U.S. prices before prescriptions were required, and lower prices in countries that have solved

the price disconnect. Given the absence of these measures in the United States, Part D highlights the importance of antitrust law.

Part III examines the five judicial analyses of product hopping. Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts limited to "hard switches," i.e., those in which the brand withdraws the original product from the market. Section B covers the *Walgreens* case, which offered a simplistic analysis of consumer choice in the context of a "soft switch" in which the brand did not withdraw the original product from the market. The first two product-hopping decisions, *TriCor* and *Walgreens*, framed the analysis for later decisions, with some courts assuming that hard switches could violate the antitrust laws but soft switches could not.

The *Suboxone* case addressed in Section C revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Doryx* case covered in Section D, in contrast, is an outlier that neglected the regime altogether. Section E then focuses on *Namenda*, which considered the regulatory regime in the context of hard switches, offering an underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars that have paid less attention to this important issue.

Part IV then presents a new framework for courts to analyze the antitrust implications of product hopping. Section A begins with two safe harbors that brand firms can use if they implement the product hop (1) outside a "Generic Window" in which generic entry is expected or (2) after a generic version of the original drug has entered the market. If the product hop occurs during one of these windows, it will be immune from antitrust liability.

For product hops subject to antitrust scrutiny, Section B introduces a test based on whether the hop would make business sense for the brand manufacturer if it did not have the effect of impairing generic competition. Courts and commentators have advocated a no-economic-sense test in other areas, but the test remarkably has not been employed in a setting tailor-made for it. If a brand acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Through the application of the no-economic-sense test, we show the errors of courts that have treated as outcome-determinative the distinction between hard and soft switches. In particular, a brand might be anticompetitively undertaking actions that make no economic sense not only when it makes a hard switch and withdraws the original product from the market, but also when it makes a soft switch, leaving the original drug on the market but reformulating the product and "cannibalizing" it (switching sales to the new version), for example by denigrating, misrepresenting features of, increasing the price of, or pulling the marketing and promotion from, its original product.

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