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Applying 'structured' rule of reason to reverse payments

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Last week, in a much-anticipated decision in *In re Cipro Cases I & II*, S198616, the California Supreme Court held that so-called "reverse payment" patent settlements (RPSAs) are evaluated under a specific "structured" rule of reason analysis, and rejected plaintiffs' arguments that settlement payments exceeding the costs of litigation or the value of services provided by a generic manufacturer are per se unlawful.

Reverse payment patent settlements

Under the Hatch-Waxman Act, a prospective manufacturer of a generic drug may file a streamlined application with the Food and Drug Administration that can reference the safety and effectiveness data of an existing pioneer. An application in which the manufacturer asserts that patents covering the pioneer drug are either invalid or not infringed by its product exposes the manufacturer to a potential patent infringement lawsuit. The Hatch-Waxman Act provides somewhat unusual settlement incentives (in the form of exclusive marketing and delayed follow-on generic application periods) to pioneer and first-to-file generic manufacturers. In an RPSA, the parties agree that (i) the generic will stay off the market for some period of time, up to the expiration of the patent term and (ii) the pioneer will pay the generic some compensation.

In the *Cipro* Cases, Bayer (the manufacturer of Cipro) sued Barr (the would-be generic entrant) for patent infringement. The parties then entered into an RPSA under which Bayer paid Barr almost $400 million. The California Supreme Court addressed indirect purchaser lawsuits alleging that the settlement violated California's Cartwright Act as well as California's Unfair Competition Law and common law prohibitions against monopolies. In the first state supreme court decision concerning RPSAs following the U.S. Supreme Court's decision in *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), the California Supreme Court held that such agreements can violate state antitrust law.

Application of *FTC v. Actavis Inc.*

In *Actavis*, the U.S. Supreme Court rejected the "scope of the patent test" adopted by a few courts of appeals, which stated that RPSAs are "immune from antitrust attack so long as [their] anticompetitive effects fall within the scope of the exclusionary potential of the patent." Instead, the Supreme Court held that such agreements should be evaluated under the rule of reason, and that RPSAs may raise significant antitrust issues where the amount of the payment made to the generic significantly exceeds the anticipated costs of litigation and the value of at least certain services the generic agreed to provide.

The California Supreme Court held that while *Actavis* "is not dispositive on matters of state law," "[w]hat does affect the weight to be accorded *Actavis* is the extent to which its analysis establishes the metes and bounds of patent law and policy," because "[p]atent law is federal law."

In the court's view, "a critical insight undergirding *Actavis* is that patents are in a sense probabilistic, rather than ironclad: they grant their holders a potential but not certain right to exclude." "The scope of the patent test is flawed precisely because it assumes away whatever level of uncertainty a given patent ... may be subject to."

Instead — and in the portion of its holding that extends most clearly beyond *Actavis* — the proper question to ask is: "What would the state of competition have been without the agreement? In the case of a reverse payment settlement, the relevant comparison is with the average level of competition that would have obtained absent settlement, i.e., if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination." "[T]he period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought. This expected life represents the baseline against which the competitive effects of any agreement must be measured."

'Structured' Rule of Reason Analysis

The California Supreme Court then agreed with *Actavis* that RPSAs are to be evaluated under the rule of reason, but went further by setting forth a particular "structured" version of rule of reason analysis to be applied to such settlements.

To make out a prima facie case, the court held, a plaintiff must show four elements: that (i) the settlement includes a limit on the settling generic challenger's entry into the market, (ii) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger, (iii) the consideration to the generic challenger exceeds the value of any other collateral products or services provided by the generic to the brand, and (iv) the amount of the payment, over and above the value of collateral products or services from the generic, also exceeds the brand's anticipated future litigation costs.

Once the plaintiff has shown an agreement involving a reverse payment and a delay, the defendants have the burden of production to come forward with evidence of litigation costs and the value of collateral products and services that might explain the compensation. If the defendants fail to do so, the plaintiff has satisfied its burden on these points. If a plaintiff establishes a prima facie case, the burden of proof then shifts to the defendants to offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive.

The court rejected plaintiffs' argument that every reverse payment in excess of litigation costs and collateral products and services is a per se violation of the Cartwright Act. Although the court did not specify what justifications may suffice, it did note that not "any justification will do. An antitrust defendant cannot argue a settlement is procompetitive simply because it allows competition earlier than would have occurred if the brand had won the patent action."

Finally, the plaintiff retains the ultimate burden to show that a challenged settlement is anticompetitive. If a plaintiff makes out its prima facie case and can dispel each additional justification the defendants put forward to explain the consideration, "the conclusion follows that the settlement payment must include, in part, consideration for additional delay in entering the market. That payment for delay is condemned by the Cartwright Act."

The decision is notable in three respects. First, The California Supreme Court answered a question left open by *Actavis*, namely, whether compensation other than a cash payment can trigger antitrust scrutiny, in the affirmative. Second, in addressing the fourth element above, the court's test would appear to permit a brand to compensate a generic by throwing it any number of business opportunities, so long as the terms of the arrangement are at arm's-length. Governmental antitrust regulators have not yet embraced this principle. Third, it may be the case that an RPSA is defensible despite the existence of a gratuitous payment if the period of delayed entry represents the "average" of what might exist if the validity of the patent were to be litigated. While the existence of any payment in excess of litigation costs and services might undermine a defense that the delay did not, in the end, injure consumers, and the court's discussion of the point is less than crystal clear, it seems a fair inference that such a showing might be attempted.

Conclusion

The California Supreme Court's decision in In re Cipro Cases I & II tracks the approach of the U.S. Supreme Court in Actavis, but somewhat uniquely sets forth a "structured" rule of reason analysis to RPSAs. The decision — which may be applied by federal courts addressing California state law claims, and which also may be followed by other states' courts — may increase the number of state court challenges to such settlements, while at the same time provide guidance to defendants about how to structure any defense.

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