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Five Takeaways from the Second Circuit's *Namenda* Decision

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The Second Circuit's recent decision in *New York v. Actavis*, a case concerning the Alzheimer's Disease treatment Namenda, grabbed headlines as the first appellate decision to uphold an injunction barring a branded pharmaceutical manufacturer from pulling a patented drug from the market. Now that the dust has settled after the ruling, it is time to assess how the decision could impact antitrust law inside and outside of the pharmaceutical industry.

Case history

Actavis manufactured a twice-daily drug known as Namenda IR ("IR"). It later released a once-daily version of the drug, Namenda XR ("XR"). Before IR's patent rights expired—which would have opened up competition to generic IR—Actavis pulled IR from the market. This move meant that a generic IR would be non-equivalent to XR, the only marketed product, effectively circumventing state generic-substitution laws and impeding patients' access to generics entirely. Patent protection for XR prevents generic XR entry until 2029.

The State of New York's lawsuit alleged that Actavis pulled IR to force Alzheimer's patients to switch to XR. In doing so, Actavis effectively prevented generic drug manufacturers from disrupting the monopoly Actavis enjoys over Namenda patients' prescriptions. The state alleged that this action violated Sherman Act§ § 1 and 2 of the Sherman Act.

The district court issued a preliminary injunction against Actavis. The court based its injunction on the state's likelihood of success in showing an antitrust violation. The court also relied upon the state's strong showing of irreparable harm to competition and consumers in the absence of the preliminary injunction.

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The United States Court of Appeals for the Second Circuit affirmed those findings on appeal.

Actavis posed two main antitrust arguments in its defense. First, Actavis contended that product hopping—releasing successive products to perpetuate patent exclusivity—is not anticompetitive or exclusionary under the Sherman Act. It essentially advocated for a bright-line rule that product switching is never anticompetitive when the ''new'' product is superior to the ''old'' one. Second, it argued that the patent rights for Namenda foreclose the possibility of antitrust liability.

The court found that the timing of the removal of IR and the release of XR, taken together, did constitute anticompetitive behavior in violation of Sherman ActSection 2. The combination of efforts coerced physicians to switch their patients to XR rather than persuading them to do so by convincing them that XR was a sufficient product improvement to justify its premium price over generic IR. In short, these concerted actions deprived consumers of a choice between IR and XR versions of the drug based only on superior qualities. The court was persuaded by evidence that, in the absence of the ''hard switch'' caused by withdrawing IR, physicians would voluntarily switch only one-third of patients to the new treatment. The court concluded that superiority of XR, standing alone, could not support the argument that the product hop was not anticompetitive.

Relying on the Supreme Court's decision in *F.T.C. v. Actavis*, the court rejected Actavis's defense based on patent rights, holding that patent rights are not a license to violate antitrust laws. The court found that introducing XR in combination with withdrawing IR allowed it to exclude generic competition in ways that its patents would not have allowed.

The court upheld the preliminary injunction, based on its finding that the actions of Actavis, if not halted, would result in two types of damage. First, the actions would harm market competition. Second, they would also incur economic harm to drug consumers.

It is unclear how much of an improvement XR represents over IR. One the one hand, extending release could lead to substantial improvements in patient compliance and could improve patients' quality of life. On the other hand, the differences between IR and XR may be of little actual consequence to Alzheimer's sufferers—after all, each formulation is an effective means of treating the same disease. Those changes are enough, however, to get around the requirements of state substitution laws – laws that cause pharmacists to substitute lower-cost therapeutically-equivalent generic versions of a prescription written for a brand name drug. Generic drug makers rely heavily on those laws to maintain their competitive foothold in pharmaceutical markets.

If the court were to allow Actavis' actions to stand, the generic equivalents of IR would find themselves frozen out of today's market. And because of patent protection, generic drug manufacturers would not be eligible to enter the market with XR equivalents until 2029. The court found that this loss of competition represented irreparable harm to generic drug manufacturers, and also roughly $300 million more in costs to payors.

Five Takeaways

The Supreme Court has long held that even a monopolist retains the ability to alter its products and choose who it will and will not do business with. The Second Circuit arguably veered away from this general rule, and in doing so may carry some lessons for pharmaceutical manufacturers, payors, and consumers, and potentially antitrust practitioners in other sectors.

- **''Product Hopping'' is a viable theory of harm for generics and purchasers of prescription medicines.** The district court and the Second Circuit confirmed that, under the right circumstances, a branded pharmaceutical manufacturer may violate antitrust laws by discontinuing a product near the time that generic competition is to enter the market for the purpose of evading competition. In the right circumstances, this may open up opportunities for generic manufacturers to challenge ''product hops''—potentially with a preliminary injunction—to protect their ability to come to market. If a branded manufacturer is able to evade generic competition through product hopping, third-party payers and other purchasers of the treatment at issue—in addition to the excluded generics—may have damages claims against the manufacturer.

- **Intellectual property rights alone do not immunize a holder from antitrust liability.** Courts and commentators now generally accept the view that the antitrust laws and patent laws express complementary policies aimed at fostering competition and innovation. It should not be surprising that the court rejected the defendants' argument that the patent laws immunized them from liability because patent rights permitted exclusivity for XR. According to the Second Circuit, patent rights are not a license to expand the scope of those rights through anticompetitive conduct.

- **In the right circumstances, courts may require pharmaceutical manufacturers to continue making treatments available against their wishes.** The district court found that Actavis engaged in its product-hopping strategy for the purpose of inhibiting competition and was unpersuaded by the alleged procompetitive justifications for the switch. On this record, the court was willing to impose a remedy—keeping IR on the market—that on other facts might fly in the face of a competitor's general right to decide with whom to deal and what products to market.

- **Unilateral duties to deal may be found in other industries.** The Hatch-Waxman Act creates a form of regulated competition that contemplates that

branded manufacturers invent treatments, patent those treatments, and allow generics to compete after those patents expire. In concluding that the defendants manipulated the system to exclude competition, the court concluded that, at least in this instance, it was reasonable to impose a duty on defendants to keep products on the market. This logic may be applied to other industries where laws or regulations require or contemplate cooperation among competitors or where a dominant firm's platform is a necessity for rivals to compete in downstream markets.

- **This is not the last antitrust investigation in the pharmaceutical sector.** If one thing is certain from the debate over this case and the effect of the *F.T.C. v. Actavis* decision, it is that state and federal antitrust enforcers are paying close attention to pharmaceutical markets. Health care is an increasingly large part of our national economy and prescriptions are an important part of health care. And because prescription prices directly affect consumers' pocketbooks, enforcers are not likely to direct their attention away from competition issues in this sector in the foreseeable future.