Justices say pay-for-delay deals with generic drug makers subject to antitrust 'rule of reason'

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Have you ever sought clarification only to receive a response that created more questions than answers? That is what happened to the litigants in the Supreme Court's most recent antitrust decision, which addressed reverse-payment settlement agreements of pharmaceutical intellectual property litigation.

In *Federal Trade Commission v. Actavis*, 2013 DJDAR 7655 (June 17, 2013), the Supreme Court held 5-3 that trial courts must apply the traditional "rule of reason" to determine whether these types of agreements violate antitrust laws. The rule of reason is a far-reaching inquiry that measures the anticompetitive effects and pro-competitive benefits of an activity or agreement through economic and other evidence within defined relevant product and geographic markets. The *Actavis* court thus settled on a case-by-case approach rather than either blessing or condemning the challenged agreements.

The parties and lower courts, by contrast, had split between different short-cuts that coalesced around either a permissive "scope-of-the-patent" test (endorsed by the 11th, 2nd and Federal Circuits) or a variant of the 3rd Circuit's "presumptively unlawful" standard. The Supreme Court resolved this circuit split by, in essence, telling the parties and lower courts to start over. It would not endorse any of the proposed "special" antitrust rules for these types of agreements that have percolated in the lower courts for years. Instead, courts must analyze reverse-payment settlement agreements just like most typical antitrust cases, through the rule of reason.

A reverse-payment settlement arises almost exclusively from patent litigation between brand-name pharmaceutical companies and generic companies under the unique setting of the Hatch-Waxman Act. That act encourages generic drug manufacturers to file abbreviated new drug applications (ANDAs) before the patents on the brand-name drug expire. But to do so, generic companies must make one of four certifications, usually that the relevant patent is invalid or would not be infringed. That certification is, under the law, an act of infringement, which inevitably leads to a patent lawsuit. The lawsuit then triggers a 30-month stay of the ANDA approval process, which is also extinguished if the litigation ends sooner. Importantly, the first generic ANDA filer receives a 180-day exclusivity period from any other generic competition.

Unlike most other patent litigation, the defendant in Hatch-Waxman Act litigation bears substantially less risk than the patentee plaintiff. That is because the generic defendant has yet to market its generic drug, so any monetary damages are minimal. By contrast, the brand-name plaintiff risks substantial financial loss because the patent itself is at stake - along with possibly several years of permissible monopoly profits. So, not surprisingly, settlement often involves compensation *to the defendant*, sometimes coupled with a compromise entry date for the defendant before patent expiration.

SPECIAL REPORT
In-House Counsel

Friday, June 21, 2013

Judges and Judiciary
Obama nominates two to fill Northern District judicial vacancies
President Barack Obama nominated San Mateo County Superior Court Judge Beth Labson Freeman and Shearman & Sterling LLP antitrust partner James Donato to fill two vacant seats on the Northern District bench on Thursday.

Government
Court blasts state over prison population, threatens contempt
A federal demanded the state begin implementing further measures to reduce its prison population to the level the court demanded four years ago, warning that failure to comply would "constitute an act of contempt."

Alternative Dispute Resolution
Paul J. Dubow
Paul J. Dubow often handles mediations with executives and upper managers at companies in disputes that frequently involve friends, or close colleagues. But Dubow says it's those cases he often finds the most interesting.

Law Practice
Law school graduate employment rates decline
Law school graduate employment rates dropped this year compared to last, though the average salary rose, according to a recent NALP survey.

Corporate
Facebook pulls new GC from within
Currently in the spotlight over the extent of access the U.S. National Security Agency has to its data, Menlo Park-based Facebook Inc. has appointed a new general counsel from within its ranks, the company announced Thursday.

U.S. Court of Appeals for the 9th Circuit
State inmate, arguing for himself, persuades 9th Circuit to grant habeas relief
A state prison inmate serving 25 years to life argued his own cause and persuaded a 9th U.S. Circuit Court of Appeals panel to grant him habeas relief Thursday on claims that California courts repeatedly mishandled his case.

Law Practice
HP replaces Morgan Lewis on Autonomy cases
Hewlett-Packard Co. replaced Morgan, Lewis & Bockius LLP with Morrison & Foerster LLP as its counsel Thursday on a series of putative class actions relating to the company's acquisition of data software company Autonomy.

But for the fact that the agreement falls within a patent's scope, this type of settlement might fail antitrust scrutiny as a per se illegal market-allocation agreement; the parties are, after all, allocating the market to the brand-name company. A patent, however, is a legally authorized monopoly, so most circuits have held that the agreement is lawful so long as any anticompetitive terms fall within the scope of the patent. Unrelenting, the FTC, in particular, kept battling against these agreements and, eventually, a federal appellate court - the 3rd Circuit - rejected the scope-of-the-patent test in favor of a presumptively unlawful standard. That created a clear circuit split, leading the U.S. Supreme Court to accept review of *Actavis*, an 11th Circuit decision applying the scope-of-the-patent test against the FTC.

