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Antitrust Alert

Another District Court Holds That "Reverse Payment" Means Cash Under *FTC v. Actavis*

On Thursday, September 4, the US District Court in Rhode Island held that *FTC v. Actavis,* 133 S. Ct. 2223 (2013) requires a monetary payment from the patent owner to the potential generic challenger to support a so-called "reverse payment" claim, dismissing direct and indirect purchaser putative class actions in which plaintiffs asserted that the patent owner provided noncash "value" to the potential generic entrant in the challenged settlement. *See In re Loestrin 24 FE Antitrust Litig.*, MDL No. 13-2472-S, DKT No. 116 (D.R.I. Sept. 4, 2014). The court thus joined the debate among district courts as to the meaning of *Actavis*, siding with those that have construed it strictly and differing from those—including one within its own circuit—that have viewed it more flexibly. The court acknowledged that what the Supreme Court meant when it said that a "large and unjustified" payment from the patent owner to the accused infringer is required before a Hatch-Waxman settlement may be challenged under the antitrust laws is an unsettled question destined for appellate review.

In *FTC v. Actavis*, the Federal Trade Commission challenged settlement agreements that included, among other things, substantial monetary payments from the branded manufacturer to settling generic firms, along with agreed-upon entry dates between the time of the settlements and the expiration of the patents at issue. Although a settlement that "splits" the patent term—allowing the generic to enter at some agreed time before patent expiry but later than it would if it prevailed in the litigation—is a plainly lawful way to compromise based on the parties' assessments of their litigation risk, the FTC claimed that the payments "bought" later entry and were a *per se* unlawful payoff to a potential competitor not to compete. The defendants argued that, as long as the settlements did not extend the patent monopoly beyond its term, the agreements were lawful, a view held by a majority of the courts that had addressed the issue to that point. The Supreme Court rejected both positions, and held that a settlement that includes a "large and unjustified" payment from the patent owner to the accused infringer must be judged under the traditional antitrust rule of reason. *FTC v. Actavis,* 133 S. Ct. at 2237.

Since that decision, trial courts have struggled to determine whether and to what extent a settlement in which noncash "value" flows from the patent owner to the alleged infringer may be challenged under the antitrust laws. Compare, e.g., *In re Lamictal Direct Purchaser Antitrust Litig*., No. 12-cv-995, 2014 WL 282755 (D.N.J. Jan. 24, 2014) (holding that a settlement must involve cash to trigger a rule of reason analysis) with *In re Wellbutrin XL Antitrust Litig*., No. 08cv-2431, DKT No. 534 (E.D. Pa. Jan. 17, 2014) (holding that a nonmonetary settlement pursuant to which the branded firm agreed not to launch an authorized generic warranted a rule of reason analysis, but noting that it was "reluctant to decide the issue definitively at this time" because of the complexity of the question).

In *Loestrin*, Warner Chilcott Company LLC, the branded manufacturer of Loestrin 24 FE, an oral contraceptive that was covered by a patent set to expire in July 2014, settled patent litigation with two potential generic competitors, under which one generic would enter six months before the patent expired and the other around the time it expired. Neither agreement called for any cash payments by Warner Chilcott. Warner Chilcott did agree, among other things, not to launch its own "authorized" generic for a certain period of time, to grant a worldwide license to one of the generic firms and to enter several co-promotion and license arrangements that would permit the generic companies to sell versions of other branded Warner Chilcott drugs. Plaintiffs claimed that these other provisions should be construed as "large and unjustified" payments under *Actavis*. Defendants argued to the contrary.

The court rejected plaintiffs' reading of *Actavis*, concluding that the majority opinion there required a cash payment for an antitrust challenge to proceed. In addition to the *Actavis* decision's repeated references to money, the court supported its conclusion by observing that the five "considerations" the Supreme Court set forth to guide the rule of reason analysis of settlements with payments require the fact finder to "calculate the true value of the payment" in order to compare it to the expected monopoly profits generated by continued monopoly sales. The *Loestrin* court concluded that making that calculation for noncash provisions would be "almost impossible." This would certainly be true of complex settlements incorporating ancillary agreements, such as other settlements, licensing or distribution arrangements, which confer value on both parties and can hardly be characterized as "giveaways."

The court nonetheless noted that "the decision to grant the motions to dismiss was not an easy one." More specifically, the court stated that it was "left with an irreconcilable quandary"—finding that the plaintiffs had met the pleading requirements of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), but recognizing the admonition in *Actavis* "that in reverse payment contexts where rule of reason scrutiny is not applicable, dismissal is required." The court cautioned that, "[g]iven this dynamic, if courts apply the literal holding of *Actavis*, noncash pay for delay arrangements are likely to evade Sherman Act scrutiny so long as pharmaceutical companies take the obvious cue to structure their settlements in ways that avoid cash payments." Nevertheless, after recognizing the policy favoring settlement of patent litigation, the court ultimately concluded that, without further guidance, it could not undertake "a cavalier extension of the *Actavis* holding to virtually any noncash settlement package that has presumably substantial value." The *Loestrin* decision certainly will not be the last word on this complex issue. Indeed, the court invited the plaintiffs there to take an interlocutory appeal of its decision.

The *Loestrin* court, and others that have permitted noncash agreements to be challenged, appeared to be concerned about the possibility that other "value" flowing from the patent owner to the alleged infringer could "buy" a later entry date—a possibility was not lost on the *Actavis* majority. But practical business and litigation considerations mandate drawing a clear line somewhere. Settlements and commercial relations are often complex. In many industries, and certainly in the pharmaceutical industry, companies often deal with each other on many fronts—as competitors, suppliers and joint venturers, to name just three of the many relationships two companies may hold at any given time. They may settle litigation one week while entering into other, unrelated, ventures with each other the next. Permitting infinitely creative complaints linking these activities in an effort to find a "payment" to justify expensive antitrust litigation could cripple both industry and the courts. Of course, finding that clear line in defining what constitutes a "payment" required under *Actavis*—and how far afield courts may look to find one—is likely to take some time. As the *Loestrin* court noted in conclusion, quoting baseball legend Yogi Berra, "'It ain't over 'til it's over.' And it certainly ain't over yet."

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