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California Supreme Court Scrutinizes Reverse Payment ANDA Settlements

Article By:

Courtenay C. Brinckerhoff

In In Re Cipro Cases I & II, the California Supreme Court laid out a four-part rule of reason analysis for evaluating ANDA settlements that involve a reverse payment to the generic challenger (also referred to as “pay for delay” settlements). Although the court’s decision interprets state antitrust laws, it may influence other states applying similarly structured laws and could be of interest to district courts applying federal antitrust laws, since it purports to follow the Supreme Court’s guidance in FTC v. Actavis.

The Settlement At Issue

The ANDA settlement at issue stemmed from the ANDA filed by Barr Laboratories, Inc. on Bayer’s blockbuster antibiotic, Cipro. As summarized by the court:

> Under the terms of the settlement, Barr agreed to postpone marketing a generic version of Cipro until [U.S. patent 4,670,444] expired. It also agreed to a consent judgment affirming the patent‘s validity and to modification of the certification in its FDA application from a paragraph IV certification, alleging invalidity, to a ?paragraph III? certification, seeking to market a generic drug upon patent expiration. …. In return, Bayer agreed to make payments to Barr and to supply it with Cipro for licensed resale beginning six months before patent expiration. (See In re Ciprofloxacin Hydrochloride Antitrust Lit., supra, 544 F.3d at pp. 1328–1329.) This head start mirrored the 180-day duopoly the Hatch-Waxman Act would have provided Barr if it had succeeded in showing invalidity or noninfringement of Bayer‘s patent…..Barr was to receive Cipro from Bayer at 85 percent of current price.

As noted by the court, pursuant to this agreement, Bayer paid Barr $398.1 million between 1997 and 2003, while Bayer’s profits on Cipro exceeded $1 billion.

California’s Four-Part Test

The court set out the following four-part test that an antitrust plaintiff must satisfy to make out a*prima* *facie* case that a reverse payment patent settlement amounts to an unlawful restraint of trade under California antitrust laws:

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 the sum of
3. the value of goods and services other than any delay in market entry provided by the generic challenger to the brand and
4. the brand's expected remaining litigation costs absent settlement.

In discussing part (3) of this test, the court cautions that "side deals should not be permitted to serve as fig leaves for agreements to eliminate competition."

While noting that the ultimate burden of persuasion rests on the antitrust plaintiff challenging the legality of the settlement, the court allocated the burden of production for elements (3) and (4) to the defendants:

> [Once a plaintiff has shown an agreement involving a reverse payment and delay, the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services. If the defendants fail to do so, because, e.g., there was no side agreement or because they do not dispute the collective amounts fall short of any payment to the generic, the plaintiff has satisfied its burden on these points. If instead the defendants do so, the plaintiff must carry the ultimate burden of persuasion that any reverse payment exceeds litigation costs and the value of collateral products or services.

The California Supreme Court made clear that these four elements "are not only necessary but also sufficient to make out a prima facie case that the settlement is anticompetitive." Once these elements are established, the burden shifts to the defendants "to offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive." In so doing, the court rejected arguments that it should declare "every reverse payment in excess of litigation costs and collateral products and services a per se [antitrust] violation," but did not offer any examples of procompetitive justifications.

A Different Scope Of The Patent

Prior to the Supreme Court decision in *FTC v. Actavis,* some courts (including California courts) applied a "scope of the patent" test to evaluate ANDA settlements, and upheld them as long as they did "not restrain competition longer than the exclusionary scope of the … patent." The California

Supreme Court found that this approach was too favorable to patents that had been challenged in an ANDA proceeding. Instead of deeming the scope of a patent equivalent to its statutory patent term, the court explained that this analysis should reflect the likely validity of the patent:

> Consider a patent with a 50 percent chance of being upheld. After litigation, on average, consumers would be subject to a monopoly for half the remaining life of the patent. A settlement that allowed a generic market entry at the midpoint of the time remaining until expiration would replicate the expected level of competition; the period of exclusion would reflect the patent's strength. But a settlement that delayed entry still longer would extend the elimination of competition beyond what the patent's strength warranted; to the extent it did, the additional elimination of the possibility of competition would constitute cognizable anticompetitive harm.

Thus, according to the California Supreme Court, "the period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought. This expected life represents the baseline against which the competitive effects of any agreement must be measured." The court assumes that the brand and generic will make this calculation when negotiating settlement, and assumes that any reverse payment reflects a market entry that is not justified by the patent's strength:

> [O]ne would expect rational parties that settle to select a market entry point roughly corresponding to their joint expectation as to when entry would have occurred, on average, if the patent's validity and infringement had been fully litigated. …. If market entry were substantially later than the generic thought it could obtain through litigation, the generic would be unwilling to settle and forgo the additional profits it thought it could earn from an earlier entry; conversely, if the entry were substantially earlier than the brand thought it could obtain through litigation, the brand would not settle and forgo an additional period of monopoly. Absent payment, one can accept an agreement to postpone market entry as a fair approximation of the expected level of competition that would have obtained had the parties litigated; absent payment, any delay in entry may be attributed to the effective strength of the challenged patent, rather than the settlement agreement.

Impact Beyond California

It will be interesting to see if other state and federal courts follow California's lead. Overall this decision does seem to be consistent with the anti-patent tenor of *FTC v. Actavis*, where the majority discussed the "anticompetitive" nature of patents and the need to ensure that reverse payment settlements do not "work unjustified anticompetitive harm," even if they already fall within the scope of the patent as granted.

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