CLIENT ALERT

CA Supreme Court Fashions 'Structural' Rule of Reason Analysis for Pay-for-Delay Settlement Agreements

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On May 7, 2015, the California Supreme Court's ruling in *In re Cipro* made clear that so called "pay-for-delay" settlement agreements are subject to challenge under California state antitrust law. *In re Cipro Cases I & II*, No. S198616, 2015 WL 2125291 (Cal. May 7, 2015) (*Cipro*). The decision, the first for the California Supreme Court, represents the latest in a line of cases in various federal and state courts throughout the country that have sought to understand and apply the framework set forth by the U.S. Supreme Court in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (*Actavis*). The ruling aligned California's position on these "reverse" settlement agreements between pharmaceutical companies with that of federal antitrust laws as set forth by the Supreme Court *Actavis* decision in 2013.

The *Cipro* opinion offers a detailed framework California courts should follow when they consider the propriety of such agreements—a "structured" rule of reason analysis. It remains to be seen whether the nuanced rule of reason approach adopted by the California Supreme Court, will be adopted by other state courts. Moreover, the California Court's rejection of federal preemption in such cases may result in California becoming a preferred location for "pay-for-delay" class action litigation.

The Pay-For-Delay Settlement Agreement Between Bayer and Barr

The *Cipro* case arose as a result of a settlement agreement between Bayer AG and Bayer Corporation (collectively, "Bayer") and Barr Laboratories, Inc. (Barr) regarding Barr's manufacture and marketing of the generic version of Cipro, a best-selling and highly-prescribed antibiotic manufactured and marketed by Bayer. Bayer was issued a patent on the active ingredient in Cipro (the "444 Patent"), ciprofloxacin hydrochloride, in 1987, and the patent expired in 2003. In 1991 (twelve years before the Cipro patent was set to expire), Barr utilized the expedited approval process provided for under the Hatch-Waxman Act and filed an application to market a generic version of Cipro.[1] Barr provided notice to Bayer of its intent to market the generic drug, and in response, Bayer filed a patent infringement suit against Barr. In 1997, the parties settled, and under the terms of the settlement agreement, Barr agreed to a consent judgment affirming the patent's validity and to postpone marketing its generic version of Cipro until the Cipro patent expired. In return, Bayer agreed to make payments to Barr, which ultimately totaled $398.1 million over the life of the agreement, and to supply it with Cipro for resale beginning six months after the patent expired.

The Lower Courts Appl[ied] a "Scope of the Patent" Test, [and] Dismiss[ed] the Complaint

Following the execution of the settlement agreement, a class of indirect purchasers in California filed a series of coordinated class action lawsuits, alleging that the Bayer-Barr reverse payment settlement violated the Cartwright Act (Bus. & Prof. Code, § 16700). The class further argued that "the 1997 agreement preserved Bayer's monopoly and ability to charge supracompetitive prices at the expense of consumers" and that "Bayer in turn split these monopoly profits with Barr."

In the initial round of decisions, the trial court granted summary judgment in favor of the defendants, holding that "the settlement agreement did not restrain competition longer than the exclusionary scope of the 444 Patent," and as a result, did not violate the Cartwright Act. The Court of Appeal affirmed the trial court, and also held that "agreements restraining competition within the scope of a patent are lawful unless the patent was procured by fraud or the suit to enforce it was objectively baseless." This test became known as the "scope of the patent" test.

In Reversing, the California Supreme Court Fashions a "Structured" Rule of Reason Analysis

In the *Cipro* decision, however, the California Supreme Court rejected the Court of Appeal's "scope of the patent" test. It noted that the assumption that a patent is valid throughout the patent's life incorrectly presumes the validity of patents in most cases and "assumes away whatever level of uncertainty a given patent ... may be subject to." The court further criticized that the "scope of the patent" test "accords excess weight to the policies motivating patent law," and "gives insufficient consideration to the concerns animating antitrust law."

Relying on *Actavis*, the California Supreme Court held that "for antitrust purposes patents are no longer treated as presumptively ironclad," and that "the period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought." As a result, a patent only grants immunity for monopolistic conduct over the course of time that "would have resulted from judicial testing." In other words, if a court had found the patent invalid after 6 years, that 6 year period constitutes the statutory grant of immunity. Following the *Actavis* requirement that the antitrust implications of reverse payment settlements be analyzed under the rule-of-reason, the California Supreme Court fashioned its own "structured" rule-of-reason analysis.

The California Supreme Court's "structured" rule-of-reason analysis sets forth a five-step process. First, the plaintiff must show that an agreement contains both a limit on the generic manufacturer's entry into the market and that it includes a measure of compensation from the patent holder to the generic. Second, if the plaintiff makes that initial showing, then it is the defendant's burden to identify the litigation costs or the value of collateral products or services that could justify the payment. Third, if the defendants meet their burden, the burden of proof then shifts back to the plaintiffs to prove that the compensation exceeds the reasonable value of litigation costs/collateral products identified by defendants.[2] Fourth, if plaintiffs establish a prima facie case by demonstrating that the compensation under the settlement agreement exceeds the litigation costs/collateral products, the defendants then have the opportunity to provide additional justifications to demonstrate that the settlement agreement is in fact procompetitive. Fifth, the plaintiffs then get a final opportunity to dispel defendants' procompetitive justifications.

Defendants argued, among other things, that the California Supreme Court's "structured" rule-of-reason analysis is preempted by *Actavis*, but the California Supreme Court noted that *Actavis* "offered only broad outlines and explicitly left to other courts the task of developing a framework for analyzing the competitive effects of reverse payment patent settlements." Federal and state courts across the country continue to do just that, with inconsistent results. It is unclear whether other courts will adopt the California Supreme Court's very specific rule-of-reason test when analyzing reverse payment settlements. But one thing is clear—the California Supreme Court's "structured" rule-of-reason test represents a forceful and easily applied test for other courts to replicate. Time will tell if they do so.

[1] Under the Hatch-Waxman Act, a prospective generic drug manufacturer can file a streamlined application asserting a generic drug's bioequivalence with an existing drug. The prospective manufacturer must make one of four certifications in its application: (i) that there is no underlying patent, (ii) that the patent is expired, (iii) that the patent will expire, or (iv) that the patent is invalid or will not infringe the brand name drug. The prospective manufacturer must then provide notice to all affected patent holders. *See* 21 U.S.C. § 355

[2] The California Supreme Court described its logic in evaluating the compensation paid under the settlement against the litigation costs/value of collateral products or services. It wrote that "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concerns that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above."

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