Second Circuit Finds "Product Hopping" By a Pharmaceutical Company to Violate Antitrust Laws

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Court upholds injunction requiring company to continue selling a superseded product in order to facilitate generic competition

Summary

In *New York v. Actavis plc*, No. 14-4624 (2nd Cir. May 22, 2015), the United States Court of Appeals for the Second Circuit became the first appellate court to address a pharmaceutical industry practice known as "product hopping."

Generally, product hopping involves transitioning patients from an older version of a drug (typically, one approaching patent expiration and imminent competition from generics) to a new version of the drug as to which there is no immediate threat of generic competition (for example, because of patents on the new version). Generic companies and some antitrust enforcers argue that the switch (or "hop") frustrates competition because generics' ability to compete depends on a continuing flow of prescriptions for the *older* version of the drug as to which patents have expired and generics have received FDA approval. On the other hand, such conduct has been defended on the ground that it fosters innovation, and that the antitrust laws should not require a company to continue selling a superseded product solely to assist its competitors.

Here, in a closely-watched case, the Second Circuit held that a scheme to *coerce* patients to switch from the old product to the new one (by withdrawing the old product from the market), with the intent and effect of thwarting generic competition, violated the antitrust laws. By contrast, the Court indicated that efforts to *persuade* patients to make the switch (while keeping the old product available for sale) should be permissible.

In the end, the Court upheld an extraordinary injunction *requiring* the pharmaceutical company (Actavis) to continue selling the older product on the same terms upon which it had been sold prior to the "hop."

Factual Background

Forest Laboratories (now part of Actavis) marketed and sold Namenda IR, a twice-daily drug for the treatment of moderate-to-severe Alzheimer's disease. As that product neared the end of its patent exclusivity period (July 2015), Forest/Actavis (hereafter, Actavis) introduced a new once-daily extended release version called Namenda XR, which retains patent exclusivity until 2029. Once the patent exclusivity for a branded drug expires, generic competitors can enter the market (assuming their products are approved by the FDA) and typically take a substantial portion of the sales, in part because the law in many states require or encourage pharmacists to fill prescriptions with generic equivalents unless the doctor specifically indicates that the prescription should be filled with the brand name version of the drug. The Court found that Namenda does not compete with other Alzheimer's drugs, and that Actavis has a 100% share of the market for that product.

According to a complaint filed by the New York Attorney General, Actavis employed various strategies to avoid the "patent cliff" that would significantly reduce sales of its Namenda products. Initially, Actavis employed what the court described as a "soft switch" strategy, in which both IR and XR remained on the market but Actavis sought to shift sales to XR by discounting its price, offering rebates, and the like.

According to the complaint, Actavis concluded that only 30% of Namenda users would "voluntarily" shift to Namenda XR prior to the entry of generic competition in July 2015.

In early 2014, according to the complaint, Actavis shifted to a more aggressive strategy described as a "hard switch" or "forced switch." Under this approach, Actavis publicly announced and notified the FDA that it would *discontinue* Namenda IR (with the exception, later, of a single supply source with limited access by customers); it urged health care providers to "discuss switching to Namenda XR" with their patients; and it requested the federal Medicare/Medicaid agency to remove Namenda IR from its formulary list (which would prevent Medicare health plans from covering the drug).

New York's Lawsuit and the District Court's Injunction

In September 2014, the New York Attorney General brought a lawsuit alleging that Actavis was violating federal and state antitrust laws by thwarting generic competition, and sued to prevent Actavis from withdrawing Namenda IR from the market.

After an evidentiary hearing, the United States District Court for the Southern District of New York (Judge Sweet) granted the State's request for a preliminary injunction. The court found, among other things, that withdrawal of IR would "force" patients to switch to XR; that pharmacists would not be permitted under state law to substitute with generic IR when a physician prescribed XR, because of differences in dosage and form between IR and XR; that patients who switched to XR were highly unlikely to switch back to IR when lower-cost generics became available in July 2015; and, for all these reasons, that the "hard switch" would likely thwart generic entry. It also found that Actavis's explicit purpose in employing the hard switch was to avoid the loss of sales to generic competition. The court referenced public comments from Actavis's CEO indicating that the company was trying to "put up barriers or obstacles" to generic competition and that the goal was to "make a [patent] cliff disappear."

The injunction required, among other things, that Actavis continue to make Namenda IR available until 30 days after July 11, 2015 (the date scheduled for generic entry) on the same terms and conditions applicable since July 21, 2013 and that Actavis inform health care providers, pharmacists, patients, caregivers, and health plans of the injunction and the continued availability of Namenda IR.

The Second Circuit's Decision

The Second Circuit granted Actavis's request for an expedited appeal, but affirmed the district court's decision and injunction.

The Court acknowledged that product innovation generally benefits consumers, but found that Actavis's product hop was both anticompetitive and "exclusionary." Specifically, the court found that Actavis crossed the line from permissible persuasion (essentially, the "soft switch") to impermissible coercion (the "hard switch"). It further found that withdrawing Namenda IR from the market, thereby converting 80-100% of patients to XR with little likelihood of them switching back to IR once a generic version was available, would substantially reduce competition. Finally, the court found that Actavis's purportedly procompetitive justifications for withdrawing IR from the market (including that launching a new product advances competition by adding an improved product to the market and paving the way for further innovation) were "pretextual," and that the record is "replete with evidence" showing that Actavis's intent was to erect obstacles to generic competition.

The court summarized its conclusion as follows: "In sum, we conclude that the combination of withdrawing a successful drug [IR] from the market and introducing a reformulated version of that drug [XR], which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act."

The court affirmed the preliminary injunction requiring Actavis to continue making Namenda IR available, without raising the price from what it charged since July 21, 2013 or restricting access to the product, until a month after generic entry. It concluded that the State had established a likelihood of success on the

merits (i.e. Actavis's monopolization or attempted monopolization), that the potential harm caused by withdrawing IR from the market was "irreparable," and that an injunction was in the public interest.

Key Takeaways

Although each case turns on its specific facts, the Court's decision may embolden future challenges to "product hopping." There are, however, lower court decisions reaching differing conclusions on these issues, and there likely will be other appellate decisions down the road. This is an area that will continue to be monitored closely by pharmaceutical companies and their counsel.

There are several specific takeaways from the Court's opinion:

- The court did not expressly draw the line between permissible and impermissible product hopping, but its language and reasoning strongly suggests that conduct along the lines of a "soft switch" (that is, keeping both products on the market and aggressively persuading patients to switch, without coercion) should be permitted. As such, the decision may provide a roadmap for companies – within and without the pharmaceutical industry – considering strategies for redesigning or replacing a product upon which others in the market may rely.
- Antitrust law typically does not require a company to assist its competitors. In its opinion, however, the Second Circuit adopted the district court's conclusion that the law "**requires [Defendants] to allow generic competitors a fair opportunity to compete** using state substitution laws" (emphasis added). It remains to be seen how that language may be applied in other pharmaceutical product hopping cases, and whether and how it may be applied outside the heavily regulated context of the pharmaceutical industry.
- Prior cases had indicated that the legality of product hopping may turn in part on whether the new product is a genuine improvement over the old product. The Second Circuit concluded, however, that whether XR is "superior" to IR was "not significant," given the existence of coercion and the evidence that Actavis had acted with the intent to restrain generic competition.
- Finally, the injunction imposed on Actavis is extraordinary. Not only does the Court mandate that the company continue selling a superseded product, but it also dictates that there can be no change in the terms upon which the product must be sold. It remains to be seen whether similar relief will be sought and obtained in other cases, or whether they are a function of the specific facts involved in this case.

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