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Calif. High Court's Cipro Ruling Is A Relief For Pharma Cos.

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Well, that was a close one. The March 3 oral argument in In re Cipro Cases I & II, Case No. S198616, left observers expecting — and the pharmaceutical industry fearing — that the California Supreme Court might one-up the U.S. Supreme Court's decision in FTC v. Actavis Inc., 133 S.Ct. 2223 (2013), and impose a stringent new antitrust test under California's Cartwright Act for settlements of brand-generic Hatch-Waxman patent infringement litigation. The result would have been a new nationwide default rule for Hatch-Waxman settlements, and a potential collision with federal antitrust and patent law and policy. And as a practical matter, initial review of those settlements might have shifted from the Federal Trade Commission to the California Attorney General's Office, which would have had a mandate to use the new tool the state Supreme Court gave it.

Instead, though, the May 7 Cipro decision hewed closely to Actavis, closely following the U.S. Supreme Court's rule-of-reason approach to these settlements. The decision shed little new light on the task before trial courts, as they try to figure out "how in the heck a trial judge (and a jury) is supposed to apply the Actavis decision to an actual case." In re AndroGel Antitrust Litig. (No. II), MDL No. 2084, Slip Op. at 2 (N.D. Ga. Oct. 23, 2013).

In Actavis, the Supreme Court held that Sherman Act Section 1 rule-of-reason analysis applies to reverse-payment settlements of Hatch-Waxman patent infringement litigation, but left "to the lower courts the structuring of the present rule-of-reason antitrust litigation." 133 S.Ct. 2223, 2238 (2013). The only factors the court identified for consideration were the reverse payment's size, its "scale in relation to the [branded firm's] anticipated future litigation costs," and any connection to "other services for which it might represent payment." 133 S.Ct. at 2237. This list, though, was not exclusive: "There may be other justifications." Id. at 2236. And although the court indicated that "it is normally not necessary to litigate patent validity to answer the antitrust question (id.), it did not close the door to the possibility that, as Justices Antonin Scalia and Anthony Kennedy had suggested at oral argument, the patent merits could form part of the rule-of-reason analysis.

The most the court could say was that, "by examining the size of the payment," the court "may well be able" to avoid "litigating the validity of the patent," and that the rule of reason does not "require the courts to insist ... that the Commission need litigate the patent's validity." Id. at 2237. Thus, while

antitrust plaintiffs understandably have sought to get as much mileage as they can out of the Court's attempts to steer clear of what Justice Scalia termed "the elephant in the room," there is still some reason to think that federal rule-of-reason analysis will have to take account of the patent merits in many cases.

The California Cipro case arose from a set of Cartwright Act complaints that were remanded to California early on in the federal multidistrict litigation, but then placed on hold while the federal litigation played out. In opposing the defendants' summary judgment motions, the plaintiffs argued that the settlement is a per se violation of the Cartwright Act, notwithstanding the federal case law, because, as the trial court put it, "horizontal agreements between competitors to allocate markets are traditionally subject to per se illegal treatment." Alternatively, plaintiffs argued that the settlement violates the Cartwright Act under the rule of reason.

Rejecting these arguments in favor of the "scope of the patent" test articulated by the federal courts, the trial court granted summary judgment for the defendants in August 2009. In an opinion that capably surveyed the then-current state of the case law on Hatch-Waxman settlements, the court of appeal affirmed, again adopting the "scope of the patent" test. Plaintiffs appealed, but the case was again stayed pending the outcome of Actavis. Finally, the case was briefed and the California Supreme Court heard oral argument on March 3.

As a practical matter, the only issue at oral argument was whether the court would decide to follow Actavis (federal antitrust case law is persuasive, but not binding, authority for Cartwright Act interpretation) or adopt a stricter standard. The lively session showed a court more than a little intrigued with the latter option. Plaintiffs' counsel's pitch for per se treatment did not get much traction, but no one pushed back when he argued that the per se rule should apply here despite Actavis because horizontal market-allocation agreements among competitors are per se Cartwright Act violations — unlike, he said, under the Sherman Act. And the court showed real interest in plaintiffs' alternative, a quick-look truncated rule-of-reason analysis.

In contrast, Barr's arguments (Bayer had settled earlier) based on the patent's strength (even $398 million represented a very small proportion of the profits that were at stake for Bayer) got very little sympathy — Justice Goodwin H. Liu pointed out that Actavis suggested that a payment directed toward mitigating even a small risk of loss embodied competitive harm. Only a few of the seven justices suggested any concern about imposing Cartwright Act liability regardless of the patent merits. The lingering impression at the close of the argument was that, over the 90 days the California Constitution gave it to issue a decision, the court would be looking hard for a California "improvement" on Actavis' murky rule of reason.

