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I. INTRODUCTION

Nearly a year after the Supreme Court held in *FTC v. Actavis*[2] that reverse-payment settlement agreements between branded and generic pharmaceutical companies are subject to antitrust scrutiny under the rule of reason, federal district courts are still struggling with such threshold questions as what constitutes a "payment" subject to antitrust challenge and whether only a monetary transfer from the patent holder to the alleged infringer can form the basis of an antitrust claim attacking the competitive effects of the settlement.

II. WHAT IS A "REVERSE-PAYMENT" SETTLEMENT?

Briefly, a reverse-payment settlement is a settlement of patent infringement litigation brought by the holder of a patent(s) covering a pharmaceutical product against a would-be generic competitor in which the generic agrees not to launch its allegedly infringing product for some period of time and the patent holder pays the generic (instead of the allegedly infringing generic paying the patentee for damages, hence the term "reverse payment").[3] The antitrust criticism of reverse-payment settlements is that they are payments in exchange for generics' agreements not to compete and therefore cost consumers billions of dollars in lower-priced drugs.

III. THE SUPREME COURT'S *ACTAVIS* DECISION

In *Actavis*, the Federal Trade Commission ("FTC") challenged patent infringement settlements between Solvay Pharmaceuticals, the patent holder of the branded low-testosterone drug AndroGel®, and various generics including Watson Pharmaceuticals (as Actavis was then known). Per the settlements, the generics would receive monetary payments ($19 – $30 million

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[2] 133 S. Ct. 2223 (2013).

[3] The generic is not liable for damages because typically the patentee has sued the generic, not for launching the generic drug, but for the statutorily infringing act of seeking "paragraph IV" FDA approval that contains a certification by the generic that the patent(s) covering the drug is invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The branded-drug manufacturer has 45 days from the paragraph IV filing date to sue the generic contender. *Id.* § 355(j)(5)(B)(iii).

per year for Watson) and "delayed licenses" to begin manufacturing generic AndroGel® five years before Solvay's patent expired.[4] Solvay also received certain marketing and drug supply services.[5]

The U.S. Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal of the FTC's challenge prior to discovery, pursuant to Federal Rule of Civil Procedure 12(b)(6). The Eleventh Circuit held, under what has been called the "scope-of-the-patent" test, that reverse-payment settlements were lawful "absent sham litigation or fraud in obtaining the patent" and "so long as [the settlement's] anticompetitive effects fall within the scope of the exclusionary potential of the patent."[6] The Eleventh Circuit upheld dismissal of the FTC's complaint because the FTC had not alleged sham litigation or fraud in obtaining the patent and because the agreements to delay generic competition to five years before patent expiration fell within the temporal scope of the patent.

The Supreme Court reversed and rejected both the "scope-of-the-patent" test applied by the Eleventh Circuit (as well as the Second and Federal Circuits) and the FTC's proposed "quick-look" or "presumptively-unlawful" test which would have shifted the burden to the defendants to show a pro-competitive justification sufficient to overcome the settlement's presumptive illegality.[7] Instead, the Court acknowledged that some reverse-payment settlements might be reasonable and lawful and, recognizing the complexity of these settlements, the majority held that the rule of reason must apply to reverse-payment settlements, and required courts to weigh their pro-competitive justifications against their anticompetitive effects.[8]

Beyond holding that the rule of reason governs reverse-payment settlements, the Supreme Court offered little guidance in analyzing them. The Court suggested only that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" and that a "large" payment indicates that the patentee possesses some degree of market power.[9] But what is a "large" reverse payment? Does "large" mean a large dollar amount or large relative to the patent holder's expected future profits?

