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Second Circuit Invites Rehearing in Reverse Settlement Case

In a recent decision regarding the validity of so-called "reverse settlement" agreements, the U.S. Court of Appeals for the Second Circuit affirmed the dismissal of plaintiffs' antitrust claims on summary judgment, but took the unusual step of inviting plaintiffs to petition for rehearing by the full Court of Appeals.[1] At issue in the case were payments made by Bayer, the manufacturer of the antibiotic Cipro, to Barr Laboratories and other companies seeking regulatory approval to market a generic version of Cipro, pursuant to an agreement settling Bayer's claims of patent infringement against the would-be generic manufacturers. Applying its own prior precedents, the Second Circuit held that plaintiffs – direct purchasers of Cipro – were barred as a matter of law from challenging the settlement agreement under the antitrust laws. The Court observed, however, that recent developments had called such precedents into question, including an *amicus* brief filed in the case by the Department of Justice Antitrust Division, at the Court's request, in which the Division argued that reverse settlements should be treated as presumptively unlawful.[2] Based on these developments, the Court invited plaintiffs to petition for rehearing *en banc*, so that the full Court could consider "the difficult questions at issue and the important interests at stake."[3]

Reverse settlements arise in the context of pharmaceutical patent litigation and involve payments made by the manufacturer of a branded pharmaceutical to a would-be competitor seeking federal regulatory approval to market a generic version of the same drug. For several years, the Federal Trade Commission has taken the position that such agreements – which it terms "pay for delay" arrangements – unreasonably restrain competition under the antitrust laws. Until recently, however, the DOJ Antitrust Division has been more circumspect in its views regarding reverse settlements, arguing that courts "should take into account the relative likelihood of success of the parties' claims" in weighing any anticompetitive effects resulting from such agreements.[4] And the federal courts of appeals, including the Second Circuit, have for the

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1 *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG* (*In re Ciprofloxacin Hydrochloride Antitrust Litig.*), ---F.3d---, 2010 WL 1710683 (2d Cir. Apr. 29, 2010) ("*Cipro*").

2 Brief for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851-cv (2d Cir. July 6, 2009) ("July 2009 DOJ Brief"). For a more detailed discussion of the Antitrust Division's brief, see our July 20, 2009 publication, "DOJ Antitrust Division Declares Reverse Settlements 'Presumptively Unlawful,'" *available at* http://www.paulweiss.com/files/upload/20Jul09DOJ.pdf.

3 *Cipro*, 2010 WL 1710683, at *8.

4 Brief for the United States as Amicus Curiae, *Joblove* v. *Barr Labs., Inc.*, No. 06-830 (May 2007), *available at* http://www.justice.gov/atr/cases/f223500/223525.pdf.

most part rejected plaintiffs' attempts to challenge reverse settlement agreements as unreasonable restraints of trade.[5]

In the decision on appeal in *Cipro*, the U.S. District Court for the Eastern District of New York granted defendants' motion for summary judgment, holding that plaintiffs failed to show that the challenged settlement agreement had an actual adverse effect on competition.[6] Observing that existing patents should be treated as presumptively valid, the district court held that the proper test for determining the validity of a reverse settlement is whether the agreement would constrain competition *beyond* the scope of the underlying patent – a showing that plaintiffs in *Cipro* were unable to make.[7]

Consistent with the district court's decision, the Second Circuit held in *Tamoxifen* – another reverse settlement case, decided the following year – that "absent an extension of the monopoly beyond the patent's scope, . . . and absent fraud, . . . the question," with respect to reverse settlements, "is whether the underlying infringement lawsuit was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[8] Moreover, the *Tamoxifen* Court held that a settlement agreement does not exceed the scope of the underlying patent where (1) there is no restriction on marketing other, non-infringing products; (2) the generic drug at issue would necessarily infringe the patent on the branded drug; and (3) the agreement does not bar other generic manufacturers from challenging the patent.[9]

In its recent appellate decision in *Cipro*, the Second Circuit noted that it was bound to review the district court's rulings under the standard set forth in *Tamoxifen*. Applying that standard, the Court determined that there was no basis for distinguishing the *Cipro* plaintiffs' claims from the claims that the Court had rejected in *Tamoxifen*. Specifically, the Court determined that the *Cipro* plaintiffs had failed to show that the settlement agreements at issue exceeded the scope of Bayer's patent on Cipro. Plaintiffs also advanced an argument that *Tamoxifen* was inconsistent with the purpose of the Hatch-Waxman Act, which was to promote the availability of low-cost generic drugs. The *Cipro* Court held that it had no authority to address such policy arguments, observing: "[T]his panel is bound by *Tamoxifen* absent a change in law by higher authority or by way of an in banc proceeding."[10]

The *Cipro* Court extended an invitation to plaintiffs to seek such a proceeding. There were several reasons, the Court noted, that *en banc* review was appropriate. First, the DOJ Antitrust Division had reversed its prior position with respect to reverse settlements, and argued in an *amicus* brief to the Court that *Tamoxifen* was wrongly decided and that reverse settlements "should be treated as presumptively unlawful under Section 1 of the Sherman Act."[11] Second, the Court took note of "evidence that the practice of entering into reverse exclusionary payment settlements has increased since we decided *Tamoxifen*."[12] Third, after *Tamoxifen*, a co-author

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5 *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005). *But see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

6 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

7 *Id*. at 540.

8 *Tamoxifen*, 466 F.3d at 213 (internal quotation marks omitted).

9 *Id*. at 213–15; *see Cipro*, 2010 WL 1710683, at *5.

10 *Cipro*, 2010 WL 1710683, at *7 (internal quotation marks omitted).

11 July 2009 DOJ Brief, *supra* note 2, at 10.

12 *Cipro*, 2010 WL 1710683, at *7.

of the Hatch-Waxman Act, Senator Orrin Hatch, strongly criticized the practice of reverse settlement agreements, stating: "I find these type[s] of reverse payment collusive arrangements appalling."[13] Finally, the Court found that "*Tamoxifen* relied on an unambiguous mischaracterization of the Hatch-Waxman Act" as providing incentives for other potential competitors to challenge a patent after the first manufacturer to file for generic approval has settled a lawsuit (which the *Cipro* Court determined was incorrect).[14]

Although the *Cipro* Court stopped short of calling for reversal of *Tamoxifen*, these observations suggest that the three-judge panel was at a minimum skeptical of the continuing validity of the prior opinion. An *en banc* rehearing, the Court noted, "could provide our full Court with an opportunity to revisit the issues in play in *Tamoxifen* and to analyze the competing interests that underlie antitrust challenges to reverse payment settlements in light of the full record and the arguments of the parties and amici, including the United States, that have been raised in this appeal."[15]

While the *Cipro* plaintiffs are certain to accept the Court's invitation and petition for *en banc* rehearing, a majority of all active judges on the Court are required to grant such a petition. And, even if granted, the outcome of a rehearing *en banc* remains uncertain. Despite such uncertainty, the *Cipro* Court's decision is likely to embolden plaintiffs – including the FTC and the DOJ – in pursuing future legal challenges to reverse settlement agreements. At the same time, Congress continues to weigh a bill that would prohibit or significantly restrict reverse settlements, and the Second Circuit's decision may provide an impetus for more immediate legislative action.

* * *

This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Any questions concerning the issues addressed in this alert may be directed to:

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[13] *Id*. at *8 (internal quotation marks omitted, alteration in original).

[14] *Id*.

[15] *Id*.