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FTC Gets Shut Down - Once Again - In Its Bid To Change How Courts View Reverse Payment Settlements

As previously reported on this blog, in January 2009, the Federal Trade Commission launched its latest challenge to the legality of reverse payment settlements in the pharmaceutical industry, this time directed at two settlements involving the brand-name drug AndroGel. A full year later, on February 22, 2010, the United States District Court for the Northern District of Georgia dismissed the FTC's complaint for failure to state a claim. *In re: AndroGel Antitrust Litig. (No. II)*, 1:09-md-02084-TWT, slip op. (N.D. Ga. Feb. 22, 2010). This is the latest in a series of setbacks for the FTC in its long-standing bid to persuade courts that reverse payment settlements are anticompetitive and pose significant harm to consumer welfare.

AndroGel, manufactured by defendant Solvay Pharmaceuticals, is a patented form of testosterone replacement therapy which has enjoyed over $1.8 billion in U.S. sales since it first came to market in 2000. In 2003, pursuant to the Hatch-Waxman Act, two generic companies, Watson Pharmaceuticals and Paddock Laboratories (in partnership with Par Pharmaceuticals), each filed Abbreviated New Drug Applications ("ANDAs") with the FDA, seeking to market much cheaper, generic versions of AndroGel well before the expiration of Solvay's patent in 2020. The ANDAs filed by Watson and Paddock/Par certified that Solvay's patent was either invalid or not infringed. Solvay quickly responded to the ANDAs with patent infringement suits. After three years of litigation, and shortly after Watson obtained final approval from the FDA to enter the market, Solvay reached settlements with both generic defendants. The generics agreed not to enter the AndroGel market until 2015, and, in return, Solvay agreed to share its profits as part of co-promotion deals reached concurrently with the settlement agreements.

The FTC alleged that defendants' reverse payment settlements harmed competition and consumer welfare by eliminating the potential for competition in the AndroGel market before 2015. These settlements, the FTC argued, were not the result of the strength of Solvay's patent, but rather, the substantial compensation Solvay provided to the generics. Absent such compensation, the generics would not have agreed to refrain from competing until 2015. Defendants' anticompetitive settlements thus allowed them to unfairly retain for themselves the hundreds of millions of dollars that consumers would have saved if generic AndroGel were made available in the market sooner than the settlements allowed.

In dismissing the FTC's antitrust allegations, the United States District Court for the Northern

District of Georgia explained that while courts ordinarily determine the legality of alleged restraints of trade by applying either a rule of reason or *per se* analysis, neither is appropriate with respect to settlement of a patent, which, by definition, has anticompetitive effects on the market. Rather, the proper framework for determining the legality of reverse payment settlements requires an 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.

In applying this framework, the court held that the FTC had failed to allege that the challenged settlements exceeded the scope of Solvay's AndroGel patent. First, the court concluded, the settlements did not exclude from the market any product other than generic AndroGel, which was covered by Solvay's patent. Second, the settlements only excluded generic AndroGel until 2015, which did not exceed the temporal scope of the patent, set to expire in 2020. Third, the settlements only restrained the actions of the generic parties to the settlement without otherwise creating a bottleneck which prevented other generics from seeking to enter the AndroGel market.

The FTC argued that the court's consideration of the scope of the patent must go beyond just the claims and temporal scope asserted on the face of the patent. The scope of the patent should instead also account for the likelihood that the patent holder could successfully enforce its patent in litigation. The court, however, rejected this argument as contrary to Eleventh Circuit precedent, which held that patent litigation is too complex and the results too uncertain to require that antitrust analysis of patent settlements account for the likelihood that the patent holder would have prevailed in continued litigation. Such an approach would discourage settlements of patent disputes, which are favored by our judicial system.

The FTC also argued that patent settlements involving reverse payments should be regarded as presumptively unlawful. The court again rejected this argument as contrary to Eleventh Circuit precedent, which explained that reverse payments are understandable consequences of the "assymmetric" allocation of risks created by the Hatch-Waxman framework, as well as the large profits at stake in the drug industry. Neither the mere presence of a reverse payment, nor its size, the Eleventh Circuit held, should dictate whether settlement is an available resolution to patent disputes.

As illustrated above, the FTC's latest judicial challenge to reverse payment settlements has, once again, proven unsuccessful. The FTC has been unable, to date, to persuade courts that reverse payment settlements are unreasonable restraints of trade under U.S. antitrust laws. Only time will tell if the FTC will have better luck with the legislative process, where a provision banning such settlements is currently being debated as part of the overall health care reform bill.

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