INNSIGHT
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GENERICSWEB
THE SEARCH IS OVER

INNsight article by Frederick (Rick) R. Ball, March 2012

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Not Just the FTC Anymore: California's Top Court to Weigh In on "Pay for Delay"

On March 14, 2012, the California Supreme Court granted a petition for *certiorari* to review *In Re: Cipro Cases I and II*. These cases involve an alleged "pay for delay" deal between Bayer and Barr.

In August 2002, lawyers for a class of California consumers and third-party payors filed a lawsuit alleging that Barr Laboratories, Inc. ("Barr") and Bayer Corporation ("Bayer") violated the Cartwright Act and the Unfair Competition Act, both California state laws. In essence, the plaintiffs argued in their suit that Bayer improperly paid $398.1 million to Barr Laboratories to avoid litigation over certain patents issued related to ciprofloxacin hydrochloride. In October 2011, the an intermediate California appellate court upheld the trial court's ruling granting judgment in favor of the defendants, Bayer and Barr. In reaching its decision, the appellate court relied on a decision of the federal Second Circuit Court of Appeals in *In Re: Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2nd Cir. 2006), and determined that neither the Cartwright Act nor the California Unfair Competition Act provided a basis for a lawsuit because the Bayer/Barr settlement arose out of a good faith patent dispute. In addition, the California appellate court determined that federal patent law preempted or foreclosed the claims brought by the plaintiffs. Attorneys for the plaintiffs then filed a petition for *certiorari* (or review) with the California Supreme Court. The California Attorney General and several other interested parties weighed in with separate briefs. The California Supreme Court has now granted the petition for *certiorari*, and will review the Bayer/Barr agreements to determine if they violate the California antitrust and unfair competition laws.

Both the plaintiffs and the California Attorney General argue that the appellate court should have analyzed the claims under the definition of an illegal "trust" under the Cartwright Act, and they claimed in their papers that the arrangement between Bayer and Barr fell precisely within the Cartwright Act because the agreement

(1.) "to limit or reduce the production, or increase the price of Cipro (Bus. & Prof. Code, § 16720, subd. (b).); (2) "to prevent competition in manufacturing, making, transportation, sale or purchase of" Cipro (Bus. & Prof. Code, § 16720, subd. (c).); and (3) "to pool, combine or directly or indirectly unite any interests that" Bayer and the generic drug maker, Barr, "may have connected with the sale or transportation of Cipro, "that its price might in any manner be affected" (Bus. & Prof. Code, § 16720, subd. (e)(4).). Under our state law, because these agreements are trusts, they are "unlawful, against public policy [,] and void." (Bus. & Prof. Code, § 16726.)

The Attorney General went on to point out that Bayer could assert in response as an affirmative defense to the alleged violation of the Cartwright Act that the commercial impact of the "pay for delay" deal did not violate the Act, and that the terms of the agreement with Barr were appropriate as a settlement of a bona fide patent dispute. The Attorney General argued, however, that the appellate court should have considered evidence relating to the strength of the underlying patents at issue in deciding whether the impact of the agreements between the brand and generic manufacturers had anticompetitive consequences.

In addition, both the plaintiff and the Attorney General argued that federal patent law did not preempt the state law antitrust claims because no conflict existed between the enforcement of the state's antitrust laws and federal patent law because, according to the Attorney General, "patent law does not protect, encourage, or preempt sham litigation claims made under state antitrust laws." The Attorney General also argued that there was a strong presumption against the federal preemption of state antitrust laws.

While it is certainly not clear that the California Supreme Court will reverse the decision of the intermediate appellate court, the acceptance of review by California's highest court presents some risk related to the vulnerability of "pay for delay" deals under state antitrust and unfair competition laws. We expect that numerous parties will weigh in during the briefing of the appeal on the merits. In addition, since California represents one of the largest purchasers of drug products through its Medicaid program, a decision overturning the appellate court's ruling could have a significant ripple effect in that a reversal may result in additional lawsuits being filed in States having similar antitrust laws.

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