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High Court Brings Economics Back To Pay-For-Delay Analysis

Law360, New York (June 17, 2013, 6:07 PM ET) -- In its much-anticipated decision in Federal Trade Commission v. Actavis Inc. et al., the U.S. Supreme Court ruled 5-3 that the analysis of so-called "reverse payment" settlements of Paragraph IV abbreviated new drug application litigation in the pharmaceutical industry should be carried out under the rule of reason. In doing so, the court resolved a circuit split, rejecting both the "scope of the patent" approach and the FTC's proposed presumption of illegality, putting the question squarely back in the realm of economics, where it belongs.

In a reverse payment settlement, the alleged infringer, a generic pharmaceutical company that has filed a Paragraph IV certification under the Hatch-Waxman Act, thereby triggering patent litigation, settles that litigation with the patentee/brand-name manufacturer as follows: The generic firm agrees not to enter the market for the drug in question until a specified future date while receiving some form of "consideration," monetary or otherwise, from the patentee.[1]

A Circuit Split

The court granted certiorari in order to address a circuit split, most notably a recent split between the Third and Eleventh Circuits. In an April 25, 2012, opinion, the Eleventh Circuit considered the FTC's allegations that Solvay Pharmaceuticals Inc., the branded manufacturer of AndroGel, a testosterone supplement, had violated Section 5(a) of the Federal Trade Commission Act. (Section 5(a) bans "unfair methods of competition" and "unfair or deceptive acts or practices.") The FTC "alleged that the settlement agreements were attempts to 'defer' generic competition with branded AndroGel by postponing the entry date of the generic drugs, thereby maintaining Solvay's monopoly and allowing the parties to share monopoly profits 'at the expense of the consumer savings that would result from price competition.'"[2]

The district court dismissed the FTC's complaint, noting that the exclusionary provisions of the settlement did not exceed the scope of the patent; indeed, they allowed generic entry before the expiration of the patent. The Eleventh Circuit agreed with the district court, stating that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anti-competitive effects fall within the scope of the exclusionary potential of the patent." A settlement's terms may extend beyond the scope of the patent if, for example, they constrain competition for products not covered by the patent or prevent entry even after expiration of the patent.

The Eleventh Circuit's view, shared by several other circuits, has become known as the "scope of the patent" approach. Advocates of that approach recognize, of course, that while patents may confer short-term market power, they are intentionally designed to do so in order to provide incentives that encourage innovation.

The Third Circuit took a very different approach in its review of a district court decision regarding another alleged reverse payment settlement. In private antitrust litigation against Schering-Plough and several generic pharmaceutical firms, the district court granted defendants' motion for summary judgment, relying on the "scope of the patent" test.[3] The Third Circuit, however, rejected that test, objecting, among other things, to the "test's almost unrebuttable presumption of patent validity"[4] and noting that "reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid."[5]

Indeed, the Third Circuit directed the district court to apply a quick look rule of reason, "treat[ing] any payment from a patent holder to a generic patent challenger as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[6]

The Supreme Court has now rejected both the "scope of the patent" approach and the quick look analysis. As it noted, agreements that appear to fall within the scope of the patent may nevertheless be anti-competitive if the patent in fact is invalid or not infringed. On the other hand, the court also rejected the FTC's proposed presumption of illegality, pointing out that the likely competitive effects of a given agreement depend on a number of factors. Therefore, a rule of reason analysis is appropriate.

In effect, the court has put the focus where it belongs, on rigorous analysis of the economic effects of the settlement agreement at issue. As we elaborate below, a given agreement's actual competitive effects cannot be discerned from simplistic characterizations of its terms.

Flaws in the FTC's Position

According to the FTC:

When parties to paragraph IV litigation settle a case by simply agreeing on a compromise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest possible entry date in order to maximize its own profits. That incentive ensures that consumer interests will receive significant protection in the negotiating process, and it provides reason for confidence that the agreed-upon entry date reflects the parties' own assessment of the likely litigation outcome. By contrast, a Hatch-Waxman settlement that includes a reverse payment allows the brand-name manufacturer to co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity.[7]

The FTC's implicit argument apparently runs as follows: If the parties have identical beliefs about the likelihood that the (brand-name) patentee will prevail in the litigation, they will agree on the "expected" time until generic entry under litigation — "expected" in the probabilistic sense. The brand-name manufacturer would refuse to allow generic entry any earlier than that expected date, and the generic challenger would refuse to settle for entry at any later date. That date, therefore, is the natural or "appropriate" date for entry under settlement, and any payment by the brand-name manufacturer to the generic firm invites the presumption that the patentee is using its monopoly profits to "bribe" the generic firm to delay its entry until a later date, to the detriment of consumers.

