Bloomberg BNA

Antitrust & Trade Regulation Report™

PATENTS

DRUGS

Actavis Court Requires Case-by-Case Analysis of Anticompetitive Effects Of Reverse-Payment Settlements




By Carl W. Hittinger, Paolo Morante, Lesli C. Esposito, and Jarod M. Bona

In a much-anticipated decision, the U.S. Supreme Court in *FTC v. Actavis, Inc.* held 5-3 that reverse-payment settlements of Hatch-Waxman Act litigation are neither immune from antitrust liability nor presumptively unlawful, but rather must be analyzed under the rule-of-reason standard on a case-by-case basis.

Carl W. Hittinger is the chairman of DLA Piper's litigation group in Philadelphia, where he concentrates his practice in complex commercial trial and appellate litigation.

Paolo Morante is a partner with DLA Piper in New York City, where he focuses on antitrust and trade regulation law.

Lesli C. Esposito is a partner with DLA Piper in Philadelphia, where she focuses her litigation practice on antitrust and unfair competition matters.

Jarod M. Bona is an antitrust and competition attorney in DLA Piper LLP's San Diego and Minneapolis offices.

In choosing the traditional antitrust standard, the decision rejected all lower court approaches to these settlements and resolved a split between the Third Circuit—which had held such agreements presumptively unlawful—and the Eleventh, Second, and Federal Circuits—which essentially had immunized the agreements as long as they fell within the exclusionary scope of the underlying patent. These lower court approaches are discussed in detail here.

Acknowledging that application of the rule of reason might require antitrust trial courts in some cases to determine the validity of the underlying patent, the Court stated 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." (Slip Op. 19). Thus, the Court directed trial judges to weigh the anticompetitive effects of a particular reverse payment by reference to "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." (Slip Op. 20).

FTC v. Actavis considerably increases the antitrust risk associated with reverse-payment settlements, leav-

ing the detailed definition of the boundaries of legality to be developed by trial courts. Careful antitrust analysis should thus continue to be a central part of any contemplated settlement of Hatch-Waxman Act litigation going forward.

In May 2003, generic drug manufacturers, including Actavis, submitted ANDAs and paragraph IV certifications for a generic formulation of AndroGel®, the patent for which was held by Solvay. Solvay filed timely infringement actions against the generic drug manufacturers. The generics argued that Solvay's patent was invalid and they should be allowed to market generic versions of the drug. In 2006, the companies reached a settlement by which the generics would not go on the market until 2015—more than five years prior to the patent expiring—and would assist Solvay in the marketing of AndroGel in exchange for payments exceeding $100 million. The Federal Trade Commission challenged the settlement, and the Eleventh Circuit, utilizing the ''scope of the patent'' test, upheld the settlement agreement. On June 17, 2013, the Supreme Court reversed the Eleventh Circuit and sent the matter back down to the lower court.

After describing the unique setting of the Hatch-Waxman Act and the underlying patent infringement lawsuit, the Court emphasized that the underlying patent ''may or may not be valid, and may or may not be infringed,'' and expressed concern about settlements in which ''plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages.'' (Slip Op. 8).

On those grounds, the Court rejected the so-called scope-of-the-patent test adopted by the Eleventh, Second and Federal Circuits and declined to immunize a reverse-payment settlement from antitrust scrutiny even when ''the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent.'' In a crucial departure from the Eleventh Circuit's decision and Chief Justice John Roberts' strongly worded dissent, both of which urged that patent validity and infringement issues should be the exclusive domain of patent law, the Court pointed to a long line of precedent and the procompetitive policies underlying the Hatch-Waxman Act to assert that ''patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly.' '' (Slip Op. 9, emphasis added). The Court also criticized the Eleventh Circuit for measuring the scope of the agreement's restriction solely against the length of the patent's term or its earning potential, instead of ''considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as [] those related to patents.'' (Slip Op. 9-10).

The Court acknowledged that its rule-of-reason approach might run counter to judicial policies favoring settlement and might lead parties to the antitrust dispute to litigate patent validity. Nevertheless, the Court set forth five considerations supporting its conclusion that the FTC should have an opportunity to prove its antitrust claim under the rule of reason.

First, ''the specific restraint at issue has the 'potential for genuine adverse effects on competition.' '' (Slip Op. 14). That is, according to the Court, the ''payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product,'' leading the patentee and the alleged infringer to split monopoly profits between themselves at the expense of consumers (Slip Op. 15). The Court found this particularly likely in the Hatch-Waxman Act context, where the 180-day exclusivity and 30-month-stay provisions enable branded manufacturers to exclude most competition by offering a sizable reverse-payment settlement to the first-to-file generic.

Second, ''these anticompetitive consequences will at least sometimes prove unjustified.'' (Slip Op. 17). The Court identified some potentially valid justifications for a reverse payment, such as avoided litigation costs or services provided by the settling generic to the patentee. Recognizing that antitrust defendants may be able to establish such justifications in some cases, the Court noted that a rule of reason analysis would enable them to do so.

Third, ''where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.'' (Slip Op. 18). The Court explained that the size of the reverse payment might be a good indicator of the branded-drug manufacturer's ability to charge supracompetitive prices and, therefore, of market power.

Fourth, ''an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed.'' (Slip Op. 18). Although litigating the patent's validity is a possibility, according to the Court it is ''normally not necessary'' to ''answer the antitrust question,'' unless, perhaps, to ''determine whether the patent litigation is a sham.'' *Id.* Instead, the Court viewed ''the size of the unexplained reverse payment'' as a ''workable surrogate for a patent's weakness.'' (Slip Op. 19). ''An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival.'' (Slip Op. 18).

Finally, ''the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.'' (Slip Op. 19). The parties, according to the Court, can settle in other ways—for example, ''by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.'' *Id.*

After rejecting the scope-of-the-patent test, the Court also declined the FTC's invitation to find reverse-payment settlements presumptively unlawful. The Court explained that such a rule, sometimes described as a ''quick-look'' analysis that shifts the initial burden onto the antitrust defendant to justify its conduct, ''is appropriate only where an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect.'' Reverse-payment settlements do not meet that test, the Court ruled, ''because the 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.'' (Slip Op. 20).

Thus, the Court concluded that these cases should be decided under the same framework as other rule-of-reason cases, but emphasized that this does not mean that antitrust litigants will be required to dispute patent validity or the overall merits of the patent system. Rather, ''as in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand,

  ATRR ISSN 0003-6021

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.''

In sum, detailed antitrust analysis should remain an essential element of any prudent settlement in the Hatch-Waxman context.