Today's GENERAL COUNSEL
AUG/SEPT 2013 VOLUME 10/NUMBER 4 TODAYSGENERALCOUNSEL.COM

Little Guidance For Lower Courts In *FTC v. Actavis*

By Leslie E. John, Jason A. Leckerman and Paul Greenberg

In June, the U.S. Supreme Court issued its long-awaited opinion in FTC v. Actavis, Inc., a decision that likely will have significant ramifications for the pharmaceutical industry. In the near term, it will embolden the Federal Trade Commission (FTC) and class action attorneys to bring additional challenges to settlements of patent infringement litigations. But more importantly, by encouraging continued litigation the case could not only impact the development and availability of new drugs but could delay the entry of generics.

In Actavis, the FTC challenged as anti-competitive under the antitrust laws settlements that brand-name and generic drug companies executed to end ongoing patent litigation when those settlements contained a cash payment from the brand to the generic companies. Under the statutory scheme for generic drug approval, known as the Hatch-Waxman Act, a generic drug manufacturer must file an application (known as an Abbreviated New Drug Application or ANDA) with the FDA before marketing its drug.

The Hatch-Waxman Act recognizes that the brand company's patents provide it with a lawful means of excluding generic competitors for a set period of time. The ANDA therefore must include a certification with respect to each of the patents used in the brand-name drug. One type, a "Paragraph IV" certification, states that the brand company's patent is invalid, unenforceable, or will not be infringed by the generic product.

When a generic files a Paragraph IV certification, it must notify the brand manufacturer, which then may decide to file a patent infringement action against the generic company. A patent infringement action filed within 45 days of the Paragraph IV notice automatically stays final approval of the generic drug for 30 months, or if and until a court rejects the infringement claim, whichever is sooner. If a generic company is the first to file an ANDA with a Paragraph IV certification, it is eligible for a period of market exclusivity of 180 days (or it may share that exclusivity if another generic has filed on the same day). Thus, generic companies strive for the lead position provided by the Act.

Consumers benefit from the development of new drugs (dynamic efficiency) and from improved access to lower-priced versions of those drugs (static efficiency). The Hatch-Waxman Act represents a compromise intended to balance the desire to allow consumers timely access to cheaper drugs with the desire to maintain brand companies' incentives to innovate. It does so mainly by providing additional protections for drug patents, while also providing incentives for generic companies to challenge these patents.

As with most business-to-business litigations (and civil litigation more generally), most Hatch-Waxman patent cases historically have settled before trial. In a small minority of cases, these settlements include a "reverse payment," meaning a cash payment from the plaintiff brand company to the defendant generic company. As part of such settlements, the parties may agree on the generic entry date.

Reverse payments have been utilized in a quarter or fewer of all settlements of Hatch-Waxman cases over the last decade. During that period, nearly all major patented brand drugs were challenged by generics, and most settlements of the ensuing patent infringement litigation assured generic entry before patent expiration.

As a result of these settlements, brand and generics achieve certainty on entry dates and generics secure greater resources and incentives, including cash incentives to challenge brands in the future.

Generics account for more than 80 percent of prescription drug volumes, a percentage that continues to grow. The effective patent life of brand drugs (i.e., time on market without a generic) has fallen. Life expectancy has increased and infant mortality has decreased in large part because of the introduction of new and improved pharmaceuticals. In other words, the Hatch-Waxman Act has been extremely successful at getting generic entrants onto the market. It has achieved its goal of increased consumer access to cheaper drugs, while preserving important incentives for innovation.

For a number of years, the FTC and class action lawyers have publicly opposed settlements that involve simultaneous financial consideration from the brand to the generic, repeatedly asking courts and Congress to consider them presumptively illegal. They have argued that these settlements amount to agreements by competitors to allocate the market

Leslie E. John is a partner at Ballard Spahr LLP and practice leader of the Antitrust Group. She concentrates on antitrust and complex litigation and has represented clients in federal and state courts and before the U.S. Department of Justice and Federal Trade Commission. **john@ballardspahr.com**

and are therefore unlawful under the antitrust laws. The FTC's complaint in Actavis asserted that the brand and generic companies violated antitrust laws when the brand company allegedly paid the generic firms cash in exchange for their agreement to abandon their challenges to the brand's patent and to refrain from marketing a generic version of AndroGel until 2015.

