Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Evaluating Pay-For-Delay Deals After FTC V. Actavis

Law360, New York (June 19, 2013, 12:10 PM ET) -- On June 17, in a 5-3 decision, the U.S. Supreme Court ruled in Federal Trade Commission v. Actavis that reverse payment settlements between branded and generic pharmaceutical companies should be subject to a rule-of-reason antitrust standard. As a result, challenges to these patent settlements will now require courts to weigh the pro- and anti-competitive effects of the settlements on a case-by-case basis, rather than by applying the more straightforward and industry-friendly "scope of the patent" test or the "presumptively unlawful" standard advocated by the FTC. The court has left the lower courts to decide how to apply a rule-of-reason standard.

Background

In some patent settlements between brand and generic pharmaceutical companies, in addition to the two companies agreeing on a generic entry date at some point in the future, the brand company is alleged to have provided consideration (a "reverse payment") to the generic company beyond dropping the patent suit.

The FTC maintains that in most cases the consideration given to the generic company by the brand company necessarily causes the negotiated generic entry date to be later than it would have been absent any payment and is thus equivalent to the brand company paying the generic company to stay out of the market.

In contrast, those opposing the FTC's position have argued that patent law grants a legal monopoly, and as long as the patent was not obtained through fraud, the patent litigation is not a sham, and restrictions in the settlement agreement do not exceed the exclusionary scope of the patent, reverse payment settlements fall within the legal rights conferred by the patent and are not anti-competitive.

The Supreme Court agreed to hear the case after circuit courts split on which antitrust standard to apply. In FTC v. Actavis, the Eleventh Circuit applied the scope of the patent test, holding that an agreement is not anti-competitive as long as it does not exceed the exclusionary scope of the patent and the patent litigation was not a sham. In contrast, in In re K-Dur Antitrust Litigation, the Third Circuit applied a presumptively unlawful standard, holding that a payment from a brand company to a generic company should be considered prima facie evidence of an unreasonable restraint of trade.

The Supreme Court adopted a rule-of-reason approach not advocated by either party, rejecting both the scope of the patent test and the presumptively unlawful standard. The court rejected the scope of the patent test based on "five sets of considerations":

1. Reverse payment settlements have the "potential for genuine adverse effects on competition" by removing "from consideration the manufacturer most likely to introduce competition."

2. The anti-competitive consequences of reverse payment settlements may not be justified by other pro-competitive considerations.

3. The ability of the patentee to make a large reverse payment indicates "the patentee likely has the power to bring about that harm in practice."

4. "[A]n antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. It is normally not necessary to litigate patent validity to answer the antitrust question."

5. "[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuits. ... [T]hey may settle in other ways."

The court rejected the presumptively unlawful standard, holding that:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects 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. ... These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

The court's decision makes clear that lower courts will have to grapple with two very important questions (among others):

1. Will brand companies be allowed to use a validity defense?
2. How will the size of the reverse payment be used to evaluate whether a settlement is anti-competitive?

Will Brand Companies Be Allowed To Use a Validity Defense?

As Chief Justice John Roberts noted in his dissent:

> [T]he defendant (patent holder) will want to use the validity of his patent as a defense. ... I therefore don't see how the majority can conclude that it won't normally be "necessary to litigate patent validity to answer the antitrust question," ... unless it means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit. But depriving him of such a defense — if that's what the majority means to do — defeats the point of the patent, which is to confer a lawful monopoly on its holder.

Notwithstanding Chief Justice Roberts' observations regarding the relevance of a patent's validity, the majority suggests that such an inquiry will not "normally" be necessary. According to the majority, the size of the reverse payment may serve as a surrogate for demonstrating the likely weakness of a patent, stating "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." The majority cites only one instance in which such an inquiry would be necessary — when a plaintiff asserts that the patent litigation was a "sham."

But efforts by a plaintiff to avoid litigating the underlying merits of the patent litigation should prove unsuccessful. As the majority makes clear, the burden of proving that a patent settlement violates the antitrust laws remains with the plaintiff. As part of that burden, a plaintiff must show that the anti-competitive effects of the settlement outweigh any pro-competitive benefits. But if a patent is valid and infringed, how can an agreement that does not exceed the scope of the exclusionary power of the patent be anti-competitive?

