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CIVIL PROCEDURE

Second Circuit Holds 'ProductHopping' May Violate Antitrust Laws

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Last month, an appellate court addressed for the first time whether a pharmaceutical company violates the antitrust laws by withdrawing an older brand-name drug before patent expiration in an effort to convert patients to a newer, improved form of the drug to maintain its profits—so-called "product hopping." In *New York v. Actavis*, No. 14-4624, the U.S. Court of Appeals for the Second Circuit held that such product hopping may violate antitrust laws and further, upheld an extraordinary nationwide injunction requiring defendants Actavis and its subsidiary Forest Laboratories to continue manufacturing the older version of their Alzheimer's drug Namenda for 30 days after generic forms of that drug become available. Although the defendants' Petition for Rehearing En Banc remains pending, the panel decision—whether or not it stands—raises a number of questions about when a patent monopolist can be obligated to keep an older, even inferior, product on the market in order to help generic competitors who will make the older product following patent expiration.

Background

Namenda, which is used to treat moderate-to-severe Alzheimer's disease, has been approved by the FDA in two formulations: a twice-daily immediate-release drug, Namenda IR, which has been available since 2004, and a once-daily extended-release drug, Namenda XR, which has been marketed since 2013. Due to patent protection and other rights, the defendants have the exclusive right to sell Namenda IR until July 11, 2015, and Namenda XR until 2029. The FDA has tentatively approved several generic versions of Namenda IR that will likely enter the market when the Namenda IR exclusivity ends this summer. At that time, pharmacists in many states will generally be required to dispense a generic, rather than brand-name, version of the drug—thereby causing a rapid and steep decline in the defendants' profits.

Anticipating this outcome, the defendants engaged in two strategies to switch patients to Namenda XR before the onset of generic competition for Namenda IR. First, the defendants attempted to transition patients to the newer drug through a "soft switch," discontinuing active marketing of the older drug and selling the new and improved product for a lower price than the old product. However, after concluding that the "soft switch" would induce only about 30 percent of Namenda IR users to switch to the new drug before generic entry, the defendants announced in February 2014 that they would soon discontinue the older drug—what became known as the "hard switch."[1]

In September 2014, the state of New York sued the defendants, alleging that the planned withdrawal of Namenda IR violated federal and state antitrust laws, and seeking injunctive relief and damages. The state theorized that by withdrawing Namenda IR near the end of their exclusivity period to force patients to switch to Namenda XR (for which there would be no generic substitute for years), the defendants intended to thwart generic competition and maintain their monopoly. Following a five-day hearing, a federal district court granted the state's request for a preliminary injunction and required, among other things, that the defendants continue to make Namenda IR available until 30 days after the drug's exclusivity expires.

The Second Circuit Affirms

On May 22, 2015, following an expedited appeal, a panel of the Second Circuit Court of Appeals upheld the preliminary injunction in its entirety, marking the first time that an appellate court has relied on

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a product-hopping theory as a basis for antitrust liability.

The panel noted that courts generally are "[']very skeptical about claims that competition has been harmed by a dominant firm's product changes,'" and that "[p]roduct innovation generally benefits consumers."[2] However, the court concluded that "when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition," the product withdrawal is anticompetitive.[3] In the case of Namenda, the panel found that such "coercion" was shown because the defendants' "hard switch" forced Alzheimer's patients taking Namenda IR to switch to Namenda XR. The court contrasted this behavior with the defendants' original "soft switch" tactic, noting that as long as the defendants worked to persuade patients and their doctors to switch from IR to XR while both drugs were on the market, "patients and doctors could evaluate the products and their generics on the merits."[4]

Importantly, the panel rejected the argument that a patent owner should not be subject to antitrust liability when it chooses to introduce or not introduce, or to sell or not sell, a product within the scope of its patent. While recognizing the "tension between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies," the court explained that "patent law gives defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition 'beyond the limits of the patent monopoly.'"[5] Thus, according to the panel, the "*combination* of defendants' withdrawal of IR and introduction of XR in the context of generic substitution laws … place[d] their conduct beyond the scope of their patent rights for IR or XR individually."[6]

