# Tackling 'Pay-For-Delay' In California Supreme Court

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Last month, the California Supreme Court granted a petition for review to consider the legality of "pay-for-delay" agreements. Under these agreements, also referred to as "reverse payment settlements," a branded drug maker pays manufacturers of generic versions of the branded drug to abandon a patent challenge and delay offering the generic versions on the market.

### Overview of the Circuit Split

There is currently a split among the federal courts of appeal over the legality of pay-for-delay agreements under the Sherman Antitrust Act. The Sixth Circuit and District of Columbia Circuit fall in the first camp: Pay-for-delay agreements are *per se* unlawful under the Sherman Act because they are horizontal agreements with the purpose of eliminating competition. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Andrx Pharms., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799 (D.C. Cir. 2001). The Second, Eleventh, and Federal Circuits fall in the second camp: Pay-for-delay agreements are neither *per se* unlawful nor unreasonable restraints on competition if they fall within the exclusionary scope of the patent. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

There are pending pay-for-delay cases before the Third Circuit and the Eleventh Circuit: *In re K-Dur Antitrust Litigation*, Nos. 10-2077, 10-2078, 10-2079 (3d Cir.), and *In re Androgel Antitrust Litig.*, No. 10-12729 (11th Cir.). The federal district courts in both of those cases concluded that because the agreements were within the patent's scope, they did not violate the Sherman Act. Oral argument was held before the *Androgel* court on May 13, 2011, and before the *K-Dur* court on December 12, 2011. No opinion has yet been published by either court.

Based on its prior decisions in *Valley Drug* and *Schering-Plough*, it is likely that the Eleventh Circuit will conclude that the pay-for-delay agreement at issue does not violate the Sherman Act if the agreement falls within the exclusionary scope of the patent, absent any major factual distinctions. Because *K-Dur* will mark the first pay-for-delay case before the Third Circuit, it is currently unknown where the court will fall.

## Where California Stands in Relation to the Circuit Split

California currently falls within the second camp alongside the Second, Eleventh and Federal Circuits based on the California Court of Appeal's decision in *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Cal. Ct. App. 2011), *rev. granted and opinion superseded* (Feb. 15, 2012). The Superior Court of California and the California Court of Appeal concluded that the at-issue pay-for-delay agreements were neither per se unlawful nor violated the rule of reason under California's Cartwright Act.

The pay-for-delay agreement controversy began when Bayer's patent on the antibiotic Cipro was set to expire at the end of 2003. *Id.* at 170. In 1991, Barr Pharmaceuticals Inc., a generic manufacturer, challenged the validity of the patent pursuant to the Hatch-Waxman Act, which gives the first drug manufacturer to successfully dispute a patent an incentive in the form of 180 days to begin exclusively marketing a generic version of that drug, and filed for approval of a generic version of Cipro. *Id.* at 170-71.

After receiving notice of Barr's application, Bayer sued Barr for patent infringement. *Id.* In 1997, the parties reached a settlement under which Bayer ultimately paid Barr $398 million to accept the validity of Bayer's Cipro patent and to defer introducing a generic version of the drug for the duration of the patent. *Id.*

In 2000 and 2001, direct and indirect purchasers of Cipro filed a number of antitrust actions in federal courts, alleging that Bayer and Barr's pay-for-delay agreement violated antitrust laws. *Id.* at 172. Ultimately, these cases were appealed to the Federal Circuit and the Second Circuit. *Id.* at 172-74. Both courts concluded that the competitive restraint in the settlement was within the scope of the patent. *Id. See also Ciprofloxacin*, 544 F.3d 1323; *Tamoxifen*, 466 F.3d 187.

Consequently, the plaintiff consumers in related California state court actions sued Bayer and Barr, asserting three causes of action, including violations of the Cartwright Act. The plaintiffs primarily alleged that Bayer entered into unlawful and anti-competitive agreements with its competitors to preserve an exclusive right to manufacture and market Cipro in California, causing: (1) increased costs of Cipro; (2) increased profits to Bayer as a result of the exclusivity; and (3) large payments to be made to other parties for not producing a generic form of the drug. *Cipro Cases I & II*, 2009 WL 2700124, slip op. at 1 (Cal. Super. Ct. Aug. 21, 2009).

### *Superior Court of California Decision*

The California Superior Court granted summary judgment to Bayer, concluding that the pay-for-delay agreements did not violate the Cartwright Act because:

1. They did not fall outside the exclusionary scope of Bayer's patent;

2. The patent suit brought by Bayer against Barr was not objectively baseless; and

3. The plaintiffs failed to establish that the settlement was "otherwise unlawful." *See id.* at 1.

First, the court concluded that the pay-for-delay agreement was not *per se* unlawful under the Cartwright Act. That there was no California authority to the contrary and that California law “favor[ed] settlements” weighed in favor of the conclusion that the agreements did not exceed the scope of the patent holder’s right to exclude all patent infringers from marketing generic versions of Cipro. *Id.* at 2.

Further, relying on the similarity of the Cartwright Act and the Sherman Act and California courts’ use of federal precedent under the Sherman Act, the court cited the Second Circuit, Eleventh Circuit, and Federal Circuit decisions to conclude that the pay-for-delay agreements were likewise not per se unlawful under analogous federal law. *Id.* at 3.

