Three Years After *FTC v. Actavis*: The Evolving Landscape Surrounding Reverse Settlements
By James Miller and Vahe Mesropyan

In the 2013 landmark decision, *Federal Trade Commission v. Actavis*, 133 S. Ct. 2223 (2013), the United States Supreme Court held that reverse settlements may be subject to antitrust scrutiny. In short, a reverse settlement (or a pay-for-delay settlement) occurs when a patent holder brings a patent infringement suit, but then settles the case by paying the alleged patent infringer to stay out of the market. Following the precedent set by *Actavis*, subsequent decisions have extended the scope of settlements that constitute reverse payments in violation of antitrust laws. This article will track how *Actavis* has extended to non-cash settlements, and has also been interpreted to apply to state antitrust laws.

Background

In *Actavis*, the Federal Trade Commission ("FTC") sued Solvay Pharmaceuticals Inc.—a drug manufacturer—and several generic manufacturers, which had each sought to introduce a generic version of a drug manufactured by Solvay under the Abbreviated New Drug Application process as provided by the Hatch-Waxman Act. The FTC alleged that Solvay brought a patent infringement suit against the generic manufacturers and ultimately paid large sums of money to settle the case in exchange for the generic manufacturers' agreement to stay out of the market for several years. The FTC argued that the settlement was anticompetitive and designed to keep competitors out of the market, and not merely an enforcement of Solvay's patent rights. The district court dismissed the challenge in favor of the drug manufacturers, and the Eleventh Circuit affirmed the dismissal. The Supreme Court, however, held that the lower court erred in dismissing the FTC's challenge of the settlement, observing that such reverse settlements could be anticompetitive and should therefore be analyzed under the rule of reason if large and unjustified.

Prior to *Actavis*, courts generally did not invalidate reverse settlements, reasoning that they fell within the scope of the exclusionary potential of the patent. Howev-

-Continued on page 8-

Shifting Expert Fees In Intellectual Property Litigation
By Anne Brody and Natalie Dygert

Current case law, along with current and pending legislation, relaxes the standard for courts to award attorney fees in intellectual property cases. Despite this recent trend, the second highest cost in intellectual property litigation, expert witness fees, remains overlooked. The current fee-shifting statutes in all areas of IP do not explicitly mention "expert witness fees." Because Supreme Court and Federal Circuit case law require an explicit statutory authority to shift expert fees, courts are bound to continue to treat these fees under the original "American Rule," where each side pays their own fees. Expert fees, along with attorney fees, contribute to the exorbitant litigation costs that can force defendants to settle even frivolous lawsuits. This article proposes that as expert fees become increasingly costly in complex IP litigation, Congress should amend current IP legislation and grant explicit statutory authority for courts to shift expert fees under the same standard as attorney fees.

<u>"Attorney Fees" in Section 285 of the Patent Act Do Not Include Expert Fees</u>

Section 285 of the Patent Act states in whole that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (1952). Prior to 1991, the Federal Circuit held that "attorney fees" of Section 285 included expert fees, thus allowing expert fees to be shifted along with attorney fees. *Mathis v. Spears*, 857 F.2d 749, 759 (Fed. Cir. 1988) ("[U]nder Section 285, which authorizes an award of fees only upon a finding of 'exceptional case,' a district court may, in the exercise of its discretion . . . include an award of reasonable expert witness fees in excess of the $30/day attendance fee specified in 28 U.S.C. § 1821."). But in 1991, the Supreme Court in *West Virginia University Hospital, Inc. v. Casey* held that the term "attorney fees" in a statute does not provide courts with the explicit authority to award expert fees. 499 U.S. 83, 102 (1991). In *West Virginia*, the Supreme Court addressed whether a statute that states in relevant

-Continued on page 10-

-ADA Lawsuits: Continued from page 7-

rate with their website designers and vendors with experience in website accessibility regarding other available options to promote accessibility, as well as the risks and benefits inherent in such alternatives.