The panel also agreed that defendants' conduct would impede competition because Namenda IR's withdrawal would likely impede generic substitution through state drug substitution laws. The court cited the defendants' own predictions that a "hard switch" would leave "few or no prescriptions" for Namenda IR that could be switched to generics.[7] The court thus saw no reason to overturn the district court's factual finding that "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers."[8]

The panel also upheld the district court's finding that patients would be unlikely to "reverse commute" from XR back to the older IR after generic versions of IR entered the market. The court cited a company executive's statement that switching back to the immediate-release formulation after the "hard switch" would be "very difficult."[9] The court also credited evidence of "high transaction costs associated with reverse commuting," noting that a reverse commute would require a new prescription, and that doctors and caregivers are reluctant to change medication regimens of moderate-to-severe Alzheimer's patients because they are "especially vulnerable to changes in routine."[10]

Finally, while the court recognized that launching new products is generally procompetitive, it found that the defendants' asserted procompetitive justifications were pretextual, citing internal company documents emphasizing the need to switch patients from IR to XR to preserve their market share. Furthermore, the court rejected the notion that there is a link between the ability to replace a patent-expiring product with a new, patent-protected product, on the one hand, and procompetitive incentives to innovate, on the other. Nor could defendants justify withdrawing IR before generic entry on the basis that they should be permitted to maximize their return on a new product; rather, the court held that the withdrawal evidenced a "willingness to forsake short-term profits," indicative of anticompetitive behavior.[11]

Implications of the Namenda Decision

The panel's Namenda decision likely will embolden state attorneys general and private plaintiffs who wish to rely on product hopping as a basis for antitrust liability. However, in light of the court's deferential standard of review, particularly with respect to the district court's factual findings, it remains to be seen whether, if the facts varied even a little, other courts would follow—or if the state just barely threaded the needle here.

For example, despite significant evidence that extended-release drugs improve medication adherence and long-term clinical outcomes,[12] the panel refused to consider whether XR was superior to IR because the Defendants' "hard switch" was "coercive."[13] It is unclear why the court was so willing to disregard evidence of Namenda XR's superiority, but it may have been influenced by (1) the state's evidence that defendants had overstated XR's relative benefits and that medication changes are disruptive for Alzheimer's patients, as well as (2) statements in the defendants' own documents that less than a third of patients would switch to XR under the "soft switch" approach, at least raising questions about whether the new drug was truly superior.[14]

But what if the evidence had shown convincingly that many, or even some, patients stood to benefit from a switch from Namenda IR to Namenda XR—even if they were "forced" to make the switch? Would the product hop still be anticompetitive? Or what if a less "vulnerable" patient population were at issue, or if patients did not switch because their health plans discouraged switching to protect their profits? The panel decision does not appear to leave room for a different outcome based on such different facts. However, it is easy to imagine that another court presented with even slightly different facts would reach a different outcome—particularly in light of long-standing precedent that antitrust courts should not be in the business of judging the relative merits of technological changes.[15]

The panel also deferred to the district court's finding that high transaction costs would prevent most patients from switching back to the IR formulation after

generics became available—in particular the district court's finding that state drug substitution laws provide the only cost-efficient means for generic suppliers to compete.[16] The court briefly considered (and rejected) the defendants' argument—consistent with the practical experience of many Americans today—that generics also successfully compete due to financial incentives offered by health insurers and managed care organizations to promote the use of generics, such as significantly lower co-payments.[17] The district court, however, concluded that these efforts were insufficient to ensure competition, citing defendants' own predictions that few patients would "reverse commute," as well as evidence that the patients at issue "are extremely sensitive to changes in routine" and at least one health plan was unlikely to try to move patients from Namenda XR to the immediate-release drug.[18] This again raises the question of whether the result would change on slightly different facts. For example, what if the companies' documents had suggested that patients would not "reverse commute" because the extended release drug was superior, or if the evidence showed that health plans would drive patients to generics?

