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Pay for Delay Update: Supreme Court Enters the Fray

The day of reckoning, or perhaps vindication, could be approaching for those pharmaceutical companies daring enough to enter into reverse payments agreements to settle their patent litigation with generic challengers. On December 5, 2012, the Supreme Court announced that it had granted certiorari in a case brought by the Federal Trade Commission ("FTC"), and that it would decide what level of antitrust scrutiny should be applied by the courts when reviewing these types of agreements.[1]

Background

When a generic drug company challenges the patents of an innovator pharmaceutical company, there are basically only three possible outcomes: (i) the patents are upheld, and the generic challenger is kept off the market until the patents expire, (ii) the patents are overcome, and the generic challenger is allowed to enter the market immediately following Food and Drug Administration approval of the marketing application for the generic drug, or (iii) the companies settle the dispute.

The focal point of any settlement agreement is the date that the generic challenger should be allowed to enter the market. The parties will typically reach an agreement that gives some deference to the patents, and keeps the generic challenger off the market for a limited time period but not the full term of the patents. This aspect of the settlement is called a "patent split," and the FTC has not challenged the legitimacy of this aspect of any patent settlements.

The FTC becomes concerned when there is some other form of consideration that changes hands in the settlement that arguably sweetens the deal for the generic company, and influences it to stay off the market longer than it would have if a pure patent split was agreed upon by the parties. The FTC has assigned various terms to these deals over the years, including "reverse payment" and "pay-for-delay," but seems to be using the more neutral terminology "side deal" of late.

The first agreement of this type that the FTC challenged involved a straight payment of cash from the branded drug company to the generic challenger.[2]

1 *Federal Trade Commission v.* Watson Pharmaceuticals, et al. (U.S. Supreme Court Order 12-416, entered December 7, 2012).
2 *In re Cardizem CD Antitrust Litigation,* 332 F.3d 896 (6th Cir. 2003).

The FTC won hands down, with the Sixth Circuit Court of Appeals declaring that it would automatically deem this type of agreement invalid under the antitrust laws without any further analysis of the competitive landscape. The Sixth Circuit declared this type of agreement to be a "per se" violation of the antitrust laws.

Subsequent settlement agreements have been more difficult for the courts to evaluate, involving cooperative relationships between the two companies such as agreements for the generic challenger to manufacture product for the branded drug company, cross-licensing arrangements, and co-promotion agreements. The FTC argues that anything of value that changes hands in a patent settlement other than a pure patent split is per se anticompetitive and should be automatically deemed to violate the antitrust laws, but no court has so far adopted its stringent position.

In fact, courts have mostly been going in a direction opposite from the FTC, with three Circuit Courts of Appeal ruling these agreements are legal, and holding that courts need not consider any competitive harms as long as the parties did not exceed the "scope of the patent."[3] In practical terms, this has meant that the settlement survives antitrust scrutiny as long as the generic challenger is allowed to enter the market at some point before the patents expire.

Discussion

There are weaknesses in the "per se" approach endorsed by the FTC as well as the "scope of the patent" approach endorsed by the pharmaceutical industry which lead us to believe that the Supreme Court might adopt a middle ground when it ultimately renders its decision.

The FTC's "per se" approach suffers from its failure to consider any pro-competitive benefits that these settlements might bring, on the ground that any competitive benefits are far outweighed by their inherent anti-competitive effect. However, in the particular case going up to the Supreme Court, the trial court never received any evidence of these pro-competitive benefits because it granted a motion to dismiss at the very beginning of the lawsuit. The FTC is essentially asking the Supreme Court to form its own judgment on the issue, without any record or evidence from the very industry with the most knowledge of the competitive landscape.

The industry position is also not without its weaknesses. The "scope of the patent" test sounds reasonable, but the courts are only determining whether the agreement precludes competition beyond the patent term. In truth, the generic challenger frequently has solid grounds for challenging the patent, because it has designed around the patent or the patent is invalid. However, the scope of the patent test does not take these issues into consideration. They are only considered if the FTC or a private plaintiff is able to prove that the settlement is a "sham."

3 See *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

The stakes in the case could not be greater. According to the FTC, in 2011 alone, there were 156 patent settlements between branded and generic pharmaceutical companies, with 28 involving some consideration beyond a pure patent split.[4] A 2010 FTC staff study suggests that settlement agreements that include some sort of side deal prohibit generic entry on average 17 months later than settlement agreements that involve a pure patent split, and that consumers are losing more than $3.5 billion dollars per year as a result.[5] If the Supreme Court loosens the standards for proving an antitrust violation, we can be sure that third party payers, assisted by plaintiff's attorneys, will be knocking at the door asking for damages they suffered from the lack of earlier generic competition. They are already pursuing aggressive sham litigation claims in a number of venues.

It is also worth noting that some companies will emerge unscathed regardless of how the Supreme Court resolves the case. According to the FTC study, approximately 30% of the branded drug companies who have settled more than one patent suit over the past ten years have done so without entering into any arrangement other than a patent split. These companies apparently have decided that the risk of these types of settlements is too great, a point worth emphasizing today with the Supreme Court now entering the fray.

4 *FTC Briefing on Pharmaceutical Pay-For-Delay Settlements*, July 18, 2012, Presentation at Georgetown University.
5 *Id.*