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Recent antitrust challenges to pharmaceutical companies' efforts to transition patients from drugs nearing the end of their patent life to next-generation drugs have increased the risk of pursuing such "product hopping" strategies. Pharmaceutical and biotech companies should be cognizant of such risks as they develop marketing strategies for new versions of existing drugs.

In the first appellate court **decision** to examine product hopping, *New York v. Actavis*,the Second Circuit recently affirmed a district court injunction requiring the defendant to continue to offer its legacy drug until 30 days following patent expiration, on the same terms and conditions offered when the next generation drug was first introduced. The Second Circuit's decision may provide some guidance to lower courts, which have struggled to draw a line defining when the generally procompetitive act of introducing a new product may be an antitrust violation.

As described by the Second Circuit, the case raised a "novel question of antitrust law: under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as 'product hopping,' violate [antitrust law]." The court's answer was that "product redesign is anticompetitive when it coerces consumers and impedes competition," regardless of whether the new product is superior.

Applying this standard, the Court concluded defendants' introducing a new drug and withdrawing an old version about to go off patent "would likely impede generic competition by precluding generic substitution through state drug substitution laws." Finding that defendants' justifications for its conduct were "pretextual"—and that defendants were trying to "put up barriers or obstacles to generic competition"—the court condemned the conduct.

The battle is not over. Actavis has petitioned the Second Circuit for rehearing en banc, arguing that the holding "obliterates the rights granted by the Patent Act," "creates an unprecedented duty to continue selling a product to promote consumer 'choice' for the benefit of future competitors," and "will decimate incentives to develop incremental innovations." Given the substantial stakes, challenges to similar conduct are likely to continue to be litigated.

How did we get here?

Conduct associated with the introduction and promotion of new products has long drawn antitrust scrutiny, though courts have been reticent to condemn the potentially procompetitive conduct. As recognized in *United States v. Microsoft*, "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes."

Among the most famous cases, the Second Circuit in 1979, in *Berkey Photo, Inc. v Eastman Kodak Co.,* held that successful introduction of a new or improved product (in that case a new camera and film) was not illegal since "Kodak's success was not based on any form of coercion." As the *Actavis* court was quick to emphasize, however, in *Berkey* the court went on to note that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera," a reservation which would play a key role in its later *Actavis* decision.

Recent product hopping challenges have arisen most frequently in the pharmaceutical industry, which the Second Circuit characterized as subject to a unique and complex regulatory framework that "provides an opportunity for brand manufacturers to 'game' the system" by using innovation as a tool for exclusion.

Hard v. soft switch: An emerging line in the sand?

A distinction has emerged in the product hopping case law—explicitly recognized by the Second Circuit—between a "soft switch" and a "hard switch." The Second Circuit used the term "soft switch" to refer to marketing strategies such as actively promoting the new drug while curtailing or terminating promotion of the old drug, and selling the new drug at a discount, in the effort to convince users to make the jump to the new formulation. A "hard switch," on the other hand, entails also limiting or preventing access to the old drug, thereby, according to the court, coercing users to switch whether or not they are inclined to do so.

The paradigmatic example of a hard switch was at play in the 2006 district court decision in *Abbott v. Teva*. In that case, the plaintiffs alleged that after changing its formulation for the drug at issue and getting FDA approval, the defendant not only stopped selling the old drug, but also changed the National Drug Data File (NDDF) to obsolete, making generic substitution literally impossible. The court concluded that allegations that the defendant removed the prior drug formulations from the market and changed the NDDF codes may "result in consumer coercion" and may thus be anticompetitive.

Another district court came to a similar conclusion regarding a hard switch in *In re Suboxone Antitrust Litigation* in December 2014. The plaintiffs there alleged that defendant, among other things, developed a new formulation of the drug at issue, obtained FDA approval, raised the price of the old formulation, and eventually removed that formulation from the market. In denying defendant's motion to dismiss, the court concluded that the "threatened removal of the tablets from the market in conjunction with … alleged fabricated safety concerns could plausibly coerce patients and doctors to switch" to the new formulation. The court recognized, though, that the conduct alleged was not as extreme as that in *Abbott/Teva*.

On the other hand, courts have been less receptive to allegations that soft switches have harmed competition. In *Walgreen v. AstraZeneca*, for instance, plaintiffs alleged that AstraZeneca shifted its resources and began promoting a newly-approved prescription heartburn medication, Nexium, just as its longstanding drug Prilosec, was beginning to face generic competition. In granting AstraZeneca's motions to dismiss, the court emphasized that, rather than "defeat competition from generic substitutes" by "deliberately limit[ing] … consumers' choices," AstraZeneca had added choices to the market.

And even where a firm has withdrawn an older version of a drug, courts have upheld the conduct. In *Mylan, v. Warner Chilcott*, for instance, the district court granted summary judgment to the defendants even though defendants withdrew the prior formulation—and did so "primarily to defeat generic competition"—because generics could still "reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development." The court even chided the *plaintiff* for refusing to incur promotion costs: "Spending some of its revenue on advertising would have lessened Mylan's now-increased profits. Mylan chose not to do so, relying instead on the 'promotion' provided by state automatic substitution laws. Mylan is thus a 'victim' of its own business strategy, not Defendants' 'predatory' conduct."

Clear lines remain elusive

Unlike the *Mylan v. Warner Chilcott* Court, the Second Circuit rejected the argument that under the facts at issue generics could still compete for sales, distinguishing the earlier decision on the ground that in that case "there [was] no evidence of coercion … because generics had already entered the market at the time of defendants' product reformulation." The Second Circuit instead found that by withdrawing the legacy drug defendants had foreclosed the "only cost-efficient means of competing available to generic manufacturers," which it deemed sufficient to violate the antitrust laws, even in the absence of literal foreclosure. Thus, the Second Circuit reasoned that the district court "appropriately considered the unique market characteristics of the pharmaceutical industry in concluding that antitrust law 'requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws.'"

This tension illustrates that while some cases might be read to suggest that leaving existing drugs on the market creates something of a safe harbor from product hopping allegations, there is no clear line. For instance, merely raising the price of the legacy drug

may be viewed by some to be as "coercive" as withdrawing a product from the market.

Indeed, the injunction in *Actavis* not only required the defendants to continue marketing the legacy drug, it prohibited them from restricting access and charging more than they did when the new version was first introduced. And in the wake of the Second Circuit decision state officials have publicly suggested that soft switches that do not involve the complete withdrawal of the legacy drug may still be considered coercive, depending at least in part on the intent behind the conduct.

Against this uncertain and evolving legal landscape, pharmaceutical companies should carefully consider plans to introduce new versions of current drugs and document the procompetitive rationale for conduct, to avoid misunderstandings should the conduct ever be investigated or challenged.

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