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

Paolo Morante is a partner in DLA Piper LLP’s antitrust and competition practice, based in New York. He represents clients in commercial litigation in federal and state courts, US and international transactions, and regulatory matters before the US Department of Justice, the Federal Trade Commission and offices of the attorneys general of several states.

Jarod M. Bona is an antitrust and competition attorney in DLA Piper LLP’s San Diego office and can be reached at jarod.bona@dlapiper.com. He counsels pharmaceutical, biotech, and other technology clients on antitrust issues.

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, unsurprisingly, settlement often involves compensation to the defendant, sometimes coupled with a compromise entry date for the defendant before patent expiration.

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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 courts 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. Two months before a Legal Competition and Innovation Act of 2009 created 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.
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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