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Newsletter

In Re Cipro: California Supreme Court's "Structured" Approach to Applying the *Actavis* Standard to State Antittrust Claims

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Summary

The U.S. Supreme Court's decision in *Actavis* resolved a wide split between the appellate circuits regarding "reverse payment" settlements arising out of Hatch-Waxman litigation by holding that the "rule of reason" should be used. In the *In re Cipro Cases I & II* decision, the California Supreme Court applied the same standard, but within the bounds of its own analytic structure. This decision indicates that the policy rationale for *Actavis* – that the presumption of validity does not justify an otherwise unreasonable settlement – may be adopted by more state courts, thus providing a uniform standard for evaluating this hot-button issue.

Background

The issue addressed by the California Supreme Court in *Cipro* is the existence of so-called "pay for delay" settlements where the branded pharmaceutical company settles cases by making a so-called "reverse payment" to the generic manufacturer. In essence, these agreements permit branded manufacturers to continue selling product at branded prices, while generic companies and the public obtain certainty that a generic product will enter the market before patent expiry. Courts across the nation had been split about whether these deals presented antitrust concerns. As noted by the Court in *Cipro*, "the brand and the first-filing generic have an incentive to effectively establish a cartel through a reverse payment settlement." Slip Op. at 9. Some courts had held that the deals were presumptively valid so long as they did not extend the life of a patent, while others found them presumptively anticompetitive. In *Federal Trade Commission v. Actavis, Inc.*, 570 U.S. ___ (2013), the U.S. Supreme Court resolved the issue under federal law by finding that federal courts must evaluate Hatch-Waxman settlements under the rule of reason.

The issue remained open, however, under the various states' antitrust laws. The California Supreme Court was asked in *Cipro* to determine whether the U.S. Supreme Court's *Actavis* decision affected its prior holdings under California's state antitrust laws. In line with U.S. Supreme Court, the California Supreme Court held that such settlements must now face scrutiny under the rule of reason under a specific analytic structure.

The Cipro Dispute

The settlement agreement at issue in *Cipro* contained typical reverse payment provisions. The dispute centered on the highly successful antibiotic ciprofloxacin hydrochloride, marketed by Bayer as Cipro. Barr Laboratories, a generic manufacturer, filed an Abbreviated New Drug Application ("ANDA") for Cipro and certified that the relevant patent was invalid or not infringed by its product. Because Barr was the first to file an ANDA, it was entitled to six-month exclusivity once it received approval from the FDA to market its product, In 1997, Bayer and Barr settled their patent infringement litigation by entering into an agreement where Bayer paid Barr an immediate payment of $49 million and was allowed either (a) to sell Cipro to Barr at a reduced cost for Barr to resell to the public, or (b) to make continued payments to Barr. In exchange, Barr agreed to the validity of the relevant patent and agreed not to launch its own generic product until after patent expiry. Bayer opted to make payments to Barr under the terms of the agreement which totaled close to $400 million from 1997-2003.

Several state and federal antitrust suits followed. Indirect purchasers of Cipro, such as unions, complained that the coordinated actions by Barr and Bayer violated antitrust laws, including California's Cartwright Act. Claimants argued that the settlement allowed Bayer to continue to charge supra-competitive prices to consumers, while splitting the profits with Barr. This arrangement, according to the claimants, effectively delayed the entry of a lower-cost generic version of Cipro that would have saved purchasers millions. The claimants did not consider or address the certainty of a future generic Cipro that the settlement agreement was also providing.

The Superior Court (San Diego, Hon. Richard Strauss) court entered summary judgment against claimants after the Federal Circuit held that the settlement was valid under the Sherman Act. The California Court of Appeals affirmed, and further held that federal exclusive jurisdiction over patent law foreclosed the determination in California courts as to whether Bayer's infringement suit was objectively baseless.

The Ruling

The California Supreme Court reviewed the policies underlying antitrust and patent laws. The Court held that because patent law is federal, it was appropriate to follow the U.S. Supreme Court's determination that the presumption of patent validity does not preclude a more careful examination of patent settlements for violations of state antitrust and unfair competition laws.

The Court acknowledged that its previous standard, which avoided antitrust scrutiny so long as the life of the patent was not extended, emphasized the presumption of patent validity over antitrust concerns. The *Actavis* decision changed that valuation by finding that the presumption of patent validity "does not allow a court to skip entirely an antitrust analysis of competitive restraints within the patent's scope." Slip. Op. at 22. The *Cipro* Court held, similar to the U.S. Supreme Court, that lower courts should determine antitrust violations under the traditional rule of reason, where "inquiry is limited to whether the challenged conduct promotes or suppresses competition." Slip Op. at 25. Facts to be considered include the business at issue, the nature of the restraint, and the reason for the adoption of the restraint. *Id.*

The *Cipro* Court then set forth what it labeled the "structure of the rule of reason [analysis] as applied to patent settlements." Slip Op. at 32. To make out its prima facie case, a third-party plaintiff challenging a reverse payment agreement must show four elements: (1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services other than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement. *Id.*

In explaining the four elements, the Court was careful to note that "payment" in this context is not limited to cash transfers, but may include some side deals involving difficult-to-value assets. Slip Op. at 34. Side deals operating as "fig leaves" to eliminate competition are improper, and the Court warned that "considerable caution" is in order when evaluating settlements with side deals. *Id.*

The *Cipro* Court held that once a plaintiff establishes the elements of the reverse payment and the delay for the generic coming to market, the burden of production shifts to the defendants to come forward with evidence of litigation costs and the value of collateral products and services. Slip Op. at 36. If defendants fail in this showing, the plaintiff "has satisfied its burden on these points." If defendants meet their burden, then plaintiff carries the ultimate burden of persuasion that the reverse payment exceeds the combined values of litigation costs and other goods and services. *Id.*

After setting forth the proper "structure" for the rule of reason analysis, the *Cipro* Court held that the Superior Court and Court of Appeal had erred in treating the patent "as ironclad and us[ing] the entire period until its expiration as the relevant benchmark in order to assess whether the parties' settlement agreement had anticompetitive effects." Slip Op. at 50. The Court rejected Barr's argument that both courts below had applied the proper standard: "the rule of reason these courts applied is not the structured rule of reason . . . we articulate today. . . Accordingly, we reverse." *Id.*

The Upshot

In *Cipro*, we see that the U.S. Supreme Court's decision in *Actavis* not only resolved a split in federal courts, but also established a guide for state courts in their analysis of reverse payment agreements under state laws. As more state courts are asked to evaluate the anti-competitive effects of reverse payment agreements, and determine the applicability of *Actavis* to their own antitrust laws, the *Cipro* decision provides an initial footprint at how they might apply the rule of reason analysis. In addition, the decision joins opinions from several lower federal courts in interpreting the general teaching of *Actavis* and applying them to other specific sets of facts.

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