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July 20, 2009

DOJ Antitrust Division Declares Reverse Settlements "Presumptively Unlawful"

Departing from positions it took in a series of cases decided during the Bush administration, the Department of Justice Antitrust Division argued recently – in a brief filed in the U.S. Court of Appeals for the Second Circuit – that so-called "reverse settlement" agreements in the pharmaceutical industry should be treated as "presumptively unlawful" under the antitrust laws.[1] The Antitrust Division's brief suggests a closer alignment with the positions taken on reverse settlement agreements by the Federal Trade Commission and may signal a likelihood of more aggressive enforcement activity by both government agencies with respect to such agreements in the future. To the extent adopted by the Court, the government's newly articulated position would also mark a departure from recent federal court precedents involving challenges to such agreements.

Reverse settlements, also known as "pay for delay" agreements, arise in the context of pharmaceutical patent disputes in which the manufacturer of a branded drug files suit for patent infringement against a would-be competitor seeking approval from federal regulators to market a generic version of the same drug. If litigated to a judgment, such disputes typically require a court to address the validity of the patent that the branded drug manufacturer has sued to enforce. Given the risks associated with invalidation of a patent on a successful pharmaceutical product, branded drug manufacturers arguably have an incentive to settle such claims by paying the generic competitor to delay its entry into the market.

In the case currently pending before the Second Circuit, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, purchasers of the antibiotic Cipro sued Bayer, the manufacturer of Cipro, and Barr Laboratories, a generic drug manufacturer, for allegedly violating the antitrust laws by entering into a reverse settlement of a prior patent infringement suit brought by Bayer against Barr. Under the settlement agreement, Bayer allegedly made a series of payments to Barr to keep it from releasing a generic version of Cipro until six months before the Cipro patent was scheduled to expire. In 2005, the U.S. District Court for the Eastern District of New York granted the defendants' motion for summary judgment, holding that the plaintiffs had failed to prove that the challenged settlement agreement had an actual adverse effect on competition.[2] The District Court concluded that it would be "inappropriate to engage in an after-the-fact analysis of the

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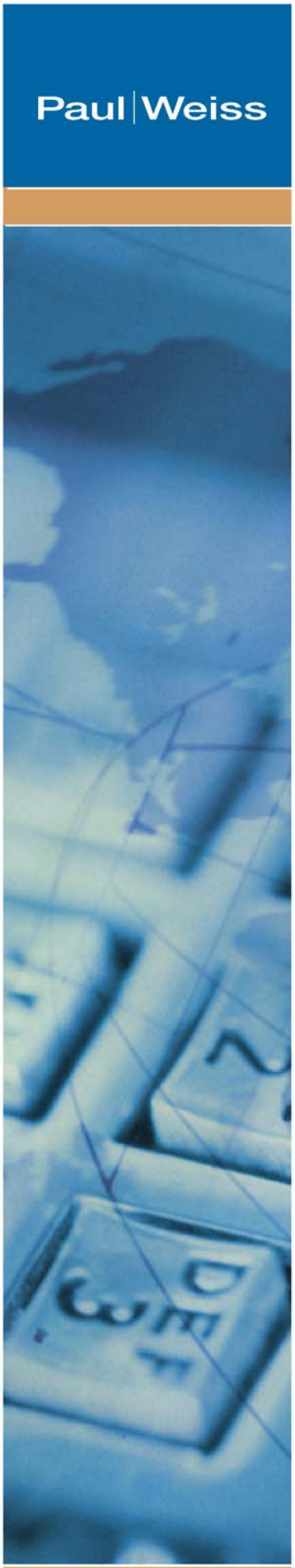
1 Brief for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851-cv (2d Cir. July 6, 2009).

2 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005).



patent's likely validity"; rather, an existing patent should be treated as presumptively valid.[3] The proper test for determining the validity of a reverse settlement agreement, the Court held, is whether the agreement would constrain competition *beyond* the scope of the underlying patent.[4] Applying this test to Bayer's settlement agreement with Barr, the Court determined that the plaintiffs had not shown any restraint of competition beyond that achieved by the Cipro patent itself.

Responding to the Second Circuit's invitation to address whether reverse settlements of the sort alleged in *Ciprofloxacin* violate the antitrust laws, the Antitrust Division – which was not a party to the lawsuit – maintained, as it had in prior cases, that such agreements do not constitute *per se* antitrust violations. Nevertheless, the Division argued for the first time that reverse settlement agreements in the pharmaceutical context "should be treated as presumptively unlawful under Section 1 of the Sherman Act." (Br. at 10.) Defendants may rebut that presumption, the Division contended, by offering evidence that the challenged payments did not purchase a reduction in competition. (*Id*. at 27-32.) For example, where a defendant can show that the settlement payment made to an alleged infringer was "no more than an amount commensurate with the patent holder's avoided litigation costs," the agreement is likely to be upheld. (*Id*. at 28.) By contrast, where the challenged payment "is greatly in excess of avoided litigation costs," and the agreement precludes generic competition throughout the term of the underlying patent, the agreement is likely to violate the Sherman Act. (*Id*. at 29.)

