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The Supreme Court's Recent Reverse-Payment Patent-Settlement Decision:

Can The Antitrust Challenge Permitted by the Court be Limited to Pharmaceutical Patent Settlements?

by Jeffery Cross and Jill Anderson

A FREEBORN & PETERS LITIGATION WHITE PAPER

ABOUT THIS WHITEPAPER:

In its decision in *Federal Trade Commission v. Actavis Inc.*, the U.S. Supreme Court adopted the rule of reason in antitrust challenges to reverse-payment patent settlements. In this White Paper, Jeffery Cross and Jill Anderson, members of the Litigation Practice Group and the Antitrust and Trade Regulation Group, discuss how the decision will affect future cases.

On June 17, 2013, the U.S. Supreme Court released its much-anticipated decision on so-called "reverse payment" settlements between brand-name drug manufacturers and generic drug makers. *Federal Trade Commission v. Actavis* involved an antitrust challenge to the settlement of patent infringement litigation brought under the Hatch-Waxman Act. The generic drug manufacturers agreed to drop their challenge to the validity of the brand-name manufacturer's patent and also agreed to delay their entry into the market to a date later than they would have entered had they prevailed in having the patent declared invalid. In turn, the brand-name manufacturer paid the generic drug manufacturers millions of dollars. Such an agreement is called a "reverse-payment" settlement because typical patent settlements involve a payment by the alleged infringer (here the generic drug manufacturer) to the patent owner (here the brand-name drug manufacturer). In this type of case, however, the payment is the "reverse." (Because these kinds of settlement result in the generic drug manufacturer delaying entry into the market, they are sometimes also called "pay-for-delay" settlements).

In *Actavis,* the FTC sued the settling parties alleging that their agreement violated the antitrust laws. According to the FTC, reverse-payment settlements are presumptively anticompetitive because the parties are colluding to split the monopoly profits of the patent holder and delay the market entry of the generic drug, denying consumers the benefits of the lower cost generics.

The lower courts, however, reasoned that the very purpose of a patent is to enable the patent owner to exclude competitors from the market during the term of the patent. Accordingly, they concluded that the settlement was immune from antitrust attack because the agreed date for the generic to enter the market was *prior to* the expiration of the patent.

The Supreme Court reversed. In a 5 to 3 decision written by Justice Stephen Breyer, the Court held that reverse-payment settlements of the type at issue had the potential to create an anticompetitive effect without justifications and therefore warranted antitrust scrutiny under the Rule of Reason. The Court, however, also rejected the FTC's position that such agreements are presumptively illegal and should be analyzed under the abbreviated "quick look," rather than the full Rule of Reason.

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Chief Justice John Roberts, joined by Justices Antonin Scalia and Clarence Thomas, dissented. In addition to finding the majority's decision a departure from settled patent and antitrust law, Chief Justice Roberts criticized the majority's claim that its holding was limited to the unique context of patent settlements under the Hatch-Waxman Act. To the Chief Justice, a "reverse-payment" can occur in many settlements of patent litigation, not just those relating to Hatch-Waxman litigation. He found that the majority's ruling was sufficiently broad to ensnare all patent settlements that involved some sort of benefit flowing from the patent holder to the alleged infringement. In this regard, he cited various examples of reverse-payment patent settlements unrelated to the Hatch-Waxman Act. For example, when Company A sues Company B for patent infringement and demands, say $100 million in damages, if Company A settles for say $40 million, Company A has provided something of value to Company B that could be considered a form of "reverse-payment." Further, if B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim.

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The majority responded by noting that it agreed that such commonplace forms of patent settlements cited by the dissent should not be subject to antitrust liability. It emphasized that it was concerned with settlements in which a party with no claim for damages walks away with money simply so it will stay away from the patentee's market.

To understand the majority's distinction, it is necessary to understand the Hatch-Waxman Act and patent infringement litigation brought under that Act. A pioneer drug manufacturer secures a patent on a drug, but cannot market the drug without obtaining FDA approval. To gain such approval, the pioneer must engage in expensive clinical trials to prove the safety and efficacy of the drug, and file a New Drug Application with the FDA detailing, among other things, these clinical trials. Once FDA approval is granted for a branded drug, identification of the patents at issue are listed in an FDA publication known as the "Orange Book."

Prior to the Hatch-Waxman Act, a generic drug manufacturer would have to engage in similar clinical trials. However, such clinical trials *themselves* could be deemed acts of infringement of the patented drug, potentially exposing the generic company to substantial damages in infringement litigation. For this reason, manufacturers of generics often waited until the brand-name manufacturer's patent expired before beginning such clinical trials. Congress found that such delay hurt consumers by delaying the benefits of cheaper generic drugs.

The Hatch-Waxman Act, enacted in part to solve this delay problem, permits a generic drug manufacturer to forego the clinical trials by "riding-on-the-coattails" so to speak of the branded manufacturer. Under the Act, a generic drug manufacturer files an *Abbreviated* New Drug Application (called an ANDA), stating essentially that the generic is the same as the patented drug.

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When a generic company files an ANDA, it also certifies the relationship of the generic drug to any patent held by the brand-name manufacturer and listed in the Orange Book under one of four different paragraphs of the Act. Certification under paragraphs I through III state that there is no patent information listed in the Orange book, or the original patent has expired, or that the generic will not manufacture the product until the patent expires. Certification under paragraph IV states that the original patent is either invalid or will not be infringed by the generic. The filing of an ANDA with a paragraph IV certification is deemed by the Hatch-Waxman Act as an act of infringement. What is significant, however, is that the generic manufacturer is not facing any potential damages from such a "technical" infringement. Furthermore, the generic typically does not have a counterclaim for damages against the branded manufacturer. It is a "reverse-payment" settlement in such a situation that the majority is concerned about.

The question becomes how frequently would there be patent litigation in which the alleged infringer is not facing any potential damage liability and has no counterclaim for damages against the patent holder. Although there might be an occasional case for a declaratory judgment concerning anticipatory infringement where there has been no actual infringement yet, these should be few. Furthermore, settlements of such anticipatory patent infringement cases where there are reverse payments raise the very concern at the heart of the majority's decision – the payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the challenged product. Arguably, an antitrust analysis of such a settlement should be undertaken.

The Supreme Court in *FTC v. Actavis* has largely left the application of the Rule of Reason in reverse-payment litigation to the lower courts. It remains to be seen whether these lower courts will limit antitrust challenges to reverse payments under the Hatch-Waxman Act or whether Chief Justice Roberts' concern will be borne out. The majority has tried to limit the reach of its decision. The lower courts may accept such limitations. But if they do not, the situations in which antitrust challenges outside of the majority's framework may be so few that the potential adverse impact on businesses holding patents implicit in the concern raised by the dissent may be minimal.

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