Suppose, for example, that the patent has 10 years left until expiration, and the parties both believe that there is a 50 percent chance that the patentee will prevail in the litigation. For simplicity, suppose, moreover, that the outcome of the trial will be revealed quickly, so that the generic challenger would enter almost immediately if it wins the litigation; if it loses, it will not be able to enter for 10 years. Then, the argument goes, the parties could settle the litigation by agreeing that the generic will enter after five years — the probability-weighted average of zero years and 10 years — without any payments. If, however, the brand-name manufacturer makes a payment to the generic firm, opponents of reverse payment settlements argue, the brand-name firm must have bribed the generic to delay entry more by more than five years.

That argument assumes that (1) a term split agreement without a reverse payment is always feasible and that (2) the patentee (the brand-name firm) would never settle for generic entry at a date that is earlier than the expected date of entry under litigation — in this example, earlier than five years from now. In fact, both assumptions may be unfounded.

For instance, the generic challenger may face liquidity constraints that make it infeasible for it to wait even three years, let alone five, to enter the market. In that case, the parties may not be able to settle the litigation without a payment from the brand-name manufacturer to the generic firm; a "reverse payment" may be the only route to settlement. Other factors, including asymmetric information and divergent discount rates, may similarly prevent a settlement without such payments.

What this means, of course, is that analysis of the competitive effects cannot proceed by comparing the settlement at issue to a hypothetical one without a payment; rather, it must compare the settlement at issue with the expected outcome of the litigation. As it turns out, a settlement with a reverse payment may in fact allow for entry earlier than might be expected with continued litigation, thus benefiting consumers.

For instance, given the sizeable cash flows generated by even the most modest branded drug, the patentee may well be risk-averse. If so, the patentee is likely to consider not only the expected outcome under litigation but also the worst-case outcome — namely, that the patentee will lose the litigation. In that case, the generic would enter almost immediately, dramatically reducing the brand-name firm's profits.

As a consequence, the brand-name manufacturer might well agree to settle the litigation by allowing the generic to enter before the expected date of entry under litigation — in this case, perhaps three years from now instead of five years from now. The certainty of knowing that the generic will not be able to enter immediately compensates for entry before the expected date under litigation. Thus, the date for generic entry to which the parties agree will not necessarily be later than the expected date had the parties litigated the patent case — even with the reverse payment. If it is not, consumers will actually benefit from the settlement.[8]

No Shortcuts

It is reassuring that the court has directed that the analysis should focus on an agreement's competitive effects. As we note above, that requires comparing the settlement to the expected outcome of the litigation. Presumably, that would require some consideration of the merits of the underlying patent suit. However, the court's suggestion that the size of the payment is a workable surrogate for the patent's weakness has no economic basis. As the dissent points out, the dollar value of the payment may reflect other considerations having nothing to do with the strength or weakness of the patent.

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[1] Because some analysts maintain that a "normal" settlement of a patent dispute includes payments by the alleged infringer to the patentee, such settlements have come to be known as reverse payment settlements. Such settlements are also sometimes known as "pay for delay" settlements.

[2] In the United States Court of Appeals for the Eleventh Circuit, No. 10-12729, Federal Trade Commission, Plaintiff-Counter Defendant-Appellant, versus Watson Pharmaceuticals Inc. Solvay Pharmaceuticals Inc. Defendants-Appellees, Par Pharmaceutical Companies Inc., Paddock Laboratories Inc., Defendants-Counter Claimants-Appellees, April 25, 2012 ("FTC v. Watson"), p. 15.

[3] United States Court of Appeals for the Third Circuit, In Re: K-Dur Antitrust Litigation, On Appeal from the United States District Court for the District of New Jersey (D.C. No. 2-01-cv-01652), filed July 16, 2012 ("K-Dur"), pp. 14-15. An earlier investigation by the FTC of the same agreements itself illustrated strikingly conflicting views about the competitive effects and legality of Schering-Plough's agreements. An administrative law judge initially dismissed the FTC's complaint, but the Commission unanimously reversed, finding that the settlements constituted unreasonable restraints of commerce. Schering-Plough then appealed to the Eleventh Circuit, which reversed the FTC's decision.

[4] Ibid., p. 27.

[5] Ibid., p. 30

[6] Ibid., pp. 32-33.

[7] In the Supreme Court of the United States, Federal Trade Commission, Petitioner v. Watson Pharmaceuticals, Inc., et al., On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit, Brief for the Petitioner, pp. 15-16.

[8] Note, moreover, that risk aversion is only one reason why the brand-name manufacturer might be willing to settle for generic entry before the expected date under litigation. The patentee may simply be unduly pessimistic about the patent litigation, or the judge or magistrate may have put particular pressure on the patentee to settle. Again, there can be no presumption that consumers would be better served if the parties were forced to litigate. For further elaboration of these and related points, see Sumanth Addanki and Alan J. Daskin, Patent Settlement Agreements, in 3 Issues in Competition Law and Policy 2127 (ABA Section of Antitrust Law 2008).