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'Pay for delay' settlements gain staying power under antitrust law

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Foreclosing the most promising non-federal venue for plaintiffs challenging "pay-for-delay" settlements, whereby branded drug makers pay to delay the introduction of generic medications, a California state appellate court affirmed summary judgment under state antitrust law for defendants Bayer AG and Barr Laboratories Inc. *In re Cipro Cases I & II*, 2011 DJDAR 15988 (4th Dist. Oct. 31, 2011).

Bayer's patent on antibiotic Cipro was set to expire at the end of 2003. In 1991, Barr challenged the validity of the patent pursuant to the Hatch-Waxman Act, which gives the first successful challenger a 180-day exclusivity period to market their generic version before other generic drug makers are allowed to compete. Bayer promptly sued Barr for patent infringement. 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.

Following the settlement, Bayer filed a request for reexamination of the patent with the U.S. Patent and Trademark Office (USPTO), which confirmed the patent's validity. Bayer also successfully fought off several challenges to the patent from other generic drug makers. In 2000 and 2001, direct and indirect purchasers of Cipro sued in federal district courts alleging that Bayer and Barr's reverse payment settlement violated the antitrust laws.

The courts consolidated the cases in the U.S. District Court for the Eastern District of New York, which granted summary judgment to defendants, noting that the settlement had not prevented other generic drug companies from challenging the patent's validity. The U.S. Court of Appeals for the Federal Circuit (in the indirect purchaser case) and the 2nd U.S. Circuit Court of Appeals (in the direct purchaser case) affirmed because the competitive restraint was within the scope of the patent. Since a patentee had the right to exclude all competition with its patent, it could choose to pay competitors to acquiesce in that exclusion.

Adopting the reasoning of the 2nd Circuit and Federal Circuit, the 4th District concluded that as long as the patent was not procured by fraud and the enforcement suit was not objectively baseless, the settling parties could agree to restrain competition within the scope of the patent. In applying California's antitrust statutes, the Cartwright Act and unfair competition law, the court found the federal appellate courts that have upheld such reverse payment settlements to be more persuasive than the one federal appellate court that has not.

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staying power of reverse-payment settlements, adding to the growing weight of authority supporting the validity of these settlements under antitrust law.

In siding with the 2nd Circuit and Federal Circuits, the 4th District distinguished a 6th U.S. Circuit Court of Appeals case that found a reverse payment settlement involving the drug Cardizem to be illegal per se. There, the generic drug maker had agreed not to market other bioequivalent or generic versions of the drug that were not at issue in the litigation and further agreed to not introduce a generic version during its 180-day exclusivity period. The court deemed such concessions to be beyond the scope of the patent. The court further concluded that per se treatment was inappropriate because, among other reasons, judicial policy favored encouraging settlement.

For now, this case significantly bolsters the staying power of reverse-payment settlements, adding to the growing weight of authority supporting the validity of these settlements under antitrust law. The court's decision, however, is binding only on state trial courts. The Federal Trade Commission, having lost a challenge to a similar pay-for-delay settlement in the 11th U.S. Circuit Court of Appeals, has recommended that Congress pass legislation banning the practice.

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