Also, what is an "unexplained" payment? Does the mere presence of some consideration received for the payment, in the form of goods, services, or intellectual property, suffice? Or must the consideration be reasonable under some still unknown standard? And although the Court rejected the Second, Eleventh, and Federal Circuits' holdings that reverse-payment settlements were lawful absent sham litigation or fraud in obtaining the patent, the Court did not foreclose inquiry into the strength of the patent(s), stating only that "it is normally not necessary to litigate patent validity to answer the antitrust question."[10]

In dissent, Chief Justice Roberts presciently warned that, with no clear rules, the majority opinion portends much confusion among district courts in crafting the proper rule-of-reason

[4] 133 S. Ct. at 2229.
[5] *Id.*
[6] *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312(11th Cir. 2012).
[7] *Actavis*, 133 S. Ct. at 2237.
[8] *Id.* at 2230-31.
[9] *Id.* at 2235-36.
[10] *Id.*

analysis for reverse-payment settlements. The questions posed above, and one even more fundamental question, have yet to be answered.

IV. ONE YEAR LATER, AND STILL AT THE BEGINNING: WHAT IS A PAYMENT?

In January 2014, the U.S. District Court for the District of New Jersey dismissed an antitrust challenge to a reverse-payment settlement in *In re Lamictal Direct Purchaser Antitrust Litigation* because there was no cash payment flowing from the patent holder to the would-be generic competitor, narrowly interpreting *Actavis* as imposing a "bright-line" requirement of a cash payment. The court therefore held that it was unnecessary to engage in the requisite rule-of-reason analysis to determine the settlement's anticompetitive effects (if any).

Just a few months earlier in September 2013 in the same district, however, a different judge took a less restrictive view of *Actavis* in *In re Lipitor Antitrust Litigation*. The *Lipitor* court treated as an open question the issue of whether an antitrust complaint could meet the "plausibility" pleading standard under *Bell Atlantic Corp. v. Twombly* where no major cash payment was involved in a reverse-payment settlement between Pfizer and Ranbaxy that allegedly unlawfully delayed generic entry of Pfizer's super-blockbuster Lipitor. Instead, Pfizer had agreed to drop its patent-infringement suit against Ranbaxy based on Pfizer's patented blood-pressure medication, Accupril, in exchange for a $1 million payment by Ranbaxy (Pfizer's claims were allegedly worth significantly more) and for Ranbaxy's dropping its action against Pfizer over Lipitor. Nevertheless, the court granted the plaintiffs leave to amend their complaint to include allegations of non-cash payments while noting that "nothing in *Actavis* strictly requires that the payment be in the form of money."

In *In re Nexium Antitrust Litigation*, the U.S. District Court for the District of Massachusetts gave *Actavis* its broadest application and denied that defendants' motion to dismiss the complaint. The court read *Actavis* as sweeping in non-monetary payments, stating that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction." The court applied *Actavis* to the brand-name manufacturer's agreements to forgive patent infringement damages in other cases and to agreements not to launch the brand-name manufacturer's own authorized generic in competition with the generic manufacturers.

In February 2014, the court administratively stayed the *Nexium* case to draft an opinion setting forth its reasoning for granting some of the defendants' motions for summary judgment on the ground that there was insufficient evidence of a "large, unjustified reverse payment" under *Actavis* and also for denying other motions for summary judgment on that same issue. A month later, the court granted two of the plaintiffs' motions for reconsideration and reopened the case for the limited purpose of allowing further briefing on, *inter alia*, the existence of a reverse payment. An opinion is expected this fall.

V. A CALL FOR REASONING IN A RULE OF REASON

As Chief Justice Roberts stated in the dissent in *Actavis,* and as many commentators stated when the Supreme Court decided *Actavis*, much if not virtually all of the guidance on the antitrust analysis of reverse-payment settlements is being left to the district courts. Divergent post-*Actavis* district-court views about what exactly constitutes a "payment," and whether cash is

required, demonstrate that district courts, almost a year after *Actavis*, are still struggling even to begin to find their way to a consistent and coherent approach to analyze the competitive effects of reverse-payment settlements within the challenging patent and regulatory environment of this important public health issue.