

Authors

Michael J. Gaertner
312-443-1722
mgaertner@lockelord.com

Andy J. Miller
312-443-1717
amiller@lockelord.com

www.lockelord.com

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FTC Suffers Setback with *AndroGel* Dismissal

Legislation Still Pending Regarding “Reverse-Payment” Settlements

The U.S. District Court for the Northern District of Georgia recently dismissed suits brought by the Federal Trade Commission (“FTC”), Direct Purchasers, and Indirect Purchasers challenging settlement agreements between Solvay Pharmaceuticals, Inc. and Watson Pharmaceuticals, Paddock Laboratories, and Par Pharmaceuticals. *In re AndroGel Antitrust Litigation*, No. 1:09-MD-2084-TWT (N.D. Ga. Feb. 22, 2010). The order, entered by Judge Thomas Thrasher, represents the latest setback in the FTC’s effort to curb “reverse-payment” settlements in Hatch-Waxman litigation. Nevertheless, FTC Chairman Jon Leibowitz continues to be a staunch critic of such settlements. The Commission recently released a report in which it once again excoriated “pay-for-delay” as anticompetitive. And although the FTC has yet to find much support for this view in the judiciary, the Commission appears to have the support of the Obama Administration and certain members of Congress, who have advanced bills to ban reverse-payment settlements.

Judge Thrasher’s Dismissal of the *AndroGel* Plaintiffs’ Reverse-Payment Allegations

Solvay markets the brand drug *AndroGel*, a synthetic testosterone replacement, and owns a patent (set to expire in 2020) that claims the use of a particular pharmaceutical gel formulation of testosterone. Watson and Paddock filed Abbreviated New Drug Applications (“ANDAs”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to market generic versions of *AndroGel*. Both Watson and Paddock made Paragraph IV Certifications in their ANDAs alleging that their proposed products did not infringe Solvay’s patent and that the patent was invalid. Watson was the first to file its ANDA and, consequently, enjoyed 180-day generic exclusivity. Solvay sued both companies for patent infringement.

In 2006, the FDA approved Watson’s ANDA. Rather than launch its generic product, Watson entered into an agreement with Solvay to settle the litigation. Under the terms of the settlement, Watson agreed that it would not launch its gener-

ic product until 2015, and that, in the meantime, Watson would promote *AndroGel* to urologists in exchange for a share of *AndroGel* profits, estimated at between \$15 and \$30 million annually. Similarly, Par (whose involvement in this litigation stemmed from an agreement with Paddock) and Paddock agreed to settle their litigation with Solvay and defer launch of their product until 2015. In the interim, Par would promote *AndroGel* to primary care physicians in exchange for a share of Solvay’s profits, estimated at about \$6 million per year, while Paddock would serve as a back-up supplier for *AndroGel* in exchange for an estimated \$2 million per year.

The FTC, as well as the Direct and Indirect Purchaser Plaintiffs, alleged that these agreements violated the antitrust laws because, absent the payments, Solvay would have lost its infringement suit or settled with the generics. The result, either way, would have meant generic entry, and thus reduced prices, before 2015. Relying primarily on *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) and *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), Judge Thrasher adopted the exclusionary-scope-of-the-patent test. See also *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub. nom., Joblove v. Barr Labs, Inc.*, 127 S. Ct. 3001 (2007). Under this approach, if the agreement does not exceed the scope of the patent, then the settlement protects a lawful monopoly and the agreement will be upheld. The “scope” of the patent is determined by what the patent claims and by the patent’s duration.

Judge Thrasher concluded that the settlements at issue did not exceed the scope of the patent. First, the settlements excluded only generic *AndroGel*—that is, the settlements excluded only products that fell within the claims of the patent. Second, the settlements precluded entry of generic *AndroGel* only until 2015, five years before the patent was set to expire. Finally, the plaintiffs did not allege that Watson would use its exclusivity to prevent other generics from entering the market. In other words, the agreements prevented only Watson, Par, and Paddock from

selling generic versions of the drug. Accordingly, Judge Thrasher held that “[b]ecause the Plaintiffs do not allege that the settlements exceed the scope of the ... patent, it does not matter if the Defendants settled their patent disputes with reverse payments.”

Importantly, Judge Thrasher’s exclusionary-scope analysis turned only on a patent’s claims and duration. The Court dismissed the FTC’s argument that the proper scope of a patent includes “the likelihood that a patent holder could assert its claims in court and win.” Indeed, because the Plaintiffs failed to allege that the agreements exceeded the scope of the claims and duration of the patent at issue, Judge Thrasher concluded that he need not even examine the resulting anticompetitive effect of the agreements.

Pay-for-Delay Settlements Are a Leading Priority for FTC

Commissioner Leibowitz has long been a vocal opponent of reverse-payment settlements. In his concurring statement supporting the FTC’s initial decision to challenge the *AndroGel* settlement, Mr. Leibowitz reiterated his view that reverse-payment settlements are “unconscionable deals” which harm competition:

This is yet another example of pharmaceutical companies turning competition on its head.... Congress enacted the landmark 1984 Hatch-Waxman Act to encourage early generic entry and save consumers money, but these anticompetitive deals threaten to destroy that benefit and make crucial portions of the Hatch-Waxman Act extinct in all but name.

