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Eleventh Circuit Rejects FTC's Approach to Pay-for-Delay Settlements as "Turducken Task"

Jeffrey May (Wolters Kluwer) · Wednesday, April 25th, 2012

The U.S. Court of Appeals in Atlanta today rejected the Federal Trade Commission's challenge to a patent litigation settlement between brand name and generic drug companies as an unlawful agreement not to compete in violation of Section 5(a) of the FTC Act.

The FTC brought the case in 2009 against Solvay Pharmaceuticals and generic manufacturers Watson Pharmaceuticals, Par Pharmaceutical, and Paddock Laboratories over a "pay for delay" or "reverse payment" patent infringement settlement agreement related to patents for AndroGel—a testosterone replacement drug often used by men whose bodies do not produce normal levels of testosterone. In 2010, the federal district court in Atlanta dismissed the complaint (687 F. Supp. 2d 1371, ((CCH) 2010-1 Trade Cases ¶76,914) because the FTC failed to allege that the settlements, which included exclusion payments to the generic drug companies, exceeded the scope of the manufacturer's patent on the drug as required by Eleventh Circuit precedent.

Under Eleventh Circuit precedent, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." On appeal, the FTC unsuccessfully argued that the underlying patent had no exclusionary potential because the brand name drug company was "not likely to prevail" in the underlying infringement action against the generic drug companies, and therefore any reverse payment settlement that excluded competition from the market necessarily exceeded the potential exclusionary scope of the patent.

The FTC's theory would require courts to decide what the likely outcome of settled patent infringement claims would have been. "The approach would require an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled," according to the court.

The appellate court wanted to avoid "deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task."

"Retroactively predicting from a past perspective a future that never occurred" was "too perilous an enterprise to serve as a basis for antitrust," in the court's view.

The court was concerned that the approach would discourage patent litigation settlements and that predictions could be unreliable. The court also reasoned that the non-specialized circuit courts, as

opposed to the U.S. Court of Appeals for the Federal Circuit, were "ill-quipped to make a judgment about the merits of a patent infringement claim." Congress had given the Federal Circuit exclusive appellate jurisdiction over patent cases, and the FTC's approach was in tension with Congress' decision to have such appeals decided by that court.

The court also rejected the FTC's "ominous forecast" if these types of agreements were to escape antitrust attack. If the patent were invalid, then another generic drug maker could come along and challenge it, according to the court. The brand name drug company might be willing to share monopoly profits with the first one or two generic challengers, but not likely more.

Other FTC Efforts to Combat Pay-for-Delay Settlements

FTC Chairman Jon Leibowitz has said that combatting anticompetitive pay-for-delay patent settlements in the pharmaceutical industry is a top priority for the agency. The Commission has supported efforts to pass proposed federal legislation; however, the bills introduced in Congress have failed to gain traction for years. A new measure (H.R. 3995) was introduced this past February.

While the FTC sees a legislative approach as a better fix, the agency continues to investigate these types of agreements and to challenge the agreements in court. The FTC has another "pay-for-delay" action pending against pharmaceutical manufacturer Cephalon, Inc. for allegedly restraining competition for its branded drug, Provigil, by paying four competing firms to refrain from selling generic versions of the drug. The federal district court in Philadelphia has denied the defendants' motion to dismiss the allegations (702 F. Supp. 2d 514, (CCH) 2010-1 Trade Cases ¶76,950).

As the case is nearing the summary judgment phase, word is expected soon from the U.S. Court of Appeals in Philadelphia in another matter on the subject of pay-for-delay agreements. The agency has submitted an *amicus* brief in support of private class action plaintiffs who challenged the legality of patent settlements between branded and generic manufacturers of the high blood pressure medication K-Dur 20. The legality of pay-for-delay patent settlements is a question of first impression in the Third Circuit. The FTC's brief urges the Third Circuit to reverse a decision of the federal district court in New Jersey granting summary judgment ((CCH) 2010-1 Trade Cases ¶76,949) in favor of the patent holder, Schering-Plough Corporation, and the alleged infringers–Upsher Smith and ESI.

The text of the April 25, 2012, decision in *FTC v. Watson Pharmaceuticals, Inc.*, No. 10-12729, is available here.

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