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March 1, 2010

Court Rejects FTC Challenge to Reverse Settlement Agreement

On February 22, a federal district court rejected claims by the Federal Trade Commission and private plaintiffs that a “reverse settlement” agreement between pharmaceutical companies violated the antitrust laws.¹ The court’s decision in *In re AndroGel Antitrust Litigation*² marks a setback in the FTC’s campaign to end such agreements, which both the Commission and the U.S. Department of Justice Antitrust Division have argued are “presumptively unlawful.”³ While the FTC has pledged to continue to challenge reverse settlements in the courts, the *AndroGel* ruling makes it more likely that regulators will focus their efforts on persuading Congress to pass legislation either banning or seriously restricting the practice.

In re AndroGel arose out of a 2006 settlement between Solvay Pharmaceuticals, which holds a patent on AndroGel—a prescription gel used to increase testosterone levels in male patients—and three competing drug manufacturers seeking to offer a generic alternative to AndroGel. Pursuant to the settlement, Solvay agreed to drop its patent infringement actions and its would-be competitors agreed not to market a generic version of AndroGel until 2015. In addition, Solvay entered into separate agreements with each of the three generic manufacturers, providing that they would market branded AndroGel to urologists in exchange for a share of the profits collected by Solvay. Under these “business promotion agreements,” Solvay estimated that it would make annual payments to each of the three manufacturers ranging from \$2 million to \$30 million.

The FTC, along with purchasers of AndroGel, filed a complaint alleging that this reverse settlement, involving payments by Solvay to the alleged infringers of its patent, ran afoul of the antitrust laws. Plaintiffs charged that the settlement agreement was, in effect, a covenant not to compete, which permitted Solvay to maintain a monopoly over sales of AndroGel while preventing consumers from gaining access to less expensive generic medications. Separately, the direct purchaser plaintiffs alleged that Solvay’s patent infringement actions were “sham litigation,” used to further a conspiracy between Solvay and the generic manufacturers to share in monopoly profits on sales of AndroGel.

¹ Reverse settlements arise in the context of a patent infringement action brought by the maker of a branded pharmaceutical product against a would-be competitor seeking government approval to enter the market with a generic version of the drug at issue. A reverse settlement – also known as a “pay for delay” agreement – involves a payment by the patent holder to the alleged infringer, usually in exchange for a commitment not to offer a competing generic product for some period of time.

² No. 1:09-MD-2084-TWT (N.D. Ga. Feb. 22, 2010).

³ See “[DOJ Antitrust Division Declares Reverse Settlements ‘Presumptively Unlawful’](#)” (July 20, 2009).

Defendants moved to dismiss, arguing that neither the FTC nor private plaintiffs had stated a valid claim for relief under the antitrust laws. With respect to plaintiffs' claim that the reverse settlement was an unreasonable restraint of trade, the court agreed with defendants. As an initial matter, the court noted that where patent settlements are concerned, neither the "rule of reason" nor "per se" analysis typically applied in antitrust actions is appropriate. Rather, the court held that reverse settlements must be analyzed according to the three-part test established by the Eleventh Circuit in a prior case involving an FTC challenge to a pharmaceutical company reverse settlement.⁴ That test requires examination of: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."⁵

In *AndroGel*, the court held that there was no need to reach the question of whether the agreements at issue resulted in anticompetitive effects because plaintiffs had failed to allege that such agreements exceeded the scope of Solvay's patent. Whereas the agreement not to market a generic version of AndroGel extended through 2015, the AndroGel patent provided exclusivity through 2020. Moreover, the settlement agreement covered AndroGel only, and did not purport to affect sales of other products or sales by manufacturers other than those who were parties to the agreement. The court rejected plaintiffs' argument that determining the scope of a patent requires an inquiry into the likelihood that the patent holder will prevail in an infringement action, noting that the Eleventh Circuit has already held that such inquiry would create too much uncertainty and would discourage settlements, thereby raising the costs of patent enforcement.⁶