A stricter standard of review than Actavis' could have rebuilt the entire Hatch-Waxman settlement landscape. Had the decision adopted a per se or presumptively illegal standard, California law likely would have become the default antitrust rule for Hatch-Waxman settlements. And because settlements for major pharmaceutical products could hardly avoid the reach of California law, settlements of abbreviated new drug application litigation from all over the nation could end up being challenged in California, including in the already-strapped state courts. The excellent and aggressive antitrust team at the California attorney general's office would need a mandate to apply the Cipro test to significant settlements, perhaps in some instances where the Federal Trade Commission might have acted. Meanwhile, California federal courts would become especially unattractive venues for Hatch-Waxman infringement suits. And courts in the relatively few other states that do not bind themselves to federal antitrust case law might have followed suit, adopting their own more stringent tests under their own

state antitrust laws.

As it turned out, though, the Cipro decision that emerged hewed closely to Actavis. The court rejected per se liability in favor of rule of reason analysis, under which a defendant could prove that a settlement including a reverse payment whose value exceeded avoided litigation costs and the value of any "side deal" was nevertheless pro-competitive. The court suggested a little more structure than did Actavis, assigning the burden of coming forward with evidence on the value of avoided litigation costs and side deals to the defendants, at least when they were likely to have that evidence. It stated explicitly that, as Actavis implied, a showing that a settlement that "limit[s] ... the settling generic challenger's entry" and contains a reverse payment of "cash or equivalent financial consideration" (slip op. at 32) that exceeded avoided litigation costs and any side deals' value constituted "a prima facie case that the settlement is anticompetitive" (id. at 37).

But what would be considered in response to the prima facie case remains nearly as murky as it does in Actavis. Like Actavis, Cipro did not identify any considerations that would weigh in a settlement's favor. In fact, the court showed some skepticism about the very existence of these other considerations: Perhaps in a nod to plaintiffs' counsel's assertion that there are no justifications for reverse payments that exceed avoided litigation costs or the value of side deals, the court said that "we cannot say with reasonable certainty — yet — that we have posited every possible justification that might render a particular reverse payment settlement procompetitive." Slip op. at 43 (citing Actavis, 133 S.Ct. at 2236). Still, the court held out "the possibility" that a brand company's risk aversion might sometimes produce an efficient settlement despite a reverse payment exceeding avoided litigation costs. See slip op. at 41.

Unlike Actavis, though the Cipro decision repeatedly articulates the test the California court wants to apply: "[T]he limit on the monopoly that may be preserved by agreement," it stated, "is the average expected duration that would have resulted from judicial testing." Id. at 31. Thus, "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." Id. at 29; see also id. at 43 ("the relevant baseline is the average period of competition that would have obtained in the absence of settlement"). But the court does not say how one proves that average, or whose burden it is to prove it — let alone whether one could prove it without resorting in some way to the patent merits and the parties' understanding of those merits at the time of the settlement.

Just as in Actavis, the most the court could say as to the role of patent merits in the rule of reason was that "'it is normally not necessary to litigate patent validity.'" Id. at 44 (quoting Actavis at 2236). Over the long run, it may well turn out that both Cipro and Actavis will, despite the courts' best efforts, have let Justice Scalia's "elephant [back] in the room."

The Cipro court accepted the U.S. Supreme Court's invitation to develop a framework for analyzing whether "reverse payment settlements" are anti-competitive. In doing so, it built on the U.S. Supreme Court's view that a patent's term is not the benchmark to evaluate anti-competitiveness. Instead, its benchmark is the "expected" life of the patent had the parties litigated to a decision. This "average" is the likely battleground. One way or another, this battleground will implicate an assessment of the strength of a branded company's patent and its chances on infringement. This is a highly factual inquiry that will have to be decided on a case-by-case basis.

Cipro, of course, addresses an early, all-cash settlement that predates the Federal Trade Commission's review of the first Hatch-Waxman settlements. Litigants are currently struggling over whether Actavis,

on a federal level, relates only to monetary "reverse payments," or extends to other nonmonetary exchanges of value — which in theory could include licenses on other products, agreements not to launch authorized generic products, and even agreements allowing generic market entry on a date certain. Dictum in Cipro shows the California Supreme Court's intent that its test should apply equally to this wide range of these other, more nuanced ANDA settlements.

Certainly, as these cases proceed through the federal and state courts, the law regarding Hatch-Waxman settlements will continue to develop, potentially diverge and may need to be re-evaluated by the U.S. Supreme Court so that there are not inconsistent decisions regarding what constitutes a "reverse payment" under the rule of reason. Until then, litigants will have to keep a watchful eye to see if other courts adopt the Cipro test, modify it or create an entirely new framework to decide if reverse payment settlements go against the rule of reason. Practitioners will have to take the Cipro test into consideration when advising their clients whether it is advisable to settle an ANDA litigation and under what circumstances.

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