

$885M IBS Drug Verdict Tests Pay-For-Delay Limits

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A federal jury in Massachusetts returned a $885 million verdict against Takeda Pharmaceuticals Co., finding that Takeda entered into an anticompetitive patent settlement that compensated a generic manufacturer to delay launching a generic version of its irritable bowel syndrome drug Amitiza, or lubiprostone.

The May 18 decision in In *re: Amitiza Antitrust Litigation* in the U.S. District Court for the District of Massachusetts consolidated complaints filed by: a class of direct purchasers, consisting of wholesalers; five individual retailers, consisting of pharmacy chains; and a class of indirect purchasers, consisting of end payors.

The practice of a branded drug manufacturer suing a generic challenger for patent infringement and then entering into a settlement containing a large payment to the generic challenger in exchange for delaying its launch is known as pay for delay.

The outcome in *Amitiza* is significant because it is the first jury trial win for private antitrust plaintiffs in a suit challenging a patent settlement reverse payment since the U.S. Supreme Court's 2013 decision in *Federal Trade Commission v. Actavis Inc*. Previous antitrust suits challenging such pay-for-delay arrangements have either settled or gone to trial and lost.

For brand and generic pharmaceutical manufacturers, the *Amitiza* decision may lead to further scrutiny of past settlements.

Rule-of-Reason Framework at Work

The *FTC v. Actavis* decision adopted the rule-of-reason legal framework for evaluating whether a reverse payment made in the context of a settlement under the Hatch-Waxman Act violates the antitrust laws. The court held 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 court in *Actavis* explained that "it is normally not necessary to litigate patent validity to answer the antitrust question" because "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness." Accordingly, establishing an antitrust violation under *Actavis* requires proving that the branded manufacturer possesses market power and that the patent settlement contains a large and unjustified payment to a generic challenger.

But private plaintiffs additionally must prove that they suffered antitrust injury and must quantify their damages based on the amount and period over which they claim to have been overcharged. This requires establishing the date on which generic entry would have occurred in a world absent the reverse payment.

The theory could be that the generic would have prevailed in the patent litigation and launched earlier, or alternatively that the parties would have settled the patent litigation on terms that did not include the reverse payment and set an earlier launch date. Private pay-for-delay suits are thus far more complex than the basic liability test articulated in *Actavis*.

Indeed, the plaintiffs in *Amitiza* offered extensive evidence about the but-for world, including expert testimony regarding patent validity. The Supreme Court suggested the FTC could avoid the problem of litigating a patent case inside an antitrust case, but it said nothing about private plaintiffs.[1]

The Amitiza Patent Settlement

In 2012, Par Pharmaceutical Co. Inc. 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 Jan. 1, 2021.

A key issue was whether Takeda in turn agreed not to launch a generic lubiprostone in competition with Par's generic. A promise by a branded company not to launch its own generic, known as an authorized generic, in competition with the generic challenger is referred to as a "no-AG" commitment. Because competition from a second generic can cut into sales and drive down the price of the medication, reducing the generic challenger's profits, a no-AG commitment can potentially be a vehicle to transfer value from the branded company to the generic challenger.

Takeda explicitly reserved the right to 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% 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% to 15%, 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 authorized generic to compete with Par. If Takeda had launched a competing authorized generic, 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 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, plus the additional elements private plaintiffs must satisfy to recover damages.

Hatch-Waxman settlements remain lawful.

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, nonexclusionary value, including, if necessary, to a jury.

Conclusion

In structuring settlements in pharmaceutical patent infringement suits, counsel should evaluate not only express terms, but also embedded economic incentives that may suggest additional implicit promises to take or refrain from actions that effectively transfer value. Pharmaceutical patent settlements are complex agreements, with consideration taking varied forms and flowing in both directions.

To manage antitrust risk, counsel must account for all types of payments that could be considered large and unjustified, including those that operate beyond the corners of the settlement agreement itself, such as an implied no-AG promise.

Counsel advising antitrust litigants in pay-for-delay suits will certainly factor this watershed outcome into their trial strategies and settlement considerations.

Institutional drug purchasers wholesalers, pharmacies and payors are sophisticated plaintiffs who are now armed with a road map from a successful antitrust challenge to a pay-for-delay patent settlement.

The result in *Amitiza* demonstrates that — where the evidence is in place — courts and juries can rise to the task of navigating the complex Hatch-Waxman regulatory backdrop, alternative but-for worlds, and econometric damages models to find liability and award significant damages.

"$885M IBS Drug Verdict Tests Pay-For-Delay Limits," *Law360*, June 30, 2026

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1 Even the FTC might not avoid this problem if pursuing equitable monetary relief as opposed to purely injunctive relief. At present, the Supreme Court has significantly curtailed the FTC's ability to seek monetary relief. *AMG Capital Management, LLC v. FTC*, 141 S. Ct. 1341 (2021). In the event that authority is legislatively restored, it remains to be seen whether the FTC's burden differs from that of private plaintiffs seeking damages. Prior pay-for-delay cases in which the FTC pursued monetary relief ended in settlements or consent orders.

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