The Federal Circuit *Cipro* Decision: Another Blow to the FTC's Fight Against Reverse Payment Settlements

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Yesterday, the Court of Appeals for the Federal Circuit weighed in on the contentious issue of reverse payment patent settlements in the pharmaceutical industry. The Federal Trade Commission had filed an amicus brief urging reversal of the district court's grant of summary judgment to the defendants, arguing that the lower court failed to apply the proper legal standard. Following the lead of the Second and Eleventh Circuits, however, the Federal Circuit held in *In re Ciprofloxacin Hydrocholoride Antitrust Litigation*[1] that, absent additional anticompetitive restraints, reverse payment settlements of a bona fide patent litigation are "within the exclusionary zone of the patent, and thus [cannot] be redressed by federal antitrust law."[2] The court rejected any notion that reverse payment patent settlements should be *per se* unlawful. The court also rejected the argument that the exclusionary power of the patent should include a consideration of the uncertainty of patent validity. Following the Eleventh Circuit, the court held that absent evidence of the fraud on the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a reverse payment settlement. The Federal Circuit's decision is therefore another rejection of the analytic framework advocated by the Federal Trade Commission to deal with reverse payment patent settlements, and represents an important new development for companies confronted with these issues.

Background

In October 1991, Barr Labs., Inc. ("Barr") filed an abbreviated new drug application ("ANDA") with the FDA to distribute a generic version of Cipro, a branded drug whose patent was held by Bayer Corp. and Bayer AG (collectively, "Bayer"). Bayer thereafter sued Barr for patent infringement. On the eve of trial, the parties entered a settlement agreement wherein Barr agreed not to challenge the validity of the Cipro patent and not to manufacture a generic version of the drug until six months before the patent expired. In exchange, Bayer agreed to make payments (characterized as "reverse payments") to Barr that totaled $398 million.

In 2000 and 2001, various plaintiffs filed suit, arguing that the settlement constituted an illegal market allocation in violation of Sections 1 and 2 of the Sherman Act because the reverse payments represented payments not to compete.[3] On cross-motions for summary judgment, the Court denied the plaintiffs' motion and granted Bayer's, holding that the settlement did not violate antitrust law because any anticompetitive effects flowed from the exclusionary zone of the Cipro patent itself. In other words, the settlement caused no anticompetitive effect beyond that already caused by the lawful right to exclude others from using the Cipro patent.

The Federal Circuit's Decision: The Analytic Framework

The Federal Circuit's decision rejected three key arguments that plaintiffs in this case and others have advanced to challenge the validity of reverse payment patent settlement agreements:

- First, the Federal Circuit rejected the plaintiffs' allegation that the settlement was *per se* illegal. The Court noted that courts will presumptively apply the rule of reason analysis and

an agreement is *per se* illegal only if the agreement has a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit[s]."[4] The Federal Circuit concluded that the record provided no basis to "confidently predict" that the Cipro settlement would have a pernicious anticompetitive effect, and the district court therefore properly applied the rule of reason.[5]

- Second, the Federal Circuit held that the district court properly applied the rule of reason by determining whether the anticompetitive effects of the settlement were within the "zone of exclusion" of the patent.[6] The Court noted that "a patent by its very nature is anticompetitive" and that it grants the inventor "the right to exclude others."[7] The district court concluded, and the Federal Circuit agreed, that the settlement caused no anticompetitive effects beyond those associated with the lawful right to exclude others from using the Cipro patent because (a) the settlement permitted Barr to enter the market before expiration of the Cipro patent, and (b) the generic defendants had not retained their 180-day exclusivity period or otherwise delayed the entry of other generic manufacturers.[8] The Court also cited to the "long-standing policy in law" in favor of settlements. Accordingly, the Court concluded, Bayer's actions were not precluded by the Sherman Act, even though it may have had "some adverse effects on competition."[9] The Court also held that provisions in the settlement that the generic defendants would not challenge the validity of the Cipro patent did not violate antitrust laws. The Court found these provisions to be common in settlement agreements, and the record showed that other generic companies had filed ANDAs, illustrating that the settlement did not prevent challenges to the validity of the Cipro patent.
- Third, the Federal Circuit rejected the argument that the district court improperly failed to consider the uncertainty of patent validity when determining whether the anticompetitive effects of the settlement fell within the exclusionary power of the patent. Rejecting the FTC's arguments, the Federal Circuit held that any consideration of this uncertainty would not be appropriate unless there was evidence of fraud on the PTO or sham litigation.[10] The court reasoned that (1) patents are presumed valid, (2) "patent law bestows the patent holder with 'the right to exclude others from profiting from the patented invention,'" and (3) a "settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled - a monopoly over the manufacture and distribution of the patented invention."[11]

The Federal Circuit's Decision: Other Jurisdictions and the FTC

The Federal Circuit also noted that its decision is consistent with the decisions of the Second[12] and Eleventh[13] Circuits. At the same time, the Court (a) expressed disagreement with the FTC's method for analyzing reverse payment settlement agreements, and (b) distinguished and disagreed with the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*,[14] the only Circuit case which has held that a reverse payment settlement agreement is *per se* illegal.

The Federal Circuit decision puts even greater importance on the FTC's *Cephalon* case, in which the FTC alleges that Cephalon entered into unlawful reverse payment settlements with four generic manufacturers. *See* FTC Takes 4-in-1 Shot at Reverse Payment Settlements, *available at* http://www.mofo.com/news/updates/files/13499.html. The decision in that case would be appealed to the Third Circuit, potentially creating the circuit split that the FTC seeks in order to bring these issues before the Supreme Court.

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Footnotes:

[1] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 08-1097 (Fed. Cir. Oct. 15, 2008), *available at*http://www.cafc.uscourts.gov/opinions/08-1097.pdf ("Slip Opinion").

[2] *Id.* at 2 (*citing to In re Ciprofloxacin Hydrochloride Antitrust Litig.* 363 F. Supp. 2d 514 (E.D.N.Y. 2005)).

[3] The plaintiffs also brought a state law antitrust claim, a consumer protection claim, and a state law *Walker Process*-type claim. The district court dismissed the claims and the Federal Circuit affirmed.

[4] Slip Opinion at 11.

[5] *Id.*

[6] *Id.* at 13-14.

[7] *Id.* at 13.

[8] In fact, four other generic manufacturers had filed ANDAs and initiated challenges to the validity of the Cipro patent.

[9] *Id.* at 14.

[10] *Id.* at 21.

[11] *Id.* at 21-22.

[12] *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

[13] *See Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); Valley *Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294 (11th Cir. 2003).

[14] 332 F.3d 896 (6th Cir. 2003).