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I. INTRODUCTION

For over a decade, the Federal Trade Commission has sought, with little success, to end "reverse settlement" payments among manufacturers of branded and generic pharmaceuticals. On April 25, 2012, the Eleventh Circuit Court of Appeals dealt another blow to the FTC's campaign against reverse settlements.

In *Federal Trade Commission* v. *Watson Pharmaceuticals*, the Court affirmed the dismissal of a complaint alleging that a reverse settlement payment, made by the holder of a pharmaceutical patent to two generic drug manufacturers, violated the antitrust laws.[2] The decision renders reverse settlements "immune from antitrust attack" in the Eleventh Circuit in most circumstances,[3] and further diminishes the FTC's chances of persuading other courts to adopt its policy position.

II. BACKGROUND

A reverse settlement involves an agreement to settle patent infringement litigation brought by the manufacturer of a branded pharmaceutical against would-be competitors seeking federal regulatory approval to market a generic version of the same drug. Instead of the defendants (generic drug manufacturers) paying the plaintiff (the branded drug manufacturer) to settle its infringement claims, the plaintiff pays the defendants and defendants agree to delay introduction of a generic version of the drug at issue for some period of time.

The FTC has long targeted reverse settlement agreements as a top enforcement priority—taking the position that such agreements, which it terms "pay for delay," unreasonably restrain competition in violation of the federal antitrust laws. In amicus briefs and enforcement actions, the FTC has argued that reverse settlement agreements should be treated as presumptively unlawful under the Sherman Act. In 2010, the Commission published a study in which it estimated that reverse settlement payments cost American consumers $3.5 billion per year in increased drug prices, by slowing the entry of generic competitors.[4]

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[2] *FTC* v. *Watson Pharmaceuticals, Inc.*, No. 10-12729, --- F.3d ----, 2012 WL 1427789 (11th Cir. Apr. 25, 2012).

[3] *Id.* at *11.

[4] FTC Staff Study, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions" (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

The Department of Justice Antitrust Division ("DOJ") traditionally has been more tolerant of reverse settlement agreements. The DOJ even opposed the FTC's request that the U.S. Supreme Court hear a challenge to a lower court ruling that went against the FTC in an earlier reverse settlement case.[5] But, in 2009, the DOJ aligned itself closely with the FTC on this issue, and argued in a brief to the Second Circuit Court of Appeals that reverse settlement agreements should be presumed to violate Section 1 of the Sherman Act.[6]

While the antitrust enforcement agencies have intensified their efforts to prohibit reverse settlement payments in recent years, the federal courts have become increasingly hostile toward the government's and private plaintiffs' claims. Early on, the FTC gained support for its position in the Sixth Circuit Court of Appeals, which held (in 2003) that a reverse settlement agreement regarding the prescription drug Cardizem CD (used to treat hypertension) was tantamount to horizontal market allocation and therefore *per se* illegal under the antitrust laws.[7] Since then, however, the Second, Eleventh, and Federal Circuits have roundly rejected challenges to pharmaceutical reverse settlements, and the Supreme Court has refused the FTC's repeated requests to take up the issue.[8]

III. *FTC V. WATSON PHARMACEUTICALS*: THE ELEVENTH CIRCUIT'S DECISION

Watson Pharmaceuticals is the latest loss for the FTC in its attempt to ban reverse settlement payments.

The case arose out of a settlement agreement between Solvay Pharmaceuticals, the owner of a patent on AndroGel—a prescription gel used to increase testosterone levels in male patients—and two competing drug manufacturers seeking to offer a generic alternative to AndroGel. The same year the Solvay patent was granted, 2003, Watson Pharmaceuticals and Paddock Laboratories filed applications with the FDA to begin marketing generic AndroGel. Solvay sued Watson and Paddock for patent infringement, triggering an automatic 30-month stay of the FDA's approval process for their proposed generics.

For the next three years, the parties litigated the patent infringement action. In 2006, with cross motions for summary judgment pending, the stay expired and the Food & Drug Administration approved Watson's application to market generic AndroGel. Watson projected that it would sell its generic product for 75 percent less than the price of branded AndroGel. As a result, Solvay stood to lose 90 percent of its business or approximately $125 million per year in

[5] Brief for the United States as Amicus Curiae, *FTC* v. *Schering-Plough Corp.*, No. 05-273 (May 17, 2006), *available at* http://www.usdoj.gov/atr/cases/f216300/216358.pdf.

