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# A look at the post-*Actavis* landscape

**We now look at where two years of antitrust litigation post-*Actavis* have left litigants and courts as they work through the implications of the case.**

By William F. Cavanaugh, Jr., David Kleban

Two years ago, the Supreme Court issued its decision in *FTC v. Actavis, Inc.*, holding that patent litigation settlement agreements in which the patentee pays the defendant to settle the patent infringement case the patentee brought — often referred to as a "reverse settlements" — can create potential antitrust liability. In dissent, Chief Justice Roberts offered "[g]ood luck to the district courts" that have to apply the *Actavis* doctrine and its "five sets of considerations."

We now look at where two years of antitrust litigation post-*Actavis* have left litigants and courts as they work through the implications of the case.

## Non-cash Payments

One noteworthy battlefront has concerned whether settlements in which the patentee does not give cash, but allegedly makes some other promise of value to the generic manufacturer — for instance, agreeing not to introduce its own "authorized generic" for some amount of time — are subject to scrutiny under *Actavis*.

That question led to different answers, with federal judges in New Jersey and Rhode Island finding that the *Actavis* doctrine applies only to settlements involving large cash payments. A greater number of courts, in Pennsylvania, Massachusetts, and New Jersey, however, held that non-monetary consideration can indeed trigger antitrust liability. The first appellate court to address the issue recently sided with the latter group. In June, the Court of Appeals for the 3rd Circuit held in *King Drug Co. of Florence, Inc. v. SmithKlineBeecham Corp.* that the "thrust of the Court's reasoning [in *Actavis*] is not that it is problematic that money is used to effect an end to the patent challenge, but rather that the patentee leverages some part of its patent power . . . to cause anticompetitive harm."

The 1st Circuit is set to address the same question in *American Sales Co. v. Warner Chilcott Co., LLC*, an appeal from a dismissal in the District of Rhode Island where the court held that patent settlements must involve cash to potentially run afoul of the antitrust laws. The FTC has submitted an amicus brief urging reversal.

Although the 3rd Circuit's ruling will be influential, it is not the end of the story. It settles (in that jurisdiction) the question of whether consideration other than cash might fall within the *Actavis* holding, but does not help courts and juries determine whether, in any given case, such consideration is "large" and "unexplained" or "unjustified." Indeed, though Judge Sheridan of the District of New Jersey agreed with the *In re Lipitor* plaintiffs even before *King Drug* that non-cash settlements can trigger *Actavis*, he nevertheless dismissed their claims with prejudice. He held that *Twombly* and *Iqbal* require a reverse-payment plaintiff to include in the complaint a plausible methodology by which to value the non-cash consideration, which plaintiffs there had not done. His decision is being appealed to the 3rd Circuit.

Moreover, even plaintiffs who are able to carry their pleading burden in non-cash reverse payment cases will face challenges as the litigation proceeds and plaintiffs no longer benefit from the permissive standards governing motions to dismiss. The already elusive nature of the *Actavis* standard is magnified where the "payment" being evaluated is not easily valued, since proportionality is at the heart of the analysis described by the Supreme Court. Indeed, this was one of the reasons Judge Smith of the District of Rhode Island, in the decision that is on appeal to the First Circuit, held that a transfer of cash is a necessary element of these claims.

## Private Litigation

There are other indications that, despite the Supreme Court's green light for litigation over reverse payments, it is not clear that these suits will represent a gold rush for plaintiffs.

The first significant case to go to trial, *In re Nexium*, resulted in a verdict of no liability, despite the District of Massachusetts jury's finding that the generic manufacturer received "a large and unjustified payment" from patentee AstraZeneca. The jury determined there was insufficient evidence that the generic manufacturer would have been able to enter the market any earlier had there been no such settlement. The plaintiffs have moved for a new trial, arguing that the court bungled the jury instructions on causation and relevant evidentiary rulings. But regardless of the outcome there, similar causation issues may hamper future plaintiffs.

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## Government Enforcement

The challenges outlined above have not deterred the FTC. Emboldened by *Actavis*, the Commission continues to be an aggressive opponent of arrangements in which it perceives the generic has received any benefit beyond a negotiated date of entry. It made headlines when it announced in late May that it had reached a settlement with Cephalon under which the drug maker would pay disgorgement of over $1 billion in connection with alleged reverse payments.

More recently, though, the agency suffered a setback in its reverse payment suit against AbbVie and other defendants where it alleges that the patentees made an illicit reverse payment to the generic manufacturer to settle claims concerning testosterone drug AndroGel. The FTC claims that the patentees initiated "sham" litigation against generic manufacturer Teva, then settled the case by (1) permitting Teva to market a generic six years before the expiration of the relevant patent and (2) agreeing to license to Teva an authorized generic version of the cholesterol drug Tricor (it is alleged that Teva was having trouble obtaining FDA approval for its own generic version of Tricor).

The District Court for the Eastern District of Pennsylvania found that these allegations failed to state an antitrust claim. Both aspects of the agreement, reasoned Judge Bartle, *facilitate* competition by allowing a new entrant (a generic version of Tricor) and thus "are good for the consumer." This decision came before the *King Drug* ruling, however, and the FTC now seeks reconsideration under the "framework" for analyzing non-cash settlements created by the 3rd Circuit in that case.

## Conclusion

The past two years have not led to a settled body of "reverse payment" case law; they have merely begun, as Justice Roberts predicted, the lower courts' long and rocky road to give shape to *Actavis*.

## About the Authors

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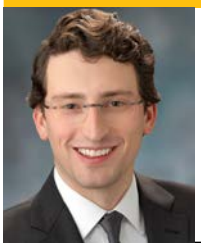

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