The FTC and others (including the court's majority) might argue that this question is irrelevant because, without a reverse payment, the parties would simply have agreed to an earlier generic entry date. This argument suggests that the relevant comparison is the difference between the negotiated generic entry date and the entry date the parties would have negotiated absent a reverse payment. Yet the strength of the brand company's patent case is potentially relevant when assessing what entry date the parties would have negotiated absent a reverse payment.

Moreover, this argument does not hold when the parties would have litigated the patent case absent the ability to include a reverse payment in the settlement. Such situations may be quite common — the FTC's own statistics indicate that pharmaceutical patent cases were settled at much lower rates prior to the Eleventh Circuit's adoption of the scope of the patent test, suggesting that reverse payments do enhance litigants' ability to settle cases. If the brand company would have won the patent case, it is hard to see how a reverse payment settlement was anti-competitive. Yet determining which party would have prevailed requires litigating patent validity.

How Will the Size of the Reverse Payment Be Used To Evaluate Whether a Settlement Is Anti-Competitive?

As already noted, the majority suggests that an assessment of the size of the reverse payment may be able to substitute for an investigation into patent validity. Despite the majority's claim that a "large reverse payment itself" is indicative of the brand company's views as to the strength of its patent case, economists have long argued that reverse payment settlements can occur for many reasons other than to delay generic entry. Real-world complexities such as asymmetric information, differing beliefs regarding the likelihood of prevailing in litigation, differing discount rates, cash constraints, and risk aversion could lead the parties to negotiate patent settlements that involve reverse payments.

Chief Justice Roberts discussed risk aversion as a legitimate factor that could result in a large reverse payment. Relative to generic companies, brand companies may more strongly favor the certainty of settlement because brand companies generally have more money at stake and also because certainty allows brand companies to make important decisions, such as how much to invest in marketing and whether to conduct research into additional indications.

For these reasons, generic companies may be able to extract payments from brand companies that are large compared to the potential profits the generic company could earn by entering the market. Determining whether a reverse payment was motivated by a desire to delay generic entry or by other legitimate factors such a risk aversion will generally require a detailed economic analysis of the case facts.

Other Considerations

The court's decision does not clarify what will constitute a reverse payment. Payments in the form of monetary compensation are obvious, but often the payment is alleged to have been hidden within contemporaneous business agreements — e.g., patent licenses, supply agreements and agreements for promotional support — or in agreements related to brand-authorized generics. Determining whether such agreements hide a reverse payment requires a valuation of the various components of the agreements, which are often complex and unique. The potential for anti-competitive delay in generic entry exists only if it is determined that there was a reverse payment. Such a determination is likely to be an important issue in reverse payment settlement cases going forward.

It is also worth noting that in some cases there may also be benefits to consumers when generic entry is delayed; for example, in underserved markets, the benefits of the brand company's educational efforts, which end with generic entry, may outweigh the costs of higher prices absent generic entry. While these situations might be rare, courts will need to weigh the costs of delayed generic entry against any benefits that may accrue to consumers in order to determine whether consumers were harmed by the delay.

Conclusion

The Supreme Court decision in FTC v. Actavis does not eliminate the uncertainty regarding antitrust scrutiny that brand and generic companies previously had in entering reverse payment settlements. Brand and generic companies choosing to enter into such settlements in the future will need to be prepared for potentially extensive litigation under a full-blown rule-of-reason approach in which courts will weigh the pro-competitive effects against anti-competitive effects on a case-by-case basis. The anticipation of such an analysis may affect the characteristics of the settlements themselves and whether or not the parties choose to settle at all.

--By Rahul Guha, Sally Woodhouse, Carlos Brain and Anna Taub, Cornerstone Research, and William Cavanaugh, Patterson Belknap Webb & Tyler LLP.

Rahul Guha and Sally Woodhouse are vice presidents at Cornerstone Research in the firm's New York and Boston offices, respectively. Carlos Brain is a senior manager, and Anna Taub is an associate, both based in Cornerstone Research's Menlo Park, Calif. office. William Cavanaugh is co-chairman of Patterson Belknap in New York.

Cornerstone Research vice presidents Rahul Guha and Sally Woodhouse, along with other authorities, were signatories to an amicus brief filed in this case in support of the respondents, Solvay Pharmaceuticals Inc., Actavis Inc., Paddock Laboratories Inc. and Par Pharmaceutical Cos. William Cavanaugh of Patterson Belknap Webb & Tyler was counsel of record.

The opinions expressed are those of the authors and do not necessarily reflect the views of the firms, their clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.