Second, the court concluded that the agreement did not violate the “Rule of Reason” under the Cartwright Act, where a violation occurs if the conduct “unreasonably impairs competition and harms consumers” and is therefore an “unreasonable restraint of trade.” *Id.* at 3. As with the *per se* illegality analysis, the Superior Court noted that there was no governing California authority, and therefore relied extensively on the Federal Circuit’s decision in the related *Ciprofloxacin* case, which held that the pay-for-delay agreement fell within the “exclusionary zone” of the patent and accordingly, no antitrust remedy was available. *Id.* at 4.

Further, the court again looked to California antitrust and patent case law as standing for the proposition that “conduct falling within the scope of a patent is not an antitrust violation.” Relying extensively on *Fruit Machinery Co. v. F.M. Ball & Co.*, 118 Cal. App. 2d 748 (Cal. Ct. App. 1953), the Superior Court reasoned that California law supports the conclusion that unless an agreement goes “beyond the scope of the patent rights,” there is no antitrust violation.

Based on the scope of coverage of the patent, the Superior Court ruled that Bayer had the right to exclude infringing competition from all forms of generic Cipro. The agreement between Bayer and Barr “precluded no more competition than was already precluded under the patent.” *Cipro Cases I & II*, 2009 WL 2700124, slip op. at 5. Finally, the court noted that the size of the payment to Barr was of no significance to the antitrust analysis. *Id.* at 6.

*California Court of Appeal Decision*

The California Court of Appeal affirmed the Superior Court’s decision and held that pay-for-delay agreements did not violate the Cartwright Act “[b]ecause the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the [] patent.” *Cipro Cases I & II*, 134 Cal. Rptr. 3d at 169.

The Court of Appeal relied heavily on the Second Circuit’s decisions in *Tamoxifen* and *Arkansas Carpenters*, the Eleventh Circuit’s decisions in *Valley Drug* and *Schering-Plough*, and the Federal Circuit’s decision in *Ciprofloxacin* to conclude that “[u]nder the Cartwright Act, as under the Sherman Act, the ‘illegal per se’ designation is reserved for agreements or practices that have a pernicious effect on competition and lack any redeeming virtue.” *Id.* at 184. Because the pay-for-delay agreements did not restrain competition outside of the exclusionary zone of the patent, and important public policies underlying patent law and favoring settlement of patent litigation, the court held that the agreements were not per se unlawful. *Id.*

Applying the "Rule of Reason" test and the Federal Circuit's analysis, the Court of Appeal also noted that because patents are presumed valid and provide patent holders the right to exclude others from marketing the patented invention, the patent holder—here, Bayer—is "legally entitled" to a monopoly over the patented invention. *Id.*

Therefore, Bayer and Barr's settlement of Bayer's patent infringement suit did not violate the Cartwright Act's "Rule of Reason" if it only restrained competition within the scope of the patent, unless the patent was procured by fraud or the patent enforcement suit was objectively baseless. *Id.* Mirroring the Superior Court's analysis, the court looked to *Fruit Machinery* to construe California antitrust law as confirming the rule that a pay-for-delay agreement only restrained competition if it exceeded the exclusionary scope of the patent. *Id.* at 184-85. Accordingly, the court reasoned that reverse payment settlements "are a natural byproduct of patent litigation under the Hatch-Waxman Act and . . . a rule prohibiting them could harm competition by reducing the incentive to challenge patents by reducing the challenger's settlement options in a suit for infringement." *Id.* at 185.

Significantly, the court did not reject the Sixth Circuit's analysis in *Cardizem* but instead distinguished that case on the grounds that the pay-for-delay agreement at issue in that case restricted "noninfringing and/or potentially noninfringing versions" of a generic drug—and thus, "restrained competition beyond the exclusionary zone of the subject patent." *Id.* at 185-86.

*California Supreme Court and Impact of Pending Cases*

On February 15, 2012, the California Supreme Court granted the plaintiffs' petition for review of the California Court of Appeal's decision in *Cipro Cases I & II*. It is currently unknown if the pending Third and Eleventh Circuit decisions will impact the California Supreme Court's decision, but it seems likely that the California Supreme Court will affirm the decision of the Court of Appeal absent a departure from the weight of federal authority.

Unless the Eleventh Circuit departs from its precedent in *Valley Drug* and *Schering-Plough*, it seems likely that the California Supreme Court will affirm the California Court of Appeal for two reasons. First, as the California Court of Appeal noted, California courts had not previously dealt with pay-for-delay agreements. As noted by both the Superior Court and the Court of Appeal, however, California case law supports settlement of patent infringement suits and the general limitation of antitrust liability to patent holders who act beyond "that which was necessary or incidental to the scope of [its] patent." *See Fruit Machinery*, 118 Cal. App. 2d 748.

Second, in light of the lack of state-specific case law on pay-for-delay agreements, the fact that California does not have any governing authority on pay-for-delay agreements gives more weight to the federal decisional law on the issue, supported by California courts' previous reliance on the Sherman Act in construing the Cartwright Act.

Assuming that the California Supreme Court agreed with: (1) the Court of Appeal's construction of California antitrust and patent case law; and (2) the relevance of federal decisions on the Sherman Act, it seems unlikely that the California Supreme Court will reverse the Court of Appeal's decision. The exception would probably involve any significant shift in the circuit split or the Third Circuit joining the Sixth and District of Columbia Circuits. Regardless of how the California Supreme Court rules, it is safe to say that in 2012, we should watch for how state and federal courts deal with the growing frequency of pay-for-delay agreements.

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