[6] Brief for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851-cv (2d Cir. July 6, 2009), *available at* http://www.usdoj.gov/atr/cases/f247700/247708.pdf.

[7] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *see also Andrx Pharms. Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001).

[8] *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); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98 (2d Cir. 2010).

profits upon the entry of generic competitors. As the Court of Appeals observed: "A lot was riding on the outcome of the patent litigation."[9]

Before the district court ruled on the summary judgment motions, the parties agreed to settle Solvay's infringement claims. Watson and Paddock agreed not to market a generic version of AndroGel until 2015—five years before Solvay's patent would expire. In addition, Watson agreed to promote branded AndroGel to urologists, in exchange for a share of Solvay's profits on AndroGel sales. Solvay projected that its payments to Watson would range from $19 million to $30 million per year, through 2015. Paddock agreed to serve as a backup manufacturer for branded AndroGel, in exchange for payments by Solvay of $2 million per year. The agreement was reported to the FTC, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[10]

The FTC sued Solvay, Watson, and Paddock, alleging that their settlement—which involved significant payments by Solvay to the alleged infringers of its patent—was harmful to competition and violated the Sherman Act. The FTC charged that the settlement agreement artificially postponed the entry of generic drug competitors, thereby allowing Solvay to maintain a monopoly over sales of AndroGel. The FTC characterized Solvay's payments to Watson and Paddock as a monopolist sharing its monopoly profits with competitors in exchange for their covenant not to compete.

As the Court of Appeals observed, the "lynchpin" of the FTC's complaint was its allegation that Solvay "probably would have lost the underlying patent infringement action."[11] The FTC maintained that because Solvay was unlikely to prevail in its patent infringement action, its patent would not serve to impede generic entry. This was a crucial premise of the FTC's position that the settlement agreement harmed competition by delaying the entry of Watson and Paddock: if Solvay's patent were upheld, and the generic versions of AndroGel were found to infringe, then Watson and Paddock would be legally barred from offering their products for sale until the patent expired, in 2020.

Defendants moved to dismiss, arguing that the FTC had failed to state a valid claim for relief under the antitrust laws. The district court granted the motion. Based on prior Eleventh Circuit decisions concerning reverse settlement agreements, the district court held that analysis of such agreements under the antitrust laws requires 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.'"[12] In this case, the FTC had not alleged that the settlement agreement exceeded the scope of Solvay's patent. Whereas the agreement not to market a generic version of AndroGel extended through 2015, the patent provided exclusivity through 2020. Moreover, the settlement agreement covered AndroGel only, and did not purport to affect sales of other products or sales by manufacturers other than the parties to the agreement.

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[9] *Watson*, 2012 WL 1427789, at *5.

[10] *See id.*

[11] *Id.* at *6.

[12] *In re Androgel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371, 1377 (N.D. Ga. 2010) (quoting *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005)).

The Eleventh Circuit affirmed. After reviewing its own precedents, the Court of Appeals concluded: "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."[13] The FTC argued that it met that standard by alleging that Solvay was "not likely to prevail" in its patent infringement challenged. It reasoned that "a patent has *no* exclusionary potential if its holder was not likely to win the underlying infringement suit."[14] The Court rejected that argument. It also rejected the FTC's invitation to adopt a rule that a patent settlement be deemed unlawful if, at the time of settlement, it is more likely than not that the patent on its own would fail to block generic entry.

Patent litigation, the Court observed, can be "a high stakes, spin-the-chambers, all or nothing undertaking."[15] When both sides to a patent dispute face substantial odds of winning and losing, it is reasonable for them to settle and a settlement payment by the patent holder should not necessarily be deemed unlawful and anticompetitive.

