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Antitrust

FTC Seeks U.S. Supreme Court Review Of Ruling in AndroGel Reverse Payment Case

The U.S. Supreme Court should review a federal appeals court decision that found a branded drugmaker did not violate federal antitrust laws in paying two generic drugmakers to delay introduction of their generic version of AndroGel as part of a patent litigation settlement, according to a petition filed with the high court Oct. 4 (*FTC v. Watson Pharmaceuticals Inc.*, U.S., No. 12-416, *petition filed* 10/4/12).

The Federal Trade Commission said high court review of an April decision by the U.S. Court of Appeals for the Eleventh Circuit is necessary and appropriate because of a split in the federal appeals court circuits on the reverse payment (or pay-for-delay) issue and because the issue is of ''exceptional importance to the national economy.'' The Eleventh Circuit's decision also should be reviewed because the court wrongly concluded that a reverse payment agreement is lawful unless it imposes greater restrictions on generic competition than would a judicial ruling that the brand-name manufacturer's patent was valid and infringed, the petition argued.

The FTC filing, coming on the heels of two petitions filed in August that seek to overturn a conflicting appeals court decision, all but ensures that the Supreme Court will finally have an opportunity to decide whether agreements between branded and generic drugmakers that call for payments and delayed generic drug entry as part of a patent litigation settlement should be considered presumptively illegal. As one attorney told BNA, ''The stars clearly seem aligned to finally have the 'pay-for-delay' issue heard by the Supreme Court.''

The two petitions filed by drug companies challenge a July decision by the U.S. Court of Appeals for the Third Circuit that found that a reverse payment from a branded drug manufacturer to a generic competitor is a per se violation of antitrust laws. The appeals court's decision, in a case involving the high blood pressure drug K-Dur 20, reinstated a class action lawsuit brought by private party direct K-Dur 20 purchasers against Schering-Plough Corp. (now part of Merck & Co.) and the generic drug companies Upsher-Smith and ESI over the companies' settlements of litigation over K-Dur 20 patents (167 HCDR, 8/29/12).

Review Likely. According to James M. Burns, with Dickinson Wright PLLC in Washington, ''there is probably no better evidence of a significant split in the circuits on an issue than to have two petitions for certiorari pending at the very same time with diametrically opposed rulings. In the circumstances, it would seem to be almost a certainty that the Supreme Court will finally hear, and resolve, the 'pay for delay' issue.''

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—James M. Burns, Dickinson Wright

The FTC petition ''raises several strong reasons for why the AndroGel case is a superior vehicle for Supreme Court review than the K-Dur case, but lurking unsaid—but no doubt significant in shaping the FTC's view on the issue—is the fact that the FTC would have a greater degree of control over the proceedings before the Supreme Court in the AndroGel case than it would have in the K-Dur matter,'' Burns said.

The FTC's petition challenges an Eleventh Circuit ruling that found Solvay Pharmaceuticals, owner of a drug patent for AndroGel, as well as two generic competitors—Watson Pharmaceuticals Inc. and Paddock Laboratories Inc.—with which Solvay had entered reverse payment settlement agreements, were not subject to liability under federal antitrust laws.

The court relied on three prior rulings by the Eleventh Circuit that ''establish the rule that, 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.''

The court, after noting that the case exposed the ''tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law,'' said resolution of the case required consideration of three Eleventh Circuit decisions: *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); and *Andrx Pharmaceuticals Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).

In two of those cases, the Supreme Court rejected petitions seeking review, it noted.

Review Warranted. The FTC's petition argued that the Eleventh Circuit got it wrong, that the high court should embrace the approach adopted by the Third Circuit, and that the stakes are sufficiently high to have the court step in to resolve a circuit split on an issue that reverberates through the federal trial courts.

The Eleventh Circuit ruled erroneously because its approach ''effectively equates a brand-name manufac-

turer's allegation of infringement with a judgment in the manufacturer's favor,'' even though ''defendants often prevail in patent infringement suits,'' even though ''the Hatch-Waxman amendments are designed to facilitate judicial resolution of validity and infringement issues in the generic-drug context,'' and even though ''federal antitrust laws flatly prohibit potential competitors from forming naked agreements not to compete,'' the petition said.

''The anticompetitive potential of reverse-payment agreements—which are estimated to cost consumers billions of dollars annually—is sufficiently clear that they should be treated as presumptively unlawful under the federal competition laws,'' it added. FTC also argued that the Eleventh Circuit's decision provides ''a superior vehicle for resolving a circuit conflict on a well-defined legal issue of exceptional importance to the national economy . . . and for addressing the question presented because it is brought by an agency charged by Congress with challenging unfair methods of competition.''

The petition was filed by Willard K. Tom, John F. Daly, and Mark S. Hegedus, with the FTC, and Donald B. Verrilli Jr., Joseph F. Wayland, Malcolm L. Stewart, and Benjamin J. Horwich, with DOJ in Washington.

BY PEYTON M. STURGES

The petition is at http://op.bna.com/hl.nsf/r?Open=psts-8yslgq.