In upholding the trial court's dismissal of the FTC's complaint, the 11th Circuit applied the "scope of the patent" test, stating that, absent "sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."

The court recognized that patent law necessarily makes legal restraints of trade that the antitrust laws may otherwise prohibit. The court rejected the FTC's argument that reverse payments should be "presumptively unlawful."

Although the FTC and the defendants advocated in their briefs for the Supreme Court to adopt the "presumptively unlawful" and the "scope of the patent" tests, respectively, the Court, in a 5-3 vote, with Justice Breyer writing for the majority and with Justice Alito recused, opted instead for a middle ground: the rule of reason standard used for most antitrust cases. The rule of reason requires that courts balance the pro-competitive effects of a proposed restraint of trade against its anti-competitive effects. Under the rule of reason test, courts find unlawful any restraints of trade in which the anti-competitive effects outweigh the pro-competitive effects.

In other words, courts should balance the pro-competitive effects of a settlement that involves a payment from the brand company to the generic company against any anti-competitive effects.

But the Court's opinion leaves many questions. For instance, the Court emphasized that legality of the payment may depend in part on its size, both in absolute terms and in relation to potential litigation costs, as well as the absence of any justification for the payment other than to delay generic entry. The court also tried to downplay the need to assess the strength of the underlying patent or patents. The court spoke favorably of settlements that are based entirely on negotiation over entry dates.

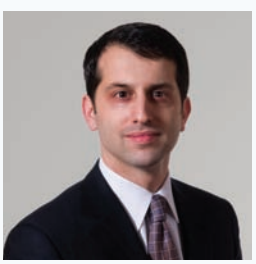
Beyond those broad parameters, the Court provided little guidance to lower courts, stating that "trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question, that of the presence of significant unjustified anti-competitive consequences."

The rule of reason test adopted by the Court presents substantial challenges and administrative burdens. Lower courts essentially will be left to develop standards for assessing reverse payments, and litigants and those they represent will have little or no certainty as to what matters. How will courts scrutinize deals that involve contemporaneous business agreements entered into by litigants? Will courts be able to assess whether a settlement is anti-competitive without assessing the strength of a patent? What does the assessment of "litigation costs" entail?

In rejecting the scope of the patent test, the Court implicitly acknowledged that it saw no need for bright-line rules for companies or to provide parties with flexibility to settle. The decision is thus a departure from previous antitrust decisions from the Supreme Court that have set bright line rules to address what the Court saw as the in terrorem effect of antitrust actions.

The Court's decision likely will have long-term, seemingly unintended, consequences for both pharmaceutical companies and consumers. As the dissenting opinion in the case observed, the decision will discourage settlement of patent litigation because, "there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue -- the question of patent validity -- as part of a defense against an antitrust suit." It likely will delay the entry of generics by reducing the incentive to challenge brand patents and discourage investments in innovation.

There will be increased litigation as litigants and the courts sort out the proper framework for these cases, and the consequences may extend beyond the pharmaceutical context. Paying an alleged infringer to drop its invalidity claim is a well-known feature of intellectual property litigation. Ultimately, this opinion may well be viewed as a Pyrrhic victory for consumers. ■



Jason A. Leckerman is a litigation partner at Ballard Spahr LLP. He focuses on antitrust, product liability, pharmaceutical, and consumer fraud litigation, and he regularly counsels clients on antitrust compliance and risk.
leckerman@ballardspahr.com

Paul Greenberg is a Managing Principal and Director of Health Economics at Analysis Group, an economic consulting firm.
pgreenberg@analysisgroup.com