In addition, the Court pointed out that the FTC's proposed rule would require the court hearing a challenge to a settlement agreement under the antitrust laws to make an after-the-fact determination of how likely a patent holder would have been to prevail on its patent infringement claims if they had been litigated to judgment and not settled. This, the Court held, would create an untenable situation for judges in antitrust cases: "Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as the basis for antitrust liability and treble damages."[16]

The Court was unmoved by the FTC's "ominous forecast" that permitting settlements like the one at issue to go forward would result in less competition and higher drug prices because potential competitors would choose to forego litigation in order to share in a patent holder's monopoly profits. The Court reasoned that if a drug patent is actually vulnerable to attack, then there will be many potential manufacturers of generics willing to challenge it and to attempt to enter the market, even after the first challenger has settled with the patent holder. "Blood in the water can lead to a feeding frenzy."[17] And, while a patent holder's monopoly profits may be enough to satisfy "the first one or two challengers, those profits will be eaten away as more and more generic companies enter the waters."[18]

IV. IMPLICATIONS FOR FUTURE CASES

Pharmaceutical manufacturers have grown emboldened by their success in defending reverse settlement payments in the courts. The number of reverse settlement agreements has been rising steadily since 2004. Based on its review of settlements reported under the Medicare Prescription Drug Act, the FTC determined that in 2010 and 2011 there were 59 agreements to settle patent disputes between brand and generic manufacturers that potentially involved "pay-

[13] *Watson*, 2012 WL 1427789, at *11.
[14] *Id.*
[15] *Id.* at *12.
[16] *Id.*
[17] *Id.* at *14.
[18] *Id.*

for-delay."[19] This was almost equal to the total number of potential reverse settlement payments the FTC identified in the preceding six years (2004-2009) combined.

The FTC has highlighted these developments, which it says are "extremely troubling," to Congress.[20] The FTC also has acknowledged, however, that it is unlikely to obtain widespread reform in the area of pharmaceutical patent settlements through the courts. As a result, the FTC has urged Congress to enact legislation banning reverse settlement agreements.

While the Obama administration initially supported the inclusion of a provision restricting reverse settlements in the health care reform law, the provision did not survive the legislative process. In February of this year, Representative Bobby Rush of Illinois introduced the Protecting Consumer Access to Generic Drugs Act of 2012, which would make reverse settlement payments unlawful subject only to certain narrow exceptions. The bill was referred to the House Subcommittee on Intellectual Property, Competition, and the Internet, and no further action has been taken on it. Several previous versions of the bill, also sponsored by Representative Rush as well as by Senators Kohl and Grassley (among others), have died in committee.

The Eleventh Circuit's strongly worded and unequivocal rejection of the FTC's arguments against reverse settlements in *Watson Pharmaceuticals* makes it less likely that the FTC will succeed in convincing other courts to adopt its policy position on this issue going forward, including courts in judicial circuits that have not yet addressed the issue.[21] Without a widening split in authority among the circuits, Supreme Court review is also unlikely. In light of these challenges, the FTC may redouble its efforts to promote reverse-settlement legislation, though the issue has failed to gain much traction in Congress thus far.

All signs suggest that the practice of reverse settlement payments will continue to grow more prevalent in pharmaceutical patent cases, or at least will not abate in the near future.

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[19] *See* "Agreements Filed With the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2011, A Report by the Bureau of Competition," *available at* http://www.ftc.gov/os/2011/10/1110mmaagree.pdf.

[20] Prepared Statement of the Federal Trade Commission, Before the United States House of Representatives Committee on the Judiciary, Subcommittee on Courts and Competition Policy (July 27, 2010), *available at* http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf.

[21] A class action challenge to a reverse settlement agreement is currently pending in the Third Circuit Court of Appeals, which has yet to weigh in on the legality of such agreements. The lower court granted the defendants' motion for summary judgment, holding that the reverse settlement payment at issue did not violate the antitrust laws. Last May, the FTC submitted an amicus brief in the case, urging the Third Circuit to adopt a "presumptively unlawful" standard. Brief of the Federal Trade Commission as *Amicus Curiae Supporting Appellants and Urging Reversal*, *In re: K-Dur Antitrust Litigation*, Nos. 10-2077, 10-2078, 10-2079 (3d Cir. May 17, 2011), *available at* http://www.ftc.gov/os/2011/05/110518amicusbrief.pdf.