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FTC Challenges “No-AG” Agreement as Illegal Reverse Payment

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On March 30 the US Federal Trade Commission filed suit in federal court alleging that settlements of patent litigation in the pharmaceutical industry in which a pioneer firm agrees not to market an "authorized generic" violate antitrust law.

The FTC is seeking disgorgement of what it alleges are "ill-gotten gains" from Endo Pharmaceuticals, Inc. and a number of generic firms in the agency's second suit challenging patent litigation settlements since the Supreme Court's decision in *FTC v. Actavis*, which declared settlements with so-called "reverse-payments" to be potentially unlawful.

The lawsuit underscores the FTC's view that *Actavis* should apply to non-cash forms of payment, including agreements by pioneer manufacturers not to introduce an authorized generic during the 180 days that the Hatch-Waxman Act prohibits the FDA from approving another generic ("no-AG" agreements). It also serves as a reminder that the FTC remains active in scrutinizing settlements of patent litigation and bringing enforcement actions.

Analytical framework applied to reverse payments: *FTC v. Actavis*

For years, the FTC has sought to end so-called "reverse payment" settlements in which parties resolve Hatch-Waxman litigation on terms that allow a generic drug to enter at some future date before the patent at issue would expire were the pioneer to win the lawsuit. The FTC views such payments as "payments for delay," arguing that the parties would have agreed to an earlier entry date in the absence of a payment.

In 2013, the Supreme Court set forth the framework that courts now use to determine whether reverse payments violate antitrust law. In ***FTC v. Actavis*, the Court held** that settlement agreements with reverse payments should be evaluated under the "rule of reason," and may be illegal when payments are "large and unjustified." The Court reasoned that the "likely anticompetitive effects" and "potential justifications" can be assessed by examining the size of a payment, taking the view that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." At the same time, the Court noted that where a reverse payment reflects "traditional settlement considerations" such as "avoided litigation costs" or "fair value for services," there is not the same concern.

Post-*Actavis*, several issues remain unresolved, including how to determine what constitutes a large payment, how one judges whether a side-deal is for fair value, and whether *Actavis* modifies the causation standard that applies to private plaintiffs.

Application of *Actavis* to no-AG agreements

The FTC has actively advocated for the application of *Actavis* to "no-AG" agreements through both speeches and amicus briefs. It argued in an amicus brief in 2012, for instance, that a "no-AG commitment provides a convenient method for branded drug firms to pay generic patent challengers for agreeing to delay entry," given that "the economic realities of a no-AG commitment are that it provides significant value to a first-filer generic company."

While some district courts initially concluded that *Actavis* did not reach no-AG agreements, most courts, including the Third Circuit, have determined that *Actavis* applies with equal force to non-cash forms of consideration, including no-AG agreements. In *King Drug v. SmithKline Beecham*, the Third Circuit reasoned that "no-AG agreements are likely to present the same types of problems as reverse payments of cash" given the "great monetary value" that a no-AG agreement represents to the generic. The defendants have submitted a petition for certiorari to the Supreme Court, arguing that the Third Circuit's decision expanded *Actavis* "well beyond its intended bounds," improperly infringing on patent holders' rights to grant licenses, including exclusive licenses.

The FTC's most recent reverse payment challenge

In *FTC v. Endo*, the FTC is challenging allegedly "anticompetitive reverse-payment agreements orchestrated by Endo" to prevent generic competition to what the FTC characterized as its "two most important branded prescription drug products": Opana ER, an opioid drug, and Lidoderm, a lidocaine patch.

The FTC is challenging three types of payments: (1) Endo's agreement not to offer a competing authorized generic, (2) a development and co-promotion agreement with the generic manufacturer of Opana that the FTC alleges "made no [independent] business or economic sense" for Endo, and (3) a distribution agreement with the generic manufacturer of Lidoderm under which the FTC asserts Endo supplied the drug "at no cost."

The FTC is seeking "restitution or disgorgement, to redress and prevent recurrence of defendants' violations," in addition to injunctive relief. This follows a trend in recent reverse payment cases in which the FTC has sought disgorgement.

In a statement issued with the complaint, FTC Chairwoman Edith Ramirez argues, "[s]ettlements between drug firms that include 'no-AG commitments' harm consumers twice – first by delaying the entry of generic drugs and then preventing additional generic competition in the market following generic entry. This lawsuit reflects the FTC's commitment to stopping pay-for-delay agreements that inflate the prices of prescription drugs and harm competition, regardless of the form they take."

The FTC simultaneously filed a stipulated order for permanent injunction with one firm, prohibiting it from engaging in certain reverse-payment agreements, including no-AG commitments, for 20 years. Interestingly, that settlement does not include any monetary relief.

Commissioner Maureen Ohlhausen dissented from the FTC's decision to file suit in federal court, taking the position that disgorgement in this case is not in the public interest and that the Commission should have pursued the matter administratively. She agreed, however, that there was "reason to believe that the Defendants violated" the law. She argued that an administrative suit "would allow the Commission to render a thoughtful decision applying the *Actavis* standard, providing much-needed guidance to courts and firms around the country."

The FTC continues to scrutinize reverse payment settlement agreements

Numerous private antitrust suits challenging settlements of patent litigation have been filed in recent years, and the FTC has weighed-in with amicus briefs, leading some to speculate that the FTC might be stepping back its case enforcement.

With this latest suit, the FTC has now filed two suits since the *Actavis* decision, including its September 2014 challenge to allegedly baseless patent litigation as well as a settlement agreement, in *FTC v. AbbVie*.

In that case, the FTC alleges that the generic manufacturers filed sham lawsuits, and that the branded manufacturer agreed to supply another drug which amounted to a reverse payment. In July 2015, the Eastern District of Pennsylvania dealt the FTC a setback, granting the defendants' partial motion to dismiss, and denying the FTC's request for partial judgment to allow immediate

appeal.

The FTC has also continued to pursue reverse payment litigation filed before the Supreme Court's decision in *Actavis*, including *Actavis* itself. In June 2015, it reached a landmark $1.2 billion settlement with Teva, stemming from its 2008 lawsuit that alleged that Cephalon (now owned by Teva) paid generic manufacturers to forgo marketing generic Provigil for six years. Teva also agreed to a permanent injunction prohibiting it from engaging in certain types of reverse payment agreements.

While the FTC's complaint may only be the latest development in the reverse payment saga, it confirms that the FTC remains active not just in filing amicus briefs and making public statements (indeed, it has filed three amicus briefs already in 2016), but also in bringing reverse payment enforcement actions. Pharmaceutical companies considering settling patent litigation should therefore carefully weigh the risk of FTC enforcement in addition to private enforcement.

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