

Recent Rulings Highlight Risk to Japanese Drugmakers in Settling Pharmaceutical Litigations

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In *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), the US Supreme Court addressed the legality of “reverse payment” settlements in pharmaceutical patent litigation. A reverse payment occurs when a brand-name drug manufacturer pays a generic drug manufacturer to settle patent litigation and delay the generic’s market entry, essentially paying the potential competitor not to compete. Since *Actavis*, pharmaceutical companies’ settlements have become more complex, often finding ways to provide value to generic companies.

On May 13, 2024, the Second Circuit Court of Appeals affirmed a trial court’s dismissal of the antitrust claims in a reverse payment case. *Watson Labs., Inc. et al. v. Forest Labs., Inc. et al.*, 101 F. 4th 223 (2d Cir. 2024). Forest Laboratories, the brand manufacturer of Bystolic settled patent litigation with seven generic nebivolol manufacturers. As part of the settlements, Forest agreed to pay the defendants their saved legal expenses (up to \$2 million) and granted each a non-exclusive royalty-free license to market generic Nebivolol. Alongside these agreements, Forest entered six additional commercial transactions with defendants, including supply agreements for active pharmaceutical ingredients, as well as development agreements for new products. The court held that plaintiffs failed to sufficiently plead that the commercial transactions were unjustified or unexplained reverse payments. The court found no plausible allegations showing that any of the transactions reflected anything other than fair value for goods and services obtained through good-faith business dealings.

Japanese drugmakers have likewise been forced to defend against reverse payment suits. In September 2025, CVS Pharmacy filed a complaint accusing Takeda Pharmaceutical and TWi Pharmaceuticals of entering into an illegal reverse payment agreement in the US market for Dexilant by agreeing that Takeda would pay TWi \$9.5 million in cash and appoint TWi as its authorized generic, ensuring that no other generic could compete against TWi. *CVS Pharma., Inc. v. Takeda Pharm. Co. et al.*, No. 3:25-cv-07646 (N.D. Cal. Sept. 9, 2025). In exchange, TWi agreed to stay off the market until January 2022, approximately 18 months after the patent that was blocking TWi from entering the market. Takeda and TWi are seeking to dismiss this lawsuit. The Dexilant antitrust

case was filed one year after Takeda settled an earlier reverse payment lawsuit, in which Takeda was accused of granting Par Pharmaceutical the right to operate as Takeda's "authorized generic" distributor for its gout drug Colcrys in exchange for a later entry date and with high royalties paid to Takeda. Plaintiffs contended this conspiracy lasted for over 4 years, during which drug prices were 1,200% higher than they would have been with generic competition. (A. Liu, Fierce Pharma, Takeda settles antitrust lawsuit over gout drug Colcrys after trial kicked off, Sept. 21, 2023, Takeda settles antitrust lawsuit over gout drug Colcrys after trial kicked off | Fierce Pharma.)

The takeaway is that plaintiff lawyers in the United States are aggressively attacking drug settlements that provide value to generic companies, such as the right to serve as the brand's "authorized generic" distributor or commercial side deals, in exchange for later entry of generic competition. Japanese drug manufacturers should carefully review these clauses or side deals when settling with generics and be prepared to defend the fair value of these provisions if a complaint is filed.

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