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Pay for Delay is Sometimes Okay

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The US Court of Appeals for the Second Circuit affirmed the dismissal of a lawsuit against pharmaceutical companies accused of violating antitrust laws by using reverse payments to delay entry of a generic version of a patented drug. *CVS Pharmacy, Inc. v. Forest Labs. Inc.*, Case Nos. 23-410; -420; -423 (2d Cir. May 13, 2024) (**Jacobs**, Sack, Nardini, JJ.)

This case involves a drug called Bystolic, which is a beta blocker designed to treat high blood pressure. Numerous purchasers of Bystolic and its generic versions brought state and federal antitrust claims against Forest Labs. and the generic manufacturers. The purchasers alleged that Forest Labs. unlawfully paid off the generic manufacturers to delay the market entry of their products and prolong Forest Labs.' ability to reap monopoly profits. The purchasers claim that Forest Labs. covered up these payments by pretextually compensating the generics for goods and services that Forest Labs. did not truly need. The purchasers claim that without such "side deals," generic versions of Bystolic would have entered the market earlier – whether by the generic manufacturers prevailing in the infringement litigation, entering at risk (*i.e.*, with litigation ongoing) or agreeing to a settlement allowing for earlier market entry.

The payments made by Forest Labs. are known as "reverse payments" because, unlike a typical settlement payment, the patent holder pays the alleged patent infringer even though they have no claim for damages. In 2013, the Supreme Court explained in *FTC v. Actavis* that such payments should be evaluated pursuant to antitrust law's rule of reason, under which courts balance anticompetitive effects against procompetitive benefits. The Supreme Court explained that while reverse payments may look dubious, they are not automatically unlawful. Instead, these payments may "sometimes" violate the antitrust laws, but only if they are both "large" and "unjustified." According to the Supreme Court, whether a reverse payment passes antitrust muster "depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification," including fair value for goods and services exchanged as part of a *bona fide* commercial relationship.

Forest Labs. and the generic manufacturers moved to dismiss the purchasers' claims for failure to state a claim. The district court granted the motion, concluding that the purchasers' allegations did not plausibly show an antitrust violation under *Actavis*. The purchasers' appealed.

The Second Circuit affirmed the dismissal. Analyzing *Actavis*, the Court explained that reverse

payments are subject to the rule-of-reason analysis and the relevant inquiry involves determining why the payment was made. The Court noted that the payments must be analyzed against a backdrop of the strong public policy favoring settlement of disputes, meaning that the payments violate antitrust law only if they are both large and unjustified or unexplainable. In turn, whether a reverse payment is "unjustified" depends on whether it "reflects traditional settlement considerations," including "fair value" for products or services provided by the generic manufacturer pursuant to a legitimate commercial relationship entered into at arm's length with the brand manufacturer.

The Second Circuit individually analyzed the commercial transactions between Forest Labs. and the generic manufacturers and found there were no allegations plausibly showing that any of the transactions reflected anything other than "fair value" for goods and services obtained as a result of good faith business dealings. Among other things, the Court found that:

- The terms of the agreements reflect bona fide business considerations.
- The sizes of payments were not sufficiently contextualized or compared to enable an inference that the payments are plausibly unjustified.
- Forest Labs.' need for alternative supplies of active pharmaceutical ingredients or finished pharmaceutical products was consistent with what Forest Labs. disclosed previously to investors.
- A lack of public disclosures about business plans or investments does not necessarily bear upon whether those ventures are truly legitimate or genuine.
- It is sensible for counterparties to enter into condensed term sheets with the expectation of subsequently negotiating more detailed, definitive agreements.
- Payments for developmental or commercial milestones or research-and-development expenses bespeak rational commercial incentives.
- Provisions in the transactions that are designed to ensure price competition did not fit with Forest Labs.' alleged intention to funnel secret overpayments to the generic manufacturers.
- The agreements' provisions trump allegations of unsupported speculation about nefarious motives.

The Second Circuit concluded that none of the reverse payments were unlawful and therefore affirmed the district court's dismissal.

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