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

Lawyers Comment On High Court's Pay-For-Delay Decision

Law360, New York (June 17, 2013, 6:34 PM ET) -- The U.S. Supreme Court ruled Monday that brand-name drugmakers can be sued for paying generic-drug manufacturers to delay the release of low-cost versions of blockbuster medicines, overturning an Eleventh Circuit finding that the agreements were generally legal. Here, attorneys tell Law360 why the 5-3 decision in Federal Trade Commission v. Actavis Inc. is significant.

Alden Atkins, Vinson & Elkins LLP
"The court's decision stands out because it says that an agreement that is entirely within the scope of a patent may violate the antitrust laws, without considering whether the validity of the patent is in doubt. The court was obviously influenced by the exchange of money in these reverse settlements, but the logic suggests that any agreement among potential competitors may create antitrust liability, even when limited to the scope of the patent. There is growing tension between the policies of the antitrust laws and the patent laws, and this decision will likely add to that tension."

Steve Bradbury, Dechert LLP
"This decision will increase the costs and legal risks of patent settlements in the drug industry, and that could end up reducing generic competition, not increasing it."

Erin E. Bryan, Banner & Witcoff Ltd.
"Although the court's decision may have an impact on pay-for-delay agreements between name-brand drug manufacturers and competing generic-drug manufacturers, the long term impact may not be overly significant. Because pay-for-delay agreements will be subject to review under the rule of reason, there is a real possibility that a majority of the agreements will be held to be valid and enforceable. However, especially in the immediate future, the drug manufacturers will likely be seriously considering and balancing the costs of pursuing patent litigation, as compared to defending the validity of a pay-for-delay agreement that is subject to antitrust scrutiny."

Richard W. Cohen, Lowey Dannenberg Cohen & Hart PC
"The Supreme Court was properly undaunted by the fact of a patent as cover for anti-competitive action. A patent reflects little more than a patent examiner's opinion and Congress never intended to give that opinion preemptive effect over antitrust law. A majority of Hatch-Waxman Act patent challenges to the validity or noninfringement of patents protecting branded drugs succeed. In the face of that empirical evidence, the Eleventh Circuit's decision was unjustified and the Supreme Court's reversal was the correct outcome."

Gregory F. Corbett, Wolf Greenfield & Sacks PC
"The Supreme Court adopted a middle-ground 'rule of reason' analysis for evaluating whether settlement of Hatch-Waxman litigation involving reverse payments violates antitrust laws. In rejecting the 'quick look' test advocated by the FTC, the court recognized that not all reverse payments are presumptively anti-competitive. However, the court also rejected the 'scope of the patent' test and the notion that any reverse payment is presumptively okay if generic entry is before patent expiration. At minimum, the court's decision allows the FTC to continue to challenge reverse-payment settlements, and imposes some amount of burden on parties and courts to evaluate them."

Steven M. Coyle, Cantor Colburn LLP
"In the short term, it is clear that so-called 'reverse settlement agreements' will be riskier for pharmaceutical patent litigants. Although the court stopped short of declaring such agreements presumptively anti-competitive, the application of the amorphous 'rule of reason' test injects much uncertainty into any settlement that involves compensation flowing from the brand to the generic company. Parties seeking to settle do so to provide finality, and the Supreme Court's decision would place any such settlement at risk of challenge. This decision will likely make settling certain Hatch-Waxman cases more difficult."

Jeffery Cross, Freeborn & Peters LLP
"One of the big issues for a full rule of reason approach, which the court adopted, is whether the patent's validity must be relitigated. Both the FTC/[U.S. Department of Justice] and the defendants took the position that such relitigation would be unworkable. [Justice Stephen Breyer] pooh-poohs this, suggesting that an unexplained large reverse payment would be suggestive of the validity of the patent. This makes sense, especially in the context of the case before the court. The multimillion-dollar payment from [Solvay Pharmaceuticals Inc.] to [Watson Pharmaceuticals Inc.] is large but explained by the pro-competitive arrangement where Watson will undertake to market AndroGel to urologists."