♦*Michael J. Chilleen is Special Counsel in Sheppard Mullin's Orange County office. He specializes in defending disability access class action claims under the ADA and state law. He can be reached at MChilleen@SheppardMullin.com.*

-Reverse Settlements: Continued from page 3-

er, the *Actavis* Court set precedent when it concluded that, because such settlements prevent the adjudication of the patent's actual validity and scope, they should be scrutinized under the antitrust laws' traditional "rule of reason." *Actavis*, 133 S. Ct. at 2237. The Court provided five reasons why the settlement in question could have been anticompetitive and held cash settlements that were "large and unjustified" were potentially anticompetitive. However, the Court stopped short of providing a bright-line rule of reason analysis for lower courts to apply. Since *Actavis*, district courts and state courts have struggled with the broad implications of the decision, which is no surprise. As Chief Justice John Roberts stated in the dissent, "[g]ood luck to the district courts" that must analyze reverse settlements based on the Court's discussion in *Actavis*.

Post-*Actavis* Decisions Have Extended Antitrust Scrutiny to Non-Cash Settlements

In earlier years, pay-for-delay cases typically challenged settlements involving large cash payments by the branded manufacturer to a would-be generic manufacturer. Subsequent to *Actavis*, challenges to settlements under pay-for-delay theories have expanded to include non-cash consideration provided in exchange for the generic challenger's delayed entry to the market.

The Third Circuit was the first court of appeals to issue a decision post-*Actavis*. It held that non-cash settlements could constitute a "payment" under *Actavis*, and are thereby subject to a rule of reason analysis. *King Drug of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403-04 (3d Cir. 2015) (holding that *Actavis* condemns payments that "negatively impact consumer welfare by preventing the risk of competition"). In *King Drug*, in exchange for the generic manufacturer's delayed entry, the branded manufacturer granted the generic early entry shortly before expiration of the patent and agreed not to launch any authorized generics during that period of exclusivity. The court found that the no authorized generic ("no-AG") agreement in question could constitute a payment under *Actavis*, stating "[t]he no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic – plus potentially more, in form of higher prices, because there will now be generic monopoly instead of a duopoly." *Id.* at 405.

For the most part, district courts have agreed that non-cash settlements, such as no-AG agreements, are within the scope of *Actavis*, and in February 2016, the First Circuit became the second appellate court to make such a finding. *See In re Loestrin*, 814 F.3d 538, 549-50 (rejecting the lower court's holding that only reverse settlements involving cash fall within the scope of *Actavis* and citing eight decisions from district courts across the country holding the same).

However, the presence of a no-AG agreement may not itself conclusively compel a finding of anticompetitive harm. The district court in *In re Wellbutrin*, 133 F. Supp. 3d 734, 754 (E.D. Penn. 2015), agreed with the defendants in that matter and granted summary judgment, finding that the settlement at issue—which included a no-AG provision—did not rise to the level of an antitrust violation. That decision is likely attributable to the overall reasonableness of the analyzed settlement, which involved, among other procompetitive provisions: (1) permitting patent litigation brought by one of the generic manufacturers to continue, which—if successful—would result in immediate market entry for all generics; (2) the patent-holder granting two sublicenses to produce a version of its patented drug, which is good for consumers; and (3) relatively early generic entry, even if the underlying patent was held to be valid. *See id.* at 746-48.