In addition to advocating for the adoption of a "presumptively unlawful" standard, the Division urged the Second Circuit to revisit its own 2006 decision in *In re Tamoxifen Citrate Antitrust Litigation*.[5] In that case, consistent with the District Court's decision in *Ciprofloxacin*, the Court of Appeals held that "absent an extension of the monopoly beyond the patent's scope, . . . and absent fraud, . . . the question is whether the underlying infringement lawsuit was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[6] This decision, the Antitrust Division asserted, was "incorrect." (Br. at 6, 15.) In particular, the Division maintained that *Tamoxifen*'s "objectively baseless" standard effectively barred antitrust scrutiny of reverse settlement agreements and offered "no protection to the public interest in eliminating undeserved patents." (*Id*. at 15.)

Finally, the Antitrust Division departed from its previous position – articulated in a brief arguing for the denial of certiorari in a reverse settlement case before the U.S. Supreme Court – that courts weighing the anticompetitive effects of a reverse settlement payment, "at a minimum should take into account the relative likelihood of success of the parties' claims" in the underlying infringement lawsuit.[7] In its *Ciprofloxacin* brief, by contrast, the Division maintained that "[i]f the settlement involves a payment in exchange for the generic manufacturer's agreement to withdraw its challenge to the patent and to delay entry, there is no need to determine whether the patent would in fact have been held invalid in order to conclude that the settlement likely disadvantaged consumers." (Br. at 26.) Aligning itself with the FTC's opinion in a case where

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3 *Id*. at 539.

4 *Id*. at 540.

5 466 F.3d 187 (2d Cir. 2006).

6 *Id*. at 213 (internal quotation marks omitted).

7 Brief for the United States as Amicus Curiae, *Joblove* v. *Barr Labs., Inc.*, No. 06-830 (May 2007).

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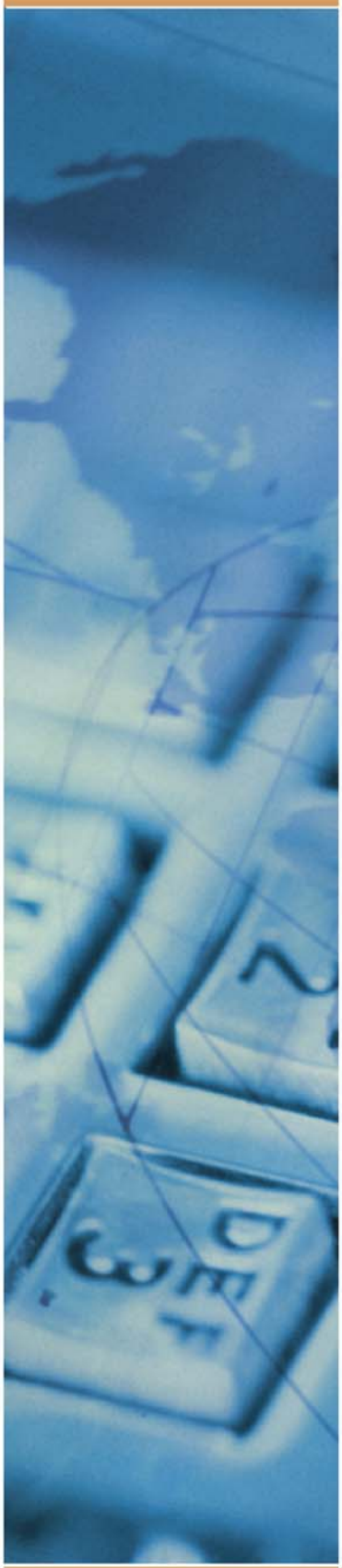

the two agencies had previously expressed contradicting views,[8] the Division argued that the possible existence of a reverse settlement payment is itself enough to raise a "red flag," mandating further inquiry by the court, without examination of whether the underlying infringement suit had merit. (*Id*. at 27.)

Whether or not ultimately endorsed by the Second Circuit in *Ciprofloxacin*, the Antitrust Division's brief reflects an important shift in the agency's views toward reverse settlement agreements in the pharmaceutical context. Such agreements have already been the subject of outspoken criticism by FTC Chairman Jon Leibowitz, who recently called on Congress to pass legislation restricting them,[9] and have also received attention from President Obama, who pledged during his campaign to "ensure that the law effectively prevents anticompetitive agreements that artificially retard the entry of generic pharmaceuticals onto the market, while preserving the incentives to innovate that drive firms to invent life-saving medications."[10] In March, Representative Bobby Rush of Illinois re-introduced a bill that would ban reverse settlement payments in the context of pharmaceutical patent disputes. That bill, known as the Protecting Consumer Access to Generic Drugs Act of 1999, is currently before the House Subcommittee on Commerce, Trade and Consumer Protection.

Given the Antitrust Division's newly articulated position, it is reasonable to expect that reverse settlements will receive increased scrutiny from both enforcement agencies going forward and, depending in part on the outcome of cases such as *Ciprofloxacin*, will continue to be the subject of private litigation in the federal courts.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues discussed in this memorandum may be addressed to any of the following:

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8 *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005).

9 Jon Leibowitz, *"Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution)*, dated June 23, 2009, available at http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.

10 Statement of Senator Barack Obama for the American Antitrust Institute, dated Sept. 27, 2007, available at http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf.