New Jersey Law Journal
STATEWIDE LEGAL AUTHORITY SINCE 1878
An ALM Publication
AUGUST 12, 2015 NJLJ.COM

'Actavis' Decision Not Limited to Cash Payments

But questions still remain

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When the Supreme Court decided *FTC v. Actavis* two years ago, holding that reverse-payment settlements of pharmaceutical patent litigation should be subjected to the antitrust "rule of reason" inquiry, it settled the long-litigated question of what standard courts should apply in such cases. But the majority's opinion—which jettisoned presumptive analyses used by the Third Circuit and some other circuit courts of appeals in favor of a more fact-intensive analysis—did not directly address the predictable question of whether the standard would apply to both cash and *non*-cash settlements.

Since *Actavis*, several district courts have been asked to evaluate whether *Actavis* antitrust scrutiny should be applied to settlements involving an agreement by a producer of a patented, brand-name drug not to produce an "authorized generic" version of the drug following expiration of the patent in exchange for dismissal of a would-be generic manufacturer's patent invalidity or noninfringement claims ("no-AG settlement"). In the first federal appellate decision to substantively examine *Actavis*, a unanimous panel of the Court of Appeals for the Third Circuit resolved an intra-circuit split by holding that a noncash, no-AG settlement agreement may also trigger antitrust scrutiny.

The case, *King Drug Co. of Florence v. SmithKline Beecham Corp.* (No. 14-1243, decided June 26, 2015), was brought by a class of direct purchasers of GlaxoSmithKline's brand-name epilepsy drug Lamictal, as an antitrust challenge to GSK's settlement of Hatch-Waxman litigation instituted in 2002 against Teva Pharmaceuticals. In the underlying patent litigation, District Judge Bissell had found the main claim of the patent covering Lamictal's active ingredient invalid, and the parties settled their dispute before the court could rule on the validity of the patent's remaining claims. Under the terms of the settlement, Teva would be permitted to market generic chewable tablets 37 months before the expiration of the patent, and GSK agreed not to market an authorized generic version during the 180-day exclusivity period engendered to Teva as the first filer of an "abbreviated new drug application" (ANDA) following the patent's expiration. No cash would change hands, but the antitrust plaintiffs alleged that the markets for generic lamotrigine tablets and chewable tablets, respectively, were worth $2 billion and $50 million annually.

The direct purchasers' challenge to the GSK-Teva settlement was initially dismissed under the "quick look rule-of reason" standard endorsed by the Third Circuit in *In re K-Dur Litigation*. However, after *Actavis* was decided, abrogating *K-Dur*, the Lamictal case was revived and remanded to the District of New Jersey for further consideration of the defendants' motion to dismiss.

District Judge Walls, on remand, interpreted *Actavis* to require a "large and unjustified" cash payment and, finding the settlement lacking such a cash payment, dismissed the plaintiffs' complaint. *In re Lamictal Direct Purchaser Antitrust Litigation*, 18 F. Supp. 3d 560 (2014). This approach was followed in cases such as In re Loestrin 24 Fe Antitrust Litigation, 45 F. Supp. 3d 180 (D.R.I. 2014), albeit "not without significant reservations." But other district courts, including another court of the District of New Jersey, found that a noncash, no-AG settlement could have such substantial value as to trigger application of *Actavis*'s rule of reason. *In re Effexor XR Antitrust Litigation*, 2014 WL 4988410 (D.N.J. Oct. 6, 2014) (Sheridan, J.); *In re Wellbutrin XL Antitrust Litigation*, No. 08-2431, slip. op. at 4 (E.D. Pa. Jan. 17, 2014) (McLaughlin, J.) (rejecting defendants' argument that "only a large cash payment from the patentee to the generic is subject to antitrust scrutiny under *Actavis*").

On appeal of Judge Walls' dismissal of the Lamictal plaintiffs' complaint, Judge Scirica for a unanimous panel (with Judges Roth and Ambro) observed that the anticompetitive consequences of a no-AG agreement "may be as harmful as those resulting from reverse payments of cash." No-AG agreements cause anticompetitive harm, the court recognized, because they result in a generic monopoly where there would otherwise have been a generic duopoly, resulting in higher generic prices for consumers. Nor was the court swayed by the defendants' contention that the no-AG agreement was a mere exclusive license of the patent, expressly permitted under the Patent Act. Because the settlement agreement permitted GSK and Teva to produce bioequivalent products during the 180-day exclusivity period—GSK's branded product and Teva's generic one—the agreement did not constitute an exclusive license, but rather constituted a use of "valuable licensing in such a way as to induce a patent challenger's delay."

