

U.S. Supreme Court to Rule on “Pay-for-Delay” Antitrust Issue

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The Supreme Court of the United States has granted the government’s petition for a writ of certiorari in ***FTC v. Watson Pharmaceuticals***, agreeing for the first time to address the antitrust and patent law implications of so-called “pay-for-delay” or “reverse payment” patent settlement agreements between branded and generic pharmaceutical manufacturers. The Court’s ruling will likely resolve this contentious issue, which has divided the federal courts and which the **Federal Trade Commission** has pursued for more than a decade.

The Supreme Court of the United States has agreed for the first time to hear a case involving the contentious “pay-for-delay” antitrust theory applied to certain patent settlement agreements between branded pharmaceutical companies and generic drug applicants.

On December 7, 2012, the Court granted the U.S. government’s petition for a writ of certiorari in *Federal Trade Commission v. Watson Pharmaceuticals Inc.*, 677 F.3d 1298 (11th Cir. 2012). The Federal Trade Commission (FTC) has opposed such agreements, also called “reverse payment” settlements, on antitrust grounds since at least 2001. Until earlier this year, however, U.S. courts of appeals have repeatedly rejected the FTC’s theory of consumer harm and ruled for defendants in upholding the agreements. That trend changed in July 2012, when, in a private antitrust challenge to a patent settlement, the U.S. Court of Appeals for the Third Circuit adopted the FTC’s analysis and ruled against the defendants. *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012). *K-Dur* reflects a “split” on the issue between the Third and Eleventh Circuits. Two other U.S. Courts of Appeals—the Second and Federal Circuits—are aligned with the Eleventh Circuit on this issue. See *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009). This split sets the stage for the Court’s resolution in *FTC v. Watson Pharmaceuticals*.

Pay-for-delay cases arise in settlements of patent infringement suits by branded drug patent-holders against generic drug applicants that defend on grounds of non-infringement or patent invalidity. The antitrust claim stems from two provisions (both necessary to trigger the claim): a restriction on generic entry until a future date and the brand’s payment of money or other value to the generic, often in the form of an ancillary agreement like a supply arrangement or patent license (coined a “reverse” payment because the plaintiff pays the defendant). The FTC argues that this paradigm

delays competition because it induces the generic to accept later entry than it would demand in settlement negotiations absent the payment or that it would obtain under exclusivity provisions if it prevailed in the lawsuit. Defendants counter that the settlements accelerate competition because they enable generic entry prior to patent expiration.

Faced with these arguments, the Eleventh, Second and Federal Circuits have applied a “scope of the patent” test to resolve them. Under this test, so long as the underlying infringement suit is not a sham, an agreement authorizing generic entry prior to patent expiration—even with a “reverse payment”—is lawfully within the brand’s patent law right to exclude. The Third Circuit rejected that test, holding that it “[e]ntitles the patent-holder to pay its potential generic competitors not to compete,” and instead applied a rebuttable presumption that the payment is an anticompetitive *quid pro quo* for delayed generic entry. It is into this state of judicial uncertainty that the Supreme Court now steps.

The “pay-for-delay” controversy is not limited to the United States. The European Commission (EC) has recently issued Statements of Objections in its first two investigations into alleged delayed generic-entry arrangements. (See European Commission press releases IP/12/834 (*Citalopram*) (July 25, 2012) and IP/12/835 (*Perindopril*) (July 30, 2012).) The EC’s analytical approach to the competition issues follows that of the FTC. Whether and to what extent the EC adopts the legal reasoning of the Supreme Court—no matter which way it resolves the split within U.S. courts—will be an important development for the pharmaceutical industry to watch. The extent to which the U.S. and EU approaches to patent settlements are harmonized will be a significant factor in how much legal uncertainty pharmaceutical companies will face when trying to settle cases.

The defendants in *K-Dur* also sought Supreme Court review, but the Court is holding that petition pending its ruling in *FTC v. Watson Pharmaceuticals*. The Court is likely to hear oral argument in *Watson Pharmaceuticals* during the last two weeks of March 2013. McDermott lawyers are closely monitoring these developments and will report promptly after the argument on the Justices’ approach to the issues in their questions and comments to counsel.

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