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TRANSACTIONS

A test for reviewing payments to keep generics at bay

By Louis E. Fogel and Shaun M. Van Horn

On May 7, the California Supreme Court announced a legal framework for evaluating "reverse payment patent settlements" reviewed under California's antitrust statute (the Cartwright Act) in *In re Cipro Cases I & II*. The new test will present challenges to brand and generic companies seeking to settle patent disputes.

The case arose from a reverse payment settlement between Bayer AG and Bayer Corporation, the manufacturer of Cipro, an antibiotic, and Barr Laboratories Inc., a generic manufacturer. When Barr sought to market a generic version of Cipro, Bayer sued for patent infringement. They eventually settled the lawsuit, with Barr agreeing to postpone its generic version for 10 years. In exchange, Bayer agreed to pay Barr almost $400 million and to supply Barr with Cipro for licensed resale beginning six months before the patent was due to expire. California purchasers sued contending, inter alia, that the settlement violated the Cartwright Act.

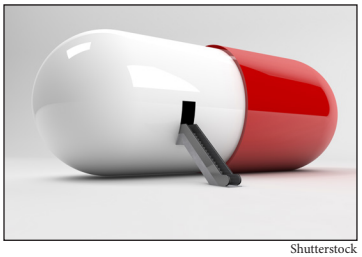
Before the state Supreme Court had the chance to review the case, the U.S. Supreme Court addressed whether reverse payment settlements are immune from scrutiny under the federal antitrust laws. In *Federal Trade Commission v. Actavis*, the court held they were not, and that these settlements should be reviewed under a rule of reason analysis. Actavis argued that because it acted within the scope of its patent, its agreement with a generic company to restrict generic competition in the market could not violate the antitrust laws. But the court did not agree that the existence of a patent can immunize an agreement from antitrust attack: "[T]he patent here may or may not be valid, and may or may not be infringed," and there should be no immunity for an invalidated patent for actions to preclude non-infringing competition. The court highlighted the risk of public harm from reverse payment settlements, noting that "payment in return for staying out of the market ... simply keeps prices at patentee-set levels."

Actavis addressed factors a court might consider in performing a rule of reason analysis of a reverse payment settlement, including "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might present payment, and the lack of any other convincing justification."

The state Supreme Court used *Actavis* as a guidepost to review the Bayer/Barr agreement under the Cartwright Act, the purpose of which was "to rein in the burgeoning power of monopolies and cartels." Although the statute technically prohibits all restraints in trade, California followed the U.S. high court's lead by interpreting it to prohibit only unreasonable restraints in trade. To be sure, the court acknowledged that the *Actavis* decision was not legally binding on its interpretation of the Cartwright Act: "States have regulated against monopolies and unfair competition for longer than the federal government, and federal law is intended only 'to supplement, not displace, state antitrust remedies.'"

Nevertheless, the court echoed *Actavis*. It found that the scope of the patent immunity defense was "flawed precisely because it assumes away whatever level of uncertainty in a given patent … may be subject to." The court focused on the concern that the public would bear a "monopoly premium," and noted that "the core policies underlying patent law are more nuanced than the cases applying a scope of patent test had recognized."

The court ruled the Bayer/Barr settlement was not immune from antitrust scrutiny and crafted a legal framework for how lower courts should apply the rule of reason analysis to such agreements. To establish a prima facie antitrust violation against the parties to a reverse payment settlement, the plaintiff must now show (1) the settlement includes a limit on the generic challenger's entry into the market; (2) that it includes cash or equivalent financial consideration flowing from the brand to the generic challenger — and that this consideration exceeds both (a) the value of goods and services other than any delay in market entry provided by the generic challenger to the brand and (b) the brand's expected remaining litigation costs absent settlement. Once the plaintiff has made out a prima facie case, the burden shifts to the defendants to show that there are pro-competitive benefits that justify the reverse payment settlement.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The *Cipro* court made a few key observations. First, "courts considering such claims should not let creative variations in the form of consideration" affect the analysis; thus, non-cash payments may support a claim. Also, that "[a] side agreement involving difficult-to-value assets might conceivably be added to a patent settlement to provide cover for the purchase of additional freedom from competition." Finally, the court made clear that its goal was to halt financial payments for delay: "If a brand is willing to pay a generic more than the costs of continued litigation, and more than the value of any collateral benefits, in order to settle and keep the generic out of the market, there is cause to believe some portion of the consideration is payment for exclusion beyond the point that would have resulted, on average, from simply litigating the case to conclusion."

The *Cipro* test presents challenges to brand and generic companies seeking to settle disputes. Unlike Actavis, which left open the means by which courts may consider settlements under the rule of reason standard, California has adopted a specific legal formula for reviewing settlements. The formula essentially prohibits using cash or other financial consideration to obtain *any* time delay for generic entry. The parties thus must either agree to a date of generic entry with the possibility of a de minimus payment, or proceed with patent litigation. This reduces flexibility in settling patent lawsuits, and may lead to more patent disputes being litigated to a final judgment.

The *Cipro* test also leaves issues open for judicial resolution. For example, parties may dispute how the drug companies value collateral benefits in a patent settlement, especially where the consideration provided for collateral goods and services is substantial vis-a-vis the patent's overall value. Defendants may try to develop more sophisticated pro-competitive justifications for the use of cash or other financial consideration to defeat prospective antitrust claims by plaintiffs, and plaintiffs can be expected to test these justifications. Finally, courts may need to develop more guidance around when the size of a reverse payment demonstrates a likely antitrust violation because payments that are small relative to the patent's value may not present a material risk to consumers, even if they arguably were made to secure an incremental delay of generic entry to the market.

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