In analyzing the potential anticompetitive effects of the no-AG provision, the *Wellbutrin* court found significant the fact that no settlement agreement was ever contemplated between the parties that did not involve such a provision. *Id.* at 756-57. Consequently, the court was not convinced that "generic competition would have occurred earlier" absent the settlement. *Id.* In other words, the *Wellbutrin* court declined to give the settlement agreement terms a "quick look" and declare that the mere existence of a no-AG provision resulted in anticompetitive harm; it instead grappled with alternate hypothetical litigation scenarios in assessing whether consumers were actually harmed by the allegedly anticompetitive settlement provision. *Id.* at 756-58. Citing *Actavis*, the court explicitly refused to make a finding that reverse settlements are presumptively unlawful. *See Actavis*, 133 S. Ct. at 2234 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires

-Continued on page 9-

-Reverse Settlements: Continued from page 8-

would also bring about competition . . . to the consumer's benefit."). The court reasoned that settlement itself may entail procompetitive benefits, and therefore each challenged settlement should undergo a full rule of reason analysis. *Wellbutrin*, 133 F. Supp. 3d at 757.

Finally, the *Wellbutrin* court found significant the fact that the FTC had an opportunity to object to the settlement, but did not object. *Id.* at 749. However, the FTC filed an amicus brief with the Third Circuit on appeal specifically stating that the district court's reliance on the FTC's inaction was flawed and that the FTC supports the notion that no-AG settlements fall within the scope of *Actavis*. Subsequently, the FTC solidified its position on no-AG settlements when it challenged two no-AG settlements in March 2016. *See Federal Trade Commission v. Endo Pharmaceuticals Inc. et al.*, No. 2:16-cv-01440-PD (dated March 31, 2016).

In sum, the First and Third Circuit's decisions, as well as the FTC's decision to challenge no-AG settlements, evidence a trend towards expanding the scope of *Actavis* to include non-cash settlements. The federal courts have not yet established a test, but courts seem likely to invalidate settlements that appear "large and unjustified" on their face, and each settlement will be analyzed in a case-by-case basis. However, the manufacturers involved in *King Drug* have asked the Supreme Court to review the Third Circuit's decision and on June 6, 2016, the Supreme Court asked the United States government to weigh in on its position. Therefore, there is some indication of the Supreme Court's willingness to make a conclusive finding on the relevance of non-cash settlements in the context of reverse settlements.

Actavis Has Been Extended To Apply To State Antitrust Laws

Although there is no established test in the federal courts, there is guidance from the California Supreme Court. The California Supreme Court in *In re Cipro Cases I & II*, 61 Cal. 4th 116 (2015), held reverse payment cases could be brought under California's competition laws. The challenged settlement involved a large cash payment by the branded manufacturer to the generic manufacturer. The California Supreme Court established a four-part test necessary to establish a prima facie case of an antitrust violation. The plaintiff must establish that:

> (1) the settlement includes a limit on the generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services *other* than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement.

Id. at 151 (emphasis in original). The court further explained that "once a plaintiff has shown an agreement involving a reverse payment and delay [the first two elements], the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services" since the defendants are more likely to have this information. *Id.* at 153.

Although the test is only applicable in California, the California Supreme Court's establishment of a clear rule of reason test for analyzing reverse settlements has potential implications in federal jurisdictions. A New Jersey district court has already adopted the analytical framework established by the California Supreme Court. *See In re K-Dur Antitrust Litigation*, 2016 WL 755623, at *13 (D.N.J. Feb 25, 2016). This suggests that other federal courts might be willing to adopt the same framework.

Conclusion

Cases interpreting the Supreme Court's decision in *Actavis* demonstrate that the full scope of the decision is far from established. The cases surveyed above indicate that courts are willing to expand the applicability of *Actavis*, but are taking a case-by-case basis approach due to the lack of higher court guidance on reverse settlement analyses. The California Supreme Court's establishment—and a New Jersey district court's subsequent adoption—of a four-part test gives hope that there may soon be a bright-line approach for analyzing reverse settlements under the rule of reason. Ideally, such a test will govern both cash and non-cash reverse settlements. Until then, courts are reviewing settlements on a case-by-case basis. Companies and practitioners should closely monitor the development of the case law in this area.

♦ *James Miller is a litigation associate at Greenberg Gross LLP; Vahe Mesropyan is an associate at Crowell & Moring, where he focuses on antitrust law.*