The case arose from ANDAs submitted for a generic formulation of Solvay's AndroGel. In 2003, Solvay filed infringement actions under the Hatch-Waxman Act against the generic drug manufacturers, who argued that Solvay's patent was invalid. The parties settled in 2006. The patent was scheduled to expire in 2020, but the parties agreed that the generics could go on the market in 2015 and, in the meantime, would help Solvay market AndroGel. Solvay also paid the generics more than $100 million. It was this payment that drew the attention of the FTC, which challenged the transaction. The 11th Circuit upheld the agreement because the generics only agreed to stay off the market (in exchange for consideration) within the "scope of the patent."

In reversing the 11th Circuit, the Supreme Court quickly disposed of an important premise of the scope-of-the-patent test - the presumption of patent validity - by asserting that "[t]he patent here may or may not be valid, and may or may not be infringed." The scope-of-the-patent test relies on the presumption of patent validity because, if the patent isn't valid, the holder lacks the right to the limited monopoly and, absent that right, the reverse-payment settlement is simply a per se unlawful market-allocation agreement between competitors. Indeed, the *Actavis* court expressed strong concern that, by entering into the reverse-payment settlement, Solvay and the generic manufacturers were simply agreeing to split monopoly profits at the expense of consumers.

Eliminating the presumption, however, left the court with the problem of having to determine patent validity on a case-by-case basis. As the underlying patent litigation has been settled, there is general agreement among most parties and commentators that fully re-litigating patent validity in the subsequent antitrust lawsuit is a bad idea.

The *Actavis* court acknowledged that applying the rule of reason might require antitrust trial courts in some cases to determine patent validity, but added that such an occurrence should be rare because the size of the reverse payment can function as a "workable surrogate for the patent's weakness." According to the court, if the reverse payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." In contrast, an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and, by implication, that the purpose of the payment must be anticompetitive. Thus, the court directed trial courts to apply the rule of reason by "considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents," and to "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question - that of the presence of significant unjustified anticompetitive consequences."

Those expecting the court to give a thumbs-up or thumbs-down to these controversial agreements were disappointed. In fact, in many ways, the lower courts must start over in deciding how to analyze them. The major short-cuts - the scope-of-the-patent and presumptive-illegality tests - are out, but the court does expect trial courts to structure their rule-of-reason inquiries to avoid the worst-case scenario of litigating the patent's validity. This new uncertainty will likely (1) lead some parties to avoid reverse payments in their settlements because of the added risk; (2) diminish the likelihood of pharmaceutical intellectual property litigation settlements because one settlement tool, the reverse payment, is now riskier; and (3) unleash the creativity of the parties, and their economists and attorneys, to structure settlement agreements to fit within the confines of this decision and subsequent lower court results.

As dissenting Chief Justice John Roberts suggested, the principle announced by the court may spill over beyond reverse-cash payments and Hatch-Waxman Act cases, and influence analysis of other forms of patent disputes. An obvious application - which companies were discussing even before this decision - concerns the biotech industry. The Biologics Price Competition and Innovation Act of 2009 creates a pathway for "biosimilar" generic drugs with important similarities to the Hatch-Waxman Act scheme. While there are also important differences, the court's *Actavis* decision will undoubtedly influence biotech companies' appetite for pursuing the "biosimilar pathway" and, consequently, the amount and character of competition in biotech drugs.

Solo and Small Firms
Firm flexes its competitive muscle
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Mergers & Acquisitions
Dealmakers
A roundup of recent mergers and acquisitions and financing activity and the lawyers involved.

Labor/Employment
LA must arbitrate with employee union over furloughs
Los Angeles must arbitrate with a public employee union over the furloughs it introduced as a budget-cutting measure in 2009, the state Supreme Court ruled Thursday in a decision that could impact other cities considering furloughs.

U.S. Supreme Court
Justices say pay-for-delay deals with generic drug makers subject to antitrust 'rule of reason'
Those expecting the Supreme Court to give a thumbs-up or thumbs-down to these controversial agreements were disappointed. By **Paolo Morante and Jarod M. Bona**

Justices rule jury must decide facts that increase mandatory minimum sentences
Justice Clarence Thomas, writing for a slim majority, overturned the court's earlier rulings that a jury verdict was not required for sentencing ranges that exceed the statutory minimum. By **Allison B. Margolin**

Administrative/Regulatory
New protections for defense contractor whistle-blowers take effect July 1
On Jan. 2, President Barack Obama signed the FY 2013 National Defense Appropriations Act, which contains new whistle-blower protections that go into effect July 1. By **R. Scott Oswald and David Scher**

U.S. Supreme Court
Justices bolster arbitrators' contract interpretations
Last week's unanimous decision in *Oxford Health* demonstrates the difficulty of getting judicial review of an arbitrator's interpretation of a contract. By **Thomas P. Gies, Jennifer Romano and Moreen O'Brien**

Litigation
Dubious trial dates causing defendants to flee ADR
From a defendant's standpoint, there is no advantage to settling a case for true value when there is no date out there when a judgment might be rendered against them. By **Eric Bonholtzer**

Judicial Profile
Mary J. Greenwood
Superior Court Judge Santa Clara County (San Jose)

Law Practice
Mayer Brown's LA office now leads firm in profitability
Boasting 40 attorneys, the L.A. office is now the busiest and most profitable of any of the Chicago-based firm's 23 outposts.

The views the authors express in this article are their own and not necessarily those of DLA Piper LLP or its clients.

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