Shifting Burdens: Structuring a Rule of Reason in Reverse-Payment Cases

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The U.S. Supreme Court's 2013 decision in *Federal Trade Commission v. Actavis, Inc.* triggered a flurry of judicial activity in relation to pharmaceutical patent settlements allegedly involving reverse payments from patent holders to potential generic competitors to delay their entry into the market. Rejecting rules of both presumptive legality and presumptive illegality, the Supreme Court instead tasked the lower courts with analyzing reverse-payment cases under the traditional antitrust "rule of reason" framework. Under the rule of reason, rather than simply presuming anti-competitive effects flowing from a given arrangement, courts must instead identify and balance the challenged restraint's demonstrated anti-competitive effects against its procompetitive benefits. While many of the early decisions interpreting *Actavis* have focused on the question of what actually constitutes a payment, the next wave of decisions will undoubtedly concentrate on the nature of the rule-of-reason analysis, including what an antitrust plaintiff must initially prove to demonstrate the requisite "significant anticompetitive effects" flowing from the challenged agreement.

The Court in *Actavis* held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects." Thus far, district courts largely have taken two different approaches in applying the rule of reason to that holding: (1) the plaintiff has the initial burden to establish that a reverse payment was both large and unjustified, or (2) the plaintiff must prove only that the payment was large, with the burden shifting to the defendant(s) to provide the justifications.

Many of the decisions that fall into the first category — while not explicitly discussing individual burdens of proof — interpreted *Actavis* as placing the initial threshold burden on plaintiffs to establish that a payment was both large and unjustified in order to trigger a rule-of-reason analysis in the first place. For example, in *United Food & Commercial Workers Local 1776 v. Teikoku (Lidoderm)*, Judge William H. Orrick agreed with "[m] ost district courts [in] read[ing] *Actavis* to hold that it is the 'large and unjustified reverse payment' that creates the anticompetitive concerns, and only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis." Similarly, Judge William E. Smith in *In re Loestrin 24 Fe Antitrust Litigation* noted that "*Actavis* appears to impose a three-part inquiry" where plaintiffs must show that (1) there was a reverse payment from a patent holder to a generic competitor, (2) it was large and unjustified, and (3) it violates the rule of reason.[1] Some courts have nested this "threshold inquiry" of whether a reverse payment must be large and unjustified within the plaintiffs' initial burden of proof under the rule-of-reason analysis. For example, in *In re Nexium (Esomeprazole) Antitrust Litigation*, Judge William G. Young explained to the jury that the "initial burden of proof lies with the Plaintiffs [to show that the payment] … exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked *'any other convincing justification,'*" and that "[o]nce this showing is made, the burden then shifts to the Defendants to show that a challenged payment was justified by some precompetitive objective." Similarly, in *In re Aggrenox Antitrust Litigation*, Judge Stefan R. Underhill made it clear that only an unexplained large payment could occasion the requisite anti-competitive harm, holding that "plaintiffs … must ultimately prove, within the rule-of-reason framework [ ] that a large and otherwise unjustified reverse-payment was made as part of the settlement in order to shore up some perceived risk of the [patent's] invalidity."

[1] *See In re Effexor XR Antitrust Litig.*, Civil Action No. 11-5479 (PGS)(LHG) (D. N.J. Oct. 6, 2014) (granting in part and denying in part defendants' motion to dismiss); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D. N.J. 2014) (granting defendants' motion to dismiss).

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Two courts have diverged from the "large and unjustifiable" directive in *Actavis* and instead permitted plaintiffs to simply show that a payment was large in order to satisfy their initial burden. In *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Judge Mitchell S. Goldberg denied the defendants' motion for summary judgment, holding that the size of the payment alone was an indicator of Cephalon's market power and finding that the plaintiffs had satisfied their initial burden by plausibly pleading only that the "large" payment had induced the generic manufacturer to abandon its claim. Separately, in *In re Cipro Cases I and II*, the California Supreme Court addressed reverse-payment claims brought under California state law. The court allocated to the plaintiff the burden of persuasion as to both a restraint on generic competition and a reverse payment to the generic in excess of both brand litigation costs and generic collateral products and services, but placed the burden of production as to litigation costs and value of collateral products and services in this initial inquiry upon the defendant. Under the *Cipro* approach, if the defendants fail to come forward with such evidence or do not dispute the shortfall between the value of the services and the payment, then the plaintiff has carried its initial burden. While these courts ostensibly rely on *Actavis*' passing statement that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present," they in effect endorse a presumption that any "large" payment, regardless of justification, raises sufficient concerns to merit further inquiry.

Thus far, the only Court of Appeals to have addressed pleading sufficiency under *Actavis* is the Third Circuit in its recent decision in *King Drug Co. of Florence Inc. v. SmithKline Beecham Corp. (Lamictal)*. *Lamictal* primarily focuses on the question of whether nonmonetary payments can trigger antitrust review. As such, it addresses the parties' respective burdens of proof only briefly, and the decision leaves much ambiguity as to which of the two standards the Third Circuit would endorse. Though the decision generally cites *Cephalon* in its discussion of burdens, throughout the opinion the court reiterates that the alleged payment may be subject to rule-of-reason scrutiny if it "represents an unexplained large transfer of value to the alleged infringer," consistent with *Actavis*' holding that only a large and unjustified payment carries with it the risk of significant anti-competitive effects. This implies that a plaintiff must allege and prove that the payment cannot be justified or explained prior to, or at least as a part of, its initial rule-of-reason burden of demonstrating significant anti-competitive effects.

Lamictal's lack of clarity surrounding the plaintiffs' initial burden will undoubtedly contribute to continued and vigorous debate over the allocation of burdens under *Actavis*. This creates all the more anticipation for forthcoming decisions in the *Lipitor* and *Effexor* appeals in the Third Circuit, the *Loestrin* appeal in the First Circuit and the *Aggrenox* appeal in the Second Circuit. These decisions might provide additional clarification regarding the application of the post-*Actavis* rule-of-reason framework to alleged reverse-payment settlements.