Justine Donahue, Michael Brockmeyer and John Collins, Frommer Lawrence & Haug LLP
"The Supreme Court held today that lower courts reviewing reverse-payment settlement agreements should apply a 'rule of reason' antitrust analysis rather than the scope of the patent test or the so-called 'quick look' approach. The size of any payment will be a threshold indicator of whether the settlement may be unlawful, placing significant emphasis on valuing settlement terms that go beyond mere cash payments. Assuming a payment, courts may apply a market power screen to evaluate a settlement's competitive effects, but even if market power is found, the patentee may still defend the antitrust suit by relying on the strength of its patent."

Eric Fastiff, Lieff Cabraser Heimann & Bernstein LLP
"The court correctly ruled that settlements of patent law disputes do not provide blanket immunity from antitrust liability. Pay-for-delay agreements involving pharmaceutical drugs significantly harm patients and insurers who are denied the benefits of a competitive market and are required to pay high monopoly prices. With individual scrutiny most, if not all, of these deals will be held illegal. This is a very good day for patients and their doctors."

Heather Kafele, Shearman & Sterling LLP
"The Supreme Court's decision eliminates the bright-line rule that circuit courts had created to determine whether a 'reverse payment' patent settlement between branded and generic pharmaceutical companies violates the antitrust laws. The court did not adopt the FTC's proposed clear rule — namely, that reverse payment settlements are presumptively anti-competitive. In that regard, it is a victory for no one. The court adopted a very fact-specific test — whether the a reverse settlement

violates the antitrust laws will now depend upon the size of the payment, the scale of the payment in relation to the anticipated future litigation costs, whether the payment is for other services and whether there are any other legitimate justifications for the payment."

Noah Leibowitz, Simpson Thacher & Bartlett LLP
"The Actavis decision will make settlement of Hatch-Waxman [abbreviated new drug application] cases more difficult and more risky for the parties involved. Uncertainty over potential antitrust liability will cause brand and generic companies to re-evaluate their settlement options and will, at the margins, chill settlement. Following the 'rule of reason' approach mandated in Actavis, antitrust cases growing out of Hatch-Waxman settlements are unlikely to be decided at the motion to dismiss, or even summary judgment, stage. Although the majority found that the issue of patent validity is not necessarily essential to the resolution of such antitrust cases, it is likely that in each such case, either the antitrust plaintiffs or defendants will find the issue important and we are more likely than not to see mini patent trials litigated within antitrust cases."

Jay L. Levine, Bradley Arant Boult Cummings LLP
"The decision today is a decisive victory for the FTC and the plaintiffs' bar, effectively holding that 'large' reverse payments by the brand to the generic will be presumed to cause anti-competitive harm. Unless the payment simply reflects avoided litigation costs or fair value for services rendered by the generic, the settlement will not pass antitrust muster. Expect to see even more reverse payment settlements that explicitly spell out various services the generic will undertake to justify the payment. The next frontier in this battle will be whether such services justify the payments being offered or do they constitute old-fashioned exclusion payments."

Kevin E. Noonan, Ph.D., McDonnell Boehnen Hulbert & Berghoff LLP
"The court's decision will likely end reverse payment settlement agreements, making generic competition less likely. Unable to settle, innovator patentees will litigate every case to conclusion, to avoid antitrust scrutiny involving the same or similar infringement and validity questions settled in ANDA litigation. Coupled with the FTC's position that transfer of 'anything of value' from the branded drugmaker to a generic competitor should merit antitrust scrutiny, there is little advantage for either party in an ANDA lawsuit to settle. This is fast becoming the most patent-unfriendly Supreme Court since [Justice William O. Douglas] sat on the bench."

Patrick L. Patras, Hinshaw & Culbertson LLP
"The court's decision will both weaken patents and, in the short term at least, increase litigation. Pharmaceutical patents become less valuable as it is more difficult for their owners to determine how best to extract economic value from them. Lower courts will become involved in complex rule of reason analyses with respect to challenged patent litigation settlements, thereby introducing antitrust litigation in the place of what had been resolved patent litigation. This complexity and uncertainty also will discourage settlements, meaning at least some patent litigation will endure longer than it would have otherwise. This is all said to be done in aid of competition and for the benefit of consumers. As the dissent points out, however, the irony is that this decision may lead to fewer generics challenging pharmaceutical patents."

