**FTC v. Actavis: Will the “Rule of Reason” End Reverse Payment Settlements?**

By George Yu  
*Spicy IP*  
June 20, 2013

On June 17, 2013, the United States Supreme Court issued a 5-3 decision (Justice Alito having recused himself) in *Federal Trade Commission v. Actavis* reversing the Eleventh Circuit Court of Appeals’s dismissal of the FTC’s complaint under the “scope of the patent test.” The majority, led by Justice Breyer, also rejected the FTC’s request to apply the “quick look” test and find reverse payment settlements presumptively illegal. Instead, the majority held that reverse payment settlements will be analyzed under the standard “rule of reason”—that is, the totality of the circumstances test typically used in antitrust cases.

Chief Justice Roberts in a vigorous dissent argued that the *Actavis* decision “will discourage settlement of patent litigation.” The Chief Justice noted that the lower barrier for bringing suit provided by the “rule of reason” analysis increases the likelihood of costly antitrust litigation. Thus, in the words of the Chief Justice, the Actavis decision “may well discourage generics from challenging pharmaceutical patents in the first place.”

**Background**

The Actavis case stems from settlements of patent litigations relating to Solvay’s AndroGel® product. (For more detail, please see my post of March 27, 2013). After Solvay settled the litigation with two generic pharmaceutical companies with reverse payments totaling $29-40M per year and allowing them to enter the market five years before patent expiration, the FTC challenged the settlement as unlawful agreements not to compete in violation of the antitrust laws. The district court dismissed the FTC’s complaint finding that the settlement did not violate the “scope of the patent” test. In other words, the settlement did not exclude generic competition beyond the term of the patent. The Eleventh Circuit affirmed following earlier decisions by the Federal Circuit (*Ciprofloxacin*) and the Second Circuit (*Tamoxifen*) in other challenges to reverse payments.

Shortly after the Eleventh Circuit’s decision in Actavis, the Third Circuit rejected the “scope of the patent test” in the *In re K-Dur Antitrust Litigation* and instead applied the “quick look” test to find the reverse payment settlement there presumptively illegal. The K-Dur Court reasoned that reverse payment settlements thwarted the Hatch-Waxman policy of promoting the introduction of generic
drugs and thus harmed consumers. The K-Dur defendants also petitioned for review by the Supreme Court.

The Actavis Majority

After recognizing the value of settlements and the costs of patent litigation, Justice Breyer, joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan, identified a set of five considerations that led the majority to conclude that the FTC should be given the opportunity to prove its antitrust claim:

1. “[T]he specific restraint at issue has the ‘potential for genuine adverse effects on competition.’” Justice Breyer found that Solvay's settlement with both of the initial filers of ANDAs removed the competitors with the most to gain and thus the greatest motivation to challenge the patents covering AndroGel®. Put another way, the Hatch-Waxman framework provides inducement for a patentee to pay an accused infringer to settle a patent infringement claim, something that almost never occurs outside of the pharmaceutical context.

2. “[T]hese anticompetitive consequences will at least sometimes prove unjustified.” The amount of the settlement or presence of consideration other delay of entry from the generic company—such as distributing the patented drug or providing marketing services—may suggest that a reverse payment settlement is not anticompetitive. But these facts would be considered as part of the “rule of reason” analysis.

3. “[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.” In other words, the patentee is willing and able to enter into a reverse payment because it is able to reap higher profits than would be possible with normal competition.

4. “An antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed.” There was significant concern regarding how courts applying a rule of reason analysis may have to delve into the strength of the asserted patents. Justice Breyer indicates that the size of the reverse payment settlement itself “may provide a workable surrogate for a patent’s weakness.”

5. “The fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.” Justice Breyer suggests that settlements can be reached that allow the generic company to enter the market before patent expiration without a reverse payment. But if a reverse payment is preferred by the parties, the courts should examine the reasons behind that preference.

These considerations led the majority to reject the “scope of the patent” test applied by the Eleventh Circuit.
However, the majority also rejected the FTC’s position that reverse payment settlements are presumptively unlawful. Justice Breyer explained that the likelihood of a reverse payment settlement leading to anticompetitive effects depends upon the amount of the settlement, its scale in relation to the patentee’s future litigation costs, whether the generic company is providing consideration other than delayed entry into the market in return for the payment, and any other convincing justification. Thus, the lower courts are left with—depending on your viewpoint—discretion to consider all the circumstances surrounding the settlement or little guidance to assess whether the settlement is anticompetitive.

**The Chief Justice’s Dissent**

Chief Justice Roberts, joined by Justices Scalia and Thomas, dissented, emphasizing that patents represent an exception to the antitrust law: “The point of patent law is to grant limited monopolies as a way of encouraging innovation.” Thus, reviewing the same case law as the majority, the Chief Justice came to the conclusion that the “scope of the patent” test is the proper test based on the existing precedent. The Chief Justice went on to criticize the analysis of the five considerations listed above as suggesting “a regime where courts ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent.”

The Chief Justice then went on to explain that exposing a patent settlement to an antitrust challenge would require the parties to relitigate the question of patent validity as a defense to the antitrust complaint. Such a process would create significant disincentives to reverse payment settlements and encourage pharmaceutical patentees to avoid settlements. That, leads to the ironic conclusion, as pointed out by the Chief Justice, that the Actavis decision may actually discourage generic drug companies from challenging pharmaceutical patents at all.

**Lessons Learned**

The principal lesson of the Actavis decision for companies considering a reverse payment settlement is that they need to include other consideration from the generic drug company, such as distributing the patented drug or providing marketing services, as evidence in favor of the settlement being pro-competitive. However, there is always the possibility that the party challenging the reverse payment settlement will assert that the additional consideration is a sham. That is exactly what happened in K-Dur, where the plaintiffs alleged that a patent license granted by the generic company to the patentee was a sham and that the entirety of the payment was for the generic company’s delayed entry into the market. Until the lower courts rule on whether specific settlements violate the antitrust laws, parties should consider avoiding reverse payment settlements.

The Supreme Court has distributed the K-Dur appeal (*Merck v. Louisiana Wholesale Drug Co.*) for the Conference of June 20, 2013. The likely result will be a “GVR”—i.e., the Supreme Court will
grant certiorari, vacate the decision of the Third Circuit, and remand for further proceedings consistent under the rule of reason analysis.

This post represents solely the views of the author and does not represent the views of Schiff Hardin LLP or any clients of Schiff Hardin LLP.