Having determined that the no-AG agreement falls within the

Actavis rule, "because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified," the Third Circuit turned to the question of whether the complaint plausibly alleged an antitrust claim under the rule of reason, and found that it did. Because it would have been rational for GSK to participate in the market for generic lamotrigine tablets, "its agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed."

Thus, the court found, the plaintiffs had adequately alleged that any allegedly precompetitive aspects of the settlement agreement, such as Teva's early entry into the generic chewables market, was outweighed by the anticompetitive harm to the much more substantial generic tablets market. Moreover, the court noted, *Actavis* does not require an antitrust plaintiff to plead that defendants could have reached another, more competitive settlement. The Third Circuit therefore remanded the case to the district court to undergo further rule-of-reason analysis.

Actavis "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation" in the context of settlements of Hatch-Waxman litigation, a task that Chief Justice Roberts noted in his dissent would prove difficult ("Good luck to the district courts") absent the presumptive frameworks that the majority decision rejected. The Third Circuit's decision in *King Drug Co.* provides strong guidance to the district courts, and persuasive authority to its sister courts of appeals (including the pending appeal of *In re Loestrin 24 Fe Antitrust Litigation*, currently before the First Circuit), that even noncash consideration such as a no-AG agreement can trigger antitrust scrutiny. But, in doing so, it decimates one of the bright lines—the existence of a "large and unjustified" cash payment from a patentee to a generic challenger—that could arguably be gleaned from *Actavis*. Now, as Hatch-Waxman litigants conjure up new settlement terms as alternatives to reverse payments, courts will be faced with determining whether other purported inducements can be said to constitute an illegal "payment" and thus fall within the scope of *Actavis*.

The Third Circuit in *King Drug Co.* noted that "parties may still find other ways to settle," such as allowing the generic entry to the market prior to patent expiration without paying the generic to stay out of the market up to that point, and that the parties' compromise on an early-entry date may simply reflect their assessment of the strength of the patent. Such an agreement promotes competition, as the FTC recently conceded regarding a settlement involving the patentee's agreement to allow the generic challenger entry into the market six years prior to expiration of the patent, but no payment, "reverse or otherwise," to the challenger. See *FTC v. AbbVie*, 2015 WL 2114380, at *6 (E.D. Pa. May 6, 2015) (Bartle, J.).

But *King Drug Co.* does not address the situation where that early entry might be accompanied by, for instance, the patentee supplying the pharmaceutical to the generic challenger at below-market prices. In *Abb-Vie*, the district court determined that such an agreement was "not a reverse payment under *Actavis*." Despite the FTC's allegation that the agreement called for the generic to purchase the supply of the drug at a significantly below-market price, the *AbbVie* court declined to read *Actavis*'s definition of "an unwarranted reverse payment so broadly as to include the opportunity" to purchase a supply of a drug at below-market prices *in order to compete with the patentee*. Because that competition would ultimately benefit consumers, in contrast to the agreements at issue in *Actavis*, the court determined that antitrust liability was not warranted. A similar distinction can be made for the no-AG settlement at issue in *King Drug Co.* There, the Third Circuit did not address directly the type of supply agreement deemed pro-competitive in *AbbVie*, but did reject the defendants' attempt to recharacterize Teva's gain as resulting solely from its early entry to the market; the value of Teva's 180-day exclusivity period came not from its early entry vis-à-vis other generics, but from GSK's self-restraint via its no-AG commitment.

While *King Drug Co.* clarifies that even noncash consideration in a patent settlement may warrant antitrust scrutiny, it expressly left open the possibility that a defendant could prevail on a motion to dismiss or for summary judgment on the basis that the precompetitive benefits of a reverse payment (or, by implication, any other settlement term) outweigh the payment's alleged competitive harm—signaling to antitrust defendants that dispositive motions might be more constructively directed to the touchstone of market effect rather than arbitrary distinctions such as the cash payments/noncash consideration distinction. Whether the Third Circuit's decision sounds a death knell for no-AG settlements will depend on parties' ability to style those agreements as pro-competitive, with a little expert help. Stay tuned. ■

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