Steve Reed, Morgan Lewis & Bockius LLP
"While the court did not embrace the 'scope of the patent' test that had been adopted by the circuit courts, neither did it accept either a per se rule or the quick look rule of reason approach that the FTC sought, in which 'reversed-payment settlements' would have been presumptively illegal with the burden shifting to the defendants to justify. The upshot of the decision is that, with the exception of settlements

limited to compromises on the patent term itself, there will be increased uncertainty about whether particular settlements will pass antitrust scrutiny. This may have a chilling effect on parties' willingness to settle, and thus forego guaranteed early entry by generics."

Robert Reznick, Orrick Herrington & Sutcliffe LLP
"The Supreme Court's opinion is really a 'guidance' to courts and the industry, leaving a large middle ground to be resolved by the lower courts. Some deals simply will not get done. But in others settling parties will move to structure plausible deals more defensively, perhaps complicating them to foil a rule of reason analysis or adding agreements in which the generic is selected to profit from deals having commercially reasonable terms that are unrelated to the patent dispute. With loose dicta on both sides of the defensibility of large settlements, whether defendants will choose to, be permitted to, or even be required to conduct a mini-trial on the strength of their patents or the reasonableness of their assumptions remains unclear. Settling parties that elect to pursue more aggressive arrangements will spend a lot of money learning the answers to these questions."

Carl R. Schwartz, Quarles & Brady LLP
"For a few years Congress has been considering legislation that would outlaw (or at least render much more risky) the reverse payment practice. This Supreme Court holding may well lead Congress not to bother with such a legislative 'fix,' and leave it to the threat of rule of reason antitrust lawsuits to frighten most drug companies away from this practice. Thus, this decision (even though unfavorable to this patentee) could oddly lead to an overall pro-patent result by holding off harsher legislation. On the other hand, the thrust of the decision (that antitrust principles should not be as subservient to patent policy) may encourage more and more judges to follow [Judge Richard Posner] of the Seventh Circuit in terms of requiring patentees to undertake burdensome detailed economic analysis for more patent issues (e.g., damages calculations in order to recover)."

Hill Wellford, Bingham McCutchen LLP
"The Supreme Court might as well have banned unicorns. Companies don't make the 'large, unjustified and unexplained' naked payments that the court focuses upon. Instead, they have complex business relationships, of which settlements are only a part. Explaining the 'justifications' under the antitrust rule of reason will be the crux, and this was true even before the court's decision because the FTC has always run investigations as if the Eleventh Circuit's decisions did not exist. So in practice, today's decision will not do much to change company behavior or lawyers' strategies. All it clarifies, and in the industry's favor, is that 'quick look' skepticism does not apply and the burden of proof remains on the FTC."

John Wetherell, Pillsbury Winthrop Shaw Pittman LLP
"Considering the Supreme Court's tendency to try to strike a balance, this ruling is not surprising. It will be of critical importance to see how this will play out in terms of future litigation. This is especially true with respect to the court emphasizing the use of five considerations that should be considered in applying the 'rule of reason' which is more heavily used on an antitrust setting."

Ryan Marshall, Brinks Hofer Gilson & Lione
"The FTC's suit in Actavis sought a ruling that pay-to-delay agreements are presumptively anti-competitive. The opinion falls short of that presumption. Instead, the Supreme Court's ruling enables the FTC to present a case demonstrating the anti-competitiveness of any agreement. Future challenges to such agreements will be on a case-by-case basis. It will also likely result in fewer cases being settled and more patents being fully challenged. As a result, generic entrants will still likely be delayed for some period of time that is the same or slightly shorter than that resulting from the now invalidated agreement periods."

David Leichtman, Robins Kaplan Miller & Ciresi LLP
"This is a decision in which no party before the court got what it wanted. The court ignored the provisions of the 2003 amendments to the Hatch-Waxman Act. Changing the standard for antitrust scrutiny from a 'quick look scope of the patent' test to a 'rule of reason' analysis should not impact the vast majority of settlements occurring after the 2003 amendments. The only thing it will do is increase litigation costs in defending the deals because they will likely now be decided on summary judgment after discovery rather than at the motion to dismiss stage."

--Editing by Katherine Rautenberg.
