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Second Circuit Cipro Decision Affirms No Per Se Antitrust Violation for Reverse-Payment Settlements, but Invites Petition for Rehearing En Banc

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The legality of "pay for delay" or "reverse payment" settlements in Hatch-Waxman litigations has been a hotly contested and closely watched topic over the past decade. On April 29, 2010, the Second Circuit, following a previous panel decision of that court, rejected a claim that reverse-payment settlements constitute *per se* antitrust violations in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("*Cipro*"). In rendering its decision, however, the court identified several reasons for potentially revisiting that precedent, inviting plaintiffs to petition for rehearing *en banc* to allow the full Court to consider the "difficult questions at issue and the important interests at stake." *Cipro*, Slip Op. at 19.

Background and Procedural History

In 1996, Bayer settled a Hatch-Waxman litigation with Barr Laboratories, Inc., which was then seeking approval to sell a generic version of Bayer's ciprofloxacin hydrochloride drug product (sold under the tradename Cipro®) before the expiration of Bayer's U.S. Patent No. 4,670,444 ("the '444 patent") directed to that active ingredient. Under the settlement, Barr agreed not to sell its proposed generic product for a period of time in exchange for Bayer: (1) paying Barr an immediate sum of $49.1 million; and (2) either making additional quarterly exclusion payments or supplying ciprofloxacin hydrochloride for Barr to sell at a 70% royalty rate. Bayer opted to make the quarterly payments, which resulted in $398.1 million in total payments to Barr under the settlement agreement. *Id*. at 6.

In 2000 and 2001, direct and indirect purchasers of Cipro® filed over thirty antitrust actions challenging this reverse-payment settlement, which were eventually consolidated in the Eastern District of New York. The district court granted summary judgment in favor of defendants, holding that the settlement was not a *per se* violation of the Sherman Act because any adverse effects of the settlement on competition was within the exclusionary scope of Bayer's '444 patent. *Id.* at 7-8.

After plaintiffs appealed the decision to the Second Circuit, that court in November 2007 granted Bayer's motion to transfer certain of plaintiffs' state law *Walker Process*-based claims to the Federal Circuit because those claims arose out of patent law. In October 2008, the Federal Circuit affirmed the district court's disposition of those claims, holding that "the Agreements were not in violation of section 1 of the Sherman Act because any anti-competitive effects caused by the Agreements were within the exclusionary zone of the patent."[1]

In addition to the Federal Circuit, three other courts of appeals have previously addressed the issue of whether reverse-payment settlements violate the antitrust laws. Like the Federal Circuit, both the Second Circuit[2] and Eleventh Circuit[3] have ruled that reverse-payment settlements are not *per se* antitrust violations. The Sixth Circuit, on the other hand, has found a reverse-payment settlement to *per se* violate the antitrust laws.[4]

The Second Circuit's *Cipro* Ruling

While acknowledging that authorities are divided on the issue,[5] the *Cipro* court stated that it was bound by the standard set forth in its prior *Tamoxifen* decision. In *Tamoxifen*, the court ruled that the plaintiffs failed to state an antitrust claim as a matter of law "because a patent holder is entitled to protect its 'lawful monopoly over the manufacture and distribution of the patented product'" during the period of patent protection. In so holding, the *Tamoxifen* court explained that,

> [u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.

Cipro, Slip Op. at 11-12 (quoting *Tamoxifen*, 466 F.3d at 213).

Applying the *Tamoxifen* standard, the *Cipro* court noted that, because "[p]laintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud," the only potential basis for an antitrust violation would be if the settlement agreement "exceeded the scope of the Cipro patent." *Id.* at 12-13. Like the patent at issue in *Tamoxifen*, however, the '444 patent is "a 'compound patent,' [which] 'by its nature, excludes all generic versions of the drug.'" *Id.* at 13 (quoting *Tamoxifen*, 466 F.3d at 214). The court therefore affirmed the judgment of the district court.

Despite determining the result to be mandated by *Tamoxifen*, the panel nevertheless stated that "there are several reasons why this case might be appropriate for reexamination by our full Court," including:

(1) the DOJ's "urg[ing of the court] to repudiate *Tamoxifen*" in favor of a rule "that excessive reverse payment settlements be deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs";

(2) the increased frequency of reverse-payment settlements following the court's *Tamoxifen* decision;

(3) the criticism of reverse-payment settlements levied by a principal drafter of the Hatch-Waxman Act; and

(4) the panel's belief that the decision in *Tamoxifen* was based, "in no small part," upon the erroneous view that reverse-payment settlements "'open[] the [relevant] patent to immediate challenge by other potential generic manufacturers . . . spurred by the additional incentive . . . of potentially securing the 180-day exclusivity period."

Cipro, Slip Op. at 16-19.

For now, at least, reverse-payment settlements that do not extend the exclusionary scope of a patent do not violate the antitrust laws according to the Second Circuit. Stay tuned, though — the panel hinted at the possibility of the full court deepening the current circuit split over the legality of such settlements.

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1 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008).

2 *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *as amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007) ("*Tamoxifen*").

3 *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert denied*, 548 U.S. 919 (2006).

4 *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert denied, Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004).

5 In addition to the case law cited above, the DOJ submitted a brief at the invitation of the Second Circuit arguing (in contrast to its previous position) that reverse-payment settlements are presumptively unlawful. The DOJ's current view is consistent with that of the FTC and numerous legal commentators. *Cipro*, Slip Op. at 10-11.