F.T.C. v. Watson, [Concurring Statement of Commissioner Jon Leibowitz](#).

In addition, upon assuming the role of Chairman of the FTC, Mr. Leibowitz sin-

gled out reverse-payment settlements as a priority for the FTC in the Commission’s 2009 *Annual Report*:

A leading priority has been attacking collusive “pay-for-delay” settlements in the pharmaceutical industry, where the brand name drug company pays the generic drug company to delay its entry into the market. These deals cost billions of dollars – for consumers and ultimately for the government, which pays almost one-third of the nation’s prescription drug costs.

FTC Annual Report, March 2009, [Letter from the Chairman](#).

In January 2010, the FTC issued a special report entitled “[Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions](#).” Chairman Leibowitz issued a separate statement about the report and the Commission announced the creation of a new pay-for-delay website.

The Commission’s report reaffirms that reverse-payment settlements will continue to be one of its priorities. Thus, despite setbacks in court, the FTC can be expected to continue to challenge such settlements and to advocate for legislation in Congress. Legislation in particular, the Chairman has said, “would offer a simple, effective and straightforward solution to the problem by banning payments from the brand to the generic while permitting legitimate settlements.” *F.T.C. v. Watson*, [See Concurring Statement of Commissioner Jon Leibowitz](#).

Legislative Action

The Obama Administration’s Health Reform proposal, released on the same day that Judge Thrasher issued his opinion in *AndroGel*, specifically supports legislation that would provide the FTC the enforcement authority to address reverse-payment settlements.

The proposal:

Adopts a provision from the bipartisan legislation that gives the FTC enforcement authority to address [the reverse-payment] problem. Specifically, it makes anti-competitive and unlawful any agreement in which a generic drug manufacturer receives anything of value from a brand-name drug manufacturer that contains a provision in which the generic drug manufacturer agrees to limit or forego research, development, marketing, manufacturing or sales of the generic drug. This presumption can only be overcome if the parties to such an agreement demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement. The proposal also requires the Chief Executive Officer of the branded pharmaceutical company to certify to the accuracy and completeness of any agreements required to be filed with the FTC.

[The President’s Proposal](#), February 22, 2010.

Chairman Leibowitz, on behalf of the FTC, expressed his “delight” with the initiative. [See February 22, 2010 Statement of FTC Chairman Jon Leibowitz on Ending “Pay-for-Delay” Drug Settlements](#).

The President’s proposal echoes legislation that has been introduced in Congress. In the Senate, S.369, the “Preserve Access to Affordable Generics Act,” was passed out of the Judiciary Committee last year. That Bill would amend the FTC Act to allow the Commission to “initiate a proceeding to enforce the provisions of [revised Sec. 28] against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement

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claim, in connection with the sale of a drug product." Reverse-payment agreements would be presumptively anticompetitive and thus unlawful unless the parties could show "by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."

In early February, the Senate issued a [Report on S.369](#), showing that there remains disagreement about the exact contours of the legislation. In particular, Sens. Orrin Hatch (R-Utah), Jon Kyl (R-Ariz.), John Cornyn (R-Texas), and Tom Coburn (R-Okla.), in the Report's "minority views," state that they do not support the legislation in its current form because they believe that the bill, in practice, "would amount to a de facto per se ban on covered settlements—and would entail all of the evils attendant to a per se ban." Although the Senators express their support for "creating a legal presumption against drug patent settlements," they nevertheless conclude that, in its present form, the burden of rebutting that presumption is too heavy. The Senators advocate the creation of a "forum in which [the parties] can quickly and fairly test whether they have overcome the presumption and whether the agreement is valid." Concomitantly, they wish to eliminate the requirement that the parties overcome the anticompetitive presumption with clear and convincing evidence—an evidentiary burden that, they suggest, sets the bar too high.

A bill similar to S.369 has passed the full House as part of The Affordable Health Care for America Act. The House version, § 2573, "Protecting Consumer Access to Generic Drugs," amends the FTC Act to add section 505(w). Like the Senate bill, the House bill would not prohibit settlements where the "value" received consists of "the right to market the generic drug before the expiration of the patent or other exclusivity period." Unlike the Senate bill, however, the House bill also allows settlements where the "value" received is "the waiver of a patent infringement claim for damages."

Conclusion

The FTC seems intent to continue advocating for legislation that would ban reverse-payment settlements. In addition, despite its loss in *AndroGel*, the Commission will also likely continue to pursue such agreements in court. To be sure, litigation challenges to such settlements are currently underway in a Pennsylvania district court (*Fed. Trade Comm'n. v. Cephalon*) and in the Second Circuit (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG*).

About the Authors

Michael J. Gaertner is the co-chair of Locke Lord's Business Litigation & Arbitration Practice Group. Mr. Gaertner represents pharmaceutical industry companies in litigation, intellectual property and regulatory matters.

Andy J. Miller is an associate in Locke Lord's litigation department. Mr. Miller focuses his practice on intellectual property and technology.