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Donald Falk & Christopher Kelly
Mayer Brown LLP

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As with patent infringement litigation in many industries, innovator pharmaceutical companies frequently settle their patent infringement litigation against would-be generic challengers by licensing the alleged infringer to market its generic version of the patented drug before patent expiration. But because generic entry costs an innovator firm far more than it profits the entrant, a license giving a generic challenger a business opportunity consistent with its valuation of its litigation prospects could pose a loss wildly out of line with the innovator's own valuation.

Consequently, settling some pharmaceutical patent infringement suits requires conveying some value to the generic aside from the license itself, a superficially counterintuitive phenomenon that antitrust plaintiffs have called a "reverse payment" that pays the generic to delay its entry.[2] Over the last 15 years, appellate courts' antitrust reviews of these settlements have ranged from extreme deference to a presumption of competitive harm. Meanwhile, as litigants awaited guidance from the Supreme Court, the nature of the gap-bridging value generics arguably received evolved away from cash payments towards business opportunities.

Finally, in *FTC v Actavis*, the Court held last year that reverse-payment settlements are subject to antitrust analysis (contrary to the majority rule), but must be evaluated under the rule of reason, not (as antitrust plaintiffs had argued) subject to a presumption of anticompetitive harm.[3] Evaluating a settlement that, according to the FTC, had paid two generic firms more than the value of the business services they provided the innovator firm pursuant to the settlement, the Court reasoned that "the likelihood of a reverse payment bringing about anticompetitive effects [is not presumed, but] depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."

Actavis thus gives courts and litigants some guidance on how "reverse payment" settlements will be analyzed.[4] But there remains a fundamental question: exactly what constitutes

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[1] The authors are partners at Mayer Brown LLP. They thank their colleague Joshua Faucette for his contributions to this article.

[2] *See* Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19.2 ANNALS OF HEALTH L. 367-400 (2010, *available at* http://works.bepress.com/bret_dickey/2.

[3] *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

[4] *But see In Re: AndroGel Antitrust Litig. (No. II)*, Case No. 1:09-MD-2084-TWT, Slip op. at 2 (N.D. Ga. Oct. 23, 2013) (anticipating *Actavis*' remand, wondering "how in the heck a trial judge (and a jury) is supposed to apply the *Actavis* decision to an actual case").

a reverse payment? When a settlement provides for value to the generic beyond the grant of a license for the accused generic product, but not for any cash, does *Actavis* even apply?

The first district court decision to address the issue in detail came in the *Lamictal Direct Purchaser Antitrust Litigation* in New Jersey.[5] *Lamictal* involved an antitrust challenge to the settlement of a patent dispute between GlaxoSmithKline ("GSK") and Teva Pharmaceuticals ("Teva") At issue was GSK's patent for lamotrigine, used to make tablet and chewable forms of the anticonvulsant Lamictal. After Teva filed an Abbreviated New Drug Application ("ANDA") for Lamictal in 2002, GSK sued for infringement of its patent, which did not expire until July 2008.

In early 2005, after the district court invalidated Claim 1 of the patent, the case settled, with GSK agreeing to supply Teva with generic lamotrigine chewables for resale by Teva beginning in June 2005, and licensing Teva to sell its generic lamotrigine tablets six months before expiration of the patent (or the additional six-month pediatric exclusivity, if, as it turned out, GSK received it). As is now common in these settlements, GSK agreed not to undermine Teva's head starts by launching its own authorized generic ("AG") versions of the tablets and chewables during Teva's first six months with each product.

Direct purchasers of lamotrigine sued, claiming that the settlement violated the antitrust laws. In December 2012, the district court dismissed the complaint for failure to state a claim, holding that plaintiffs had failed to allege a reverse payment. After *Actavis* came down, the Third Circuit remanded the case to the trial court, and plaintiffs moved for reconsideration in light of the Supreme Court's decision.

In the *Lamictal* court's view, *Actavis* lays out "a three-part test." In the first two steps, the court determines whether there was a reverse payment and, if so, whether the payment was "large and unjustified." If both criteria are met, the court proceeds to rule-of-reason analysis, determining "whether the restraint had anti-competitive consequences and whether those consequences are otherwise justified."

The court found that the first step was enough. Plaintiffs had contended that they had alleged a reverse payment because the settlement "'conferred substantial benefits on Teva'—namely, through the No-AG Agreement." But the court disagreed: "nothing in *Actavis* says that a settlement contains a reverse payment when it confers substantial financial benefits or that a no-AG agreement is a 'payment.'" What *Actavis* "reek[ed] with," in contrast, was "discussion of payment of money;" the court noted pointedly that *Actavis* involved "a payment … of hundreds of millions of dollars to generic manufacturers."

Finding that the Court "considered a reverse payment to involve an exchange of money," and that it is "good jurisprudence that the result flows from the factual source," the court declined to "extend the holding of *Actavis* to the non-monetary facts before it." That the generic firm received a benefit was both obvious and immaterial: "'Without doubt Teva received consideration in the settlement. Otherwise, there would be no incentive to settle.'" *Actavis,* the

[5] *In re Lamictal Direct Purchaser Antitrust Litig.*, Case No. 12-cv-995 (WHW), slip op. (D.N.J. Jan. 24, 2014).

court concluded, meant to "give patent litigants latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring."

The *Lamictal* court left little doubt that the settlement would also survive rule of reason scrutiny. Even within its discussion of why *Actavis* did not apply, the court found "[t]hat Teva was allowed early entry, that there was no payment of money and that the duration of the No-AG Agreement was relatively brief," which "all serve to persuade this Court that the settlement was reasonable … ." And, as an alternative ground for dismissal, the court also concluded that the settlement "would most likely survive" *Actavis*' rule-of-reason analysis, finding that:

- the settlement posed "minimal" potential adverse effects on competition because (a) Teva was allowed six months of early entry, (b) there was no cash payment, and (c) the "duration of the No-AG Agreement was a relatively brief six months;"
- the No-AG agreement's value, though likely larger than the parties' avoided litigation costs, was justified in that it was "reasonably related to the removal of uncertainty" caused by the dispute, and may have reflected "ancillary benefit[s]" to GSK from Teva's licensed sales
- the existence of market power, though undetermined, was not dispositive;
- the "sweep of the settlement" did not connote an attempt to maintain supracompetitive prices and prop up a weak patent; and
- as the court had already found, the settlement "did not involve monetary reverse payments."

Lamictal's fate on appeal is unclear. Although *Actavis* categorically rejected *K-Dur*'s reflexive skepticism towards reverse payment settlements, the Third Circuit might be disinclined to restrain itself further and distinguish between cash and non-cash settlements.[6] In the meantime, the *Lamictal* decision establishes a potential bright-line rule exempting from antitrust scrutiny most patent settlements involving the transfer of only noncash benefits from the patent holder to the alleged infringer.

While, as *Lamictal* shows, rule of reason treatment of noncash settlements may turn out to be deferential in any case, a bright line that rules out even the rule of reason will reduce costs and uncertainty for both innovator and generic firms looking to eliminate uncertainty and get on with their businesses of making and selling pharmaceutical products.

[6] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217–19 (3d Cir. 2012), *vac'd and remanded in light of Actavis sub nom. Upsher-Smith Labs. v. Louisiana Wholesale Drug Co.*, 133 S.Ct. 2849 (2013).