In addition, the court rejected plaintiffs' argument that settlements of patent disputes involving reverse payments should be treated as presumptively unlawful. In July 2009, the Department of Justice Antitrust Division advanced the same argument in a brief filed with the U.S. Court of Appeals for the Second Circuit, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.⁷ The *Ciprofloxacin* case remains pending in the Court of Appeals.⁸ In *AndroGel*, however, the district court held that the argument that reverse settlement agreements are presumptively unlawful is fundamentally inconsistent with Eleventh Circuit precedent. Because plaintiffs had not alleged facts sufficient to meet the test established by the Eleventh Circuit with respect to the agreements at issue, the court dismissed their reverse settlement claims.

Nevertheless, the *AndroGel* court ruled that the private direct purchaser plaintiffs could proceed with a claim that Solvay's infringement actions amounted to "sham litigation." In their complaint, the direct purchasers alleged that Solvay's suits were "objectively baseless" because the proposed generic versions of AndroGel clearly did not infringe Solvay's patent. Such claims, the

⁴ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁵ *Id.* at 1066.

⁶ *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003).

⁷ 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), available at <http://www.justice.gov/atr/cases/f247700/247708.pdf>.

⁸ In a prior case, *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), the Second Circuit held that a reverse settlement will not be deemed unlawful unless: (1) the settlement agreement extends "the monopoly beyond the patent's scope"; (2) the patent was procured by fraud; or (3) "the underlying infringement lawsuit was objectively baseless." *Id.* at 213. In its *Ciprofloxacin* brief, the DOJ argued that this standard was incorrect and urged the Court to reconsider it.

court held, raised “questions of fact that cannot be resolved at the pleading stage.” Accordingly, the court denied defendants’ motions to dismiss with respect to that claim only.⁹

Richard Feinstein, Director of the FTC’s Bureau of Competition, described the *AndroGel* ruling as “obviously disappointing.”¹⁰ Feinstein emphasized, however, that the FTC would “continue to use all tools at its disposal to stop anti-competitive pay-for-delay tactics in the U.S. pharmaceutical industry, including litigation.”¹¹ In addition to the *Ciprofloxacin* case, which was brought by private plaintiffs, a case involving reverse settlements brought by the FTC remains pending in the Eastern District of Pennsylvania.¹²

In commenting on *AndroGel*, Feinstein also renewed the FTC’s call for legislation prohibiting reverse settlements. “A new law is the quickest and most effective way to serve the interests of the millions of U.S. consumers who take prescription drugs and deserve unfettered access to lower-cost generic alternatives,” he noted.¹³ Feinstein’s comments echo those of FTC Chairman Jon Leibowitz, who has been an outspoken advocate of such legislation. In January, Leibowitz joined with legislators—including Representative Bobby Rush of Illinois, the sponsor of a bill to end reverse settlements—in touting the results of a study by FTC economists estimating that reverse settlement agreements “cost consumers \$3.5 billion a year in higher drug prices.”¹⁴

Though the future of legislative efforts to ban reverse settlements remains uncertain, their short-term prospects may depend on the success of President Obama’s most recent proposal for overhauling healthcare more broadly, which includes such a ban.

* * *

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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⁹ Neither the FTC nor the indirect purchaser plaintiffs asserted a sham litigation claim; as a result, their complaints were dismissed in their entirety.

¹⁰ Brendan Pierson, “AndroGel Reverse Payment Suits Thrown Out,” *Law360* (Feb. 23, 2010).

¹¹ *Id.*

¹² *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa.).

¹³ Brent Kendall, “US Judge Ends FTC Challenge to AndroGel Pact,” *The Wall Street Journal* (Feb. 23, 2010).

¹⁴ Statement of Federal Trade Commission Chairman Jon Leibowitz, Pay-for-Delay Press Conference (Jan. 13, 2010), available at <http://www.ftc.gov/os/2010/01/100113stmleibowitzpfd.pdf>.