

# Lessons From Landmark Jury Verdict in *Amitiza* Reverse Payment Antitrust Case

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On May 18, a federal jury in Massachusetts returned a $885 million verdict against Takeda Pharmaceuticals, finding that Takeda entered into an anticompetitive patent settlement that compensated a generic manufacturer to delay launching a generic version of its IBS drug, Amitiza® (lubiprostone). *In re Amitiza Antitrust Litigation*, No. 1:21-cv-11057 (D. Mass.). The suit consolidated complaints filed by a class of direct purchasers (wholesalers), five individual retailers (pharmacy chains), and a class of indirect purchasers (end payors). The outcome is significant because it is the first jury trial win for private antitrust plaintiffs in a suit challenging a patent settlement reverse payment. Previous suits have either settled or gone to trial and lost. For Brand and Generic pharmaceutical manufacturers, this may lead to further scrutiny of past settlements.

## The *Actavis* Rule-of-Reason Framework At Work

The Supreme Court in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), adopted the rule-of-reason legal framework for evaluating whether a reverse payment made in the context of a Hatch-Waxman settlement violates the antitrust laws. The Court explained that a reverse payment may violate the antitrust laws where it is "large and unjustified" — i.e., where it exceeds what can be explained by legitimate settlement considerations such as avoided litigation costs or fair value for services.

## The *Amitiza* Patent Settlement

In 2012, Par Pharmaceutical submitted an Abbreviated New Drug Application seeking approval to manufacture and sell a generic version of Amitiza. Par submitted Paragraph IV certifications to a number of patents covering Amitiza. Takeda sued Par for patent infringement in 2013. The parties settled the patent litigation in 2014. Under the terms of the settlement, Par agreed not to launch a generic version of Amitiza until January 1, 2021.

Takeda explicitly reserved the right to then launch its own authorized generic to compete with Par. But the antitrust plaintiffs contended that an implicit "no-AG" agreement was embedded in the settlement's economic structure, which, according to the plaintiffs, constituted a reverse payment.

Upon launch of its generic, Par would pay a 50 percent royalty on its gross profits, followed by a declining royalty if additional generic competitors entered the market alongside Par: the royalty would drop from 50 percent to 15 percent with one additional generic, and to zero with two or more.

The plaintiffs argued that the initial 50/50 profit split, followed by a declining royalty, created a powerful economic incentive for Takeda not to launch its own AG to compete with Par. If Takeda had launched a competing AG, it would have driven down generic prices, reduced Par's unit sales, and triggered lower royalty payments, making everyone in the arrangement worse off. In effect, the settlement allegedly functioned as a *de facto* “no-AG agreement” — in exchange for delaying its entry and abandoning its patent challenge, Par would be guaranteed a monopoly in the generic market when it does enter.

Whether Takeda had implicitly agreed not to launch its own authorized generic was a key contested issue at trial.

## The Verdict At a Glance

The nine-member jury found that Takeda possessed substantial market power within the relevant market and that the settlement agreement contained a large, unjustified reverse payment based on the 50/50 profit split and the declining royalty provision. The jury likewise believed that Takeda implicitly agreed not to launch its own authorized generic. The jury also determined that, but for the anticompetitive settlement agreement, a generic version of Amitiza would have come to market earlier. Specifically, the jury determined that the generic would have launched in April 2018, which was one of the scenarios modeled by plaintiffs' experts referenced in the court's prior opinion resolving motions for summary judgment.

The jury concluded that this anticompetitive arrangement resulted in overcharges of approximately $475 million to the direct purchaser class, $347 million to the individual retailer plaintiffs, and $63 million to the end payor class. The damages awarded to the direct purchasers (wholesaler class and individual retailers) for claims brought under federal antitrust law are subject to automatic trebling, potentially increasing the total liability to approximately $2.5 billion.

Takeda has announced its intention to pursue post-trial motions and an appeal.

## Key Takeaways

**The rule of reason has teeth in pay-for-delay cases**. The biggest takeaway from Amitiza is that it provides a successful blueprint for taking *Actavis*-style pay-for-delay the distance—through class certification, past summary judgment, and all the way to a jury verdict for plaintiffs. Though an appeal may still be ahead, this case has gone further than any other private pay-for-delay case before it. The

case also demonstrates that juries can engage with complex pharmaceutical antitrust claims and find liability under the *Actavis* rule of reason framework.

**Hatch-Waxman settlements remain lawful. But the structure matters**. Parties to Hatch-Waxman litigation may lawfully settle by agreeing to a generic launch date prior to patent expiration, based on a genuine assessment of the strengths and weaknesses of the patent positions at issue. However, where the economics of the settlement suggest that a generic manufacturer has accepted a "large and unjustified" payment in exchange for delayed entry, the arrangement carries antitrust risk.

**Counsel must scrutinize reverse payments in all their forms**. Implicit economic arrangements — such as royalty structures that disincentivize competitive entry—can constitute actionable reverse payments if they are large, unjustified, and anticompetitive. Companies negotiating Hatch-Waxman settlements should carefully evaluate any aspect of a proposed agreement that could be characterized as transferring value from the patent holder to the generic challenger, and should be prepared to justify any such transfer as reflecting legitimate, non-exclusionary value, including, if necessary, to a jury.

## CONTACTS

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