The panel also rejected the argument that distinctions between the defendants' "soft switch" measures (which the court implied were perfectly legal) and the "hard switch" (which was not) could not credibly be drawn, explaining that "[h]ad defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR … ."[19] But what if, rather than pulling Namenda IR from the market, the defendants had raised the drug's price significantly? The state's economist testified that such a price hike would not be anticompetitive,[20] but it is difficult to see how making a drug prohibitively expensive is appreciably less coercive than withdrawing it altogether. It is similarly unclear how the court would factor in the influence of managed care health plans, if they took steps to encourage the use of cheaper but inferior drugs to avoid paying for more expensive but better drugs. Nor is it clear whether the outcome would change if defendants' had implemented the "hard switch" at a different time, for example, immediately after Namenda XR came to market.

Finally, the Second Circuit's opinion leaves unanswered several practical—and perhaps Constitutional—questions. The preliminary injunction requires the defendants to continue making Namenda IR, a product that (with limited exceptions) they no longer planned to make, available on the same terms and conditions since July 21, 2013. But what if the cost of a key ingredient changed, significantly altering the product's profitability? Either party could petition the district court for relief, but would the court then be required to oversee the defendants' operations? Nor did the panel address the argument raised by amicus the Chamber of Commerce that a unilateral order by a federal court that a company engage in a business it affirmatively decided to exit amounts to an unprecedented overreach of federal power "tantamount to confiscating the operations of a [private] facility."[21] In their en banc petition, the defendants similarly assert that the panel imposed an "unprecedented duty" on a manufacturer to "continue selling a product" it no longer wishes to sell "solely to maximize the sales of … [its] rivals," a rule that is "inconsistent with bedrock freedoms underpinning our economy."[22]

In light of the pending Petition for Rehearing En Banc, only time will tell whether the panel decision remains good law. And, as discussed above, even if it stands, the decision leaves unanswered important questions regarding the scope and applicability of the decision. The opinion, however, makes at least three points clear: (1) antitrust complaints based on product-hopping claims are not going away any time soon; (2) internal company documents and messaging about the nature of the product improvement and the reason for the "hop" can matter—a lot; and (3) this panel was unwilling to accept several arguments against product hopping as a basis for antitrust liability commonly advanced by the defense bar—and supported by long-standing precedent—including the risks of stifling innovation, the difficulty of weighing the relative benefits of innovation, and deference to rights under the patent laws.

Endnotes:

1. The defendants first planned to discontinue Namenda IR in August 2014, but later extended this deadline to fall 2014. They also later decided to continue to make Namenda IR available through a single mail-order pharmacy if a doctor indicated that the drug was medically required, but estimated that this option would be utilized by less than 3 percent of current Namenda IR users.

2. Slip Op. at 32 (quoting *United States v. Microsoft*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc).

3. Id. at 35-36 (citing *Berkey Photo v. Eastman Kodak*, 603 F.2d 263 (2d Cir. 1979)) (internal citations omitted).

4. Id. at 37.

5. Id. at 51-52.

6. Id. at 53.

7. Id. at 40.

8. Id. at 40-41.

9. Id. at 42.

10. Id.

11. Id. at 49 (quoting *In re Adderall*, 754 F.3d 128, 135 (2d Cir. 2014)).

12. See *New York v. Actavis*, No. 14 CIV. 7473, 2014 WL 7015198, at *12 (S.D.N.Y. Dec. 11, 2014).

13. Slip Op. at 35 n.25 ("Whether XR is superior to IR is not significant in this case.").

14. See id. at *19, *31.

15. See *ILC Peripherals v. IBM*, 458 F. Supp. 423 (N.D. Cal. 1978), aff'd 613 F.2d 727 (9th Cir. 1979).

16. Slip Op. at 40-41; see also Actavis, 2014 WL 7015198, at *27.

17. Slip Op. at 40-43; see also *Actavis*, 2014 WL 7015198, at *6-7, *21 (discussing such evidence).

18. *Actavis*, 2014 WL 7015198, at *29-30.

19. Slip Op. at 38.

20. See Defs. Opening Br. at 44.

21. Chamber of Commerce Amicus Br., at 10.

22. No. 14-4624, Defs. Pet. for Rehearing En Banc, at 3, 5.