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Eleventh Circuit Reaffirms That "Pay-For-Delay" Settlement Agreements Are Largely Immune From Antitrust Attack

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A "pay-for-delay" settlement agreement, also referred to as a reverse payment agreement, is a type of patent litigation settlement in which a patent holder pays an allegedly infringing generic drug company to delay entering the market until a specified date. This protects the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor. In the past decade, pay-for-delay agreements have been repeatedly attacked by the Federal Trade Commission. In the FTC's view, pay-for-delay agreements are unfair restraints on trade that violate federal antitrust laws because such agreements artificially preserve a patent holder's monopoly profits, which are shared with the generic drug manufacturers who have agreed to stay out of the market. In a recent decision addressing yet another challenge by the FTC to a pay-for-delay agreement, the United States Court of Appeals for the Eleventh Circuit has reaffirmed that such agreements do not run afoul of antitrust law so long as the anticompetitive effects of the agreement fall within the exclusionary potential of the patent.

In *Federal Trade Commission v.Watson Pharmaceuticals, Inc., et al*., No. 10-12729 (11th Cir. April 25, 2012), the FTC filed an antitrust lawsuit against four entities that entered into a pay-for-delay agreement to settle patent litigation. In the underlying dispute, Solvay Pharmaceuticals, Inc. filed a New Drug Application ("NDA") for the prescription drug AndroGel. After the FDA approved Solvay's NDA, Solvay filed a patent application with the U.S. Patent and Trademark Office. The PTO granted the application, jointly awarding Solvay and the drug's creator (a foreign entity) Patent Number 6,503,894 ("the '894 patent"). Solvay then asked the FDA to include the '894 patent in the Orange Book alongside the AndroGel listing.

A few months after the '894 patent issued, Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. developed generic versions of AndroGel. Watson and Paddock both filed Abbreviated New Drug Applications ("ANDA") with the FDA, with each making paragraph IV certifications that their generic AndroGel products did not infringe the '894 patent or that the patent was invalid. Within 45 days, Solvay filed a patent infringement lawsuit against Watson and Paddock in federal district court, which triggered a 30-month stay of the FDA's approval process for Watson's and Paddock's generic versions of AndroGel pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

After conducting discovery, Watson and Par/Paddock[1] filed motions for summary judgment on the validity of the '894 patent. The motions were fully briefed and ready for decision when the 30-month stay on the

FDA's approval process for Watson's ANDA ended.[2] That same month, the FDA approved Watson's generic AndroGel product. Before the motions for summary judgment were ruled on, and before any generic AndroGel product was brought to market, the parties settled their patent dispute. Under the terms of the settlement agreement, Watson, Par and Paddock agreed not to market generic AndroGel products for a period of approximately nine years—which fell within the remaining life of the '894 patent—unless another manufacturer of the generic product entered the market before then. Watson and Par further agreed to promote branded AndroGel to physicians. In exchange, Solvay agreed to pay Par/Paddock $10 million per year for six years (and another $2 million per year for serving as a backup manufacturer of the drug), and further agreed to share a portion of its AndroGel profits with Watson for the roughly nine year period Watson had agreed to stay out of the market. The payments from Solvay to Watson were projected to be between $19 million and $30 million per year. Pursuant to the settlement, the parties stipulated to the dismissal of the patent infringement lawsuit.

After receiving notice of the settlement agreements, the FTC filed an antitrust suit against Solvay, Watson, Par and Paddock. In its amended complaint, the FTC claimed that the settlement agreements were unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act.[3] The FTC alleged that the agreements postponed the entry date of the generic drugs, thereby allowing Solvay to maintain monopolistic profits—which were shared with Watson, Par and Paddock—at the expense of consumer savings that would have resulted from price competition. The amended complaint further alleged that Solvay "was not likely to prevail" in the patent litigation because the '894 patent "was unlikely to prevent generic entry" into the marketplace. Therefore, according to the FTC, Solvay's reverse payments to the generic drug producers continued and extended a monopoly that the patent laws did not authorize.

The four defendants moved to dismiss the amended complaint under Rule 12(b)(6), arguing that because the FTC had not alleged that the settlements imposed an exclusion greater than that authorized by the '894 patent, the amended complaint failed to state a viable claim. The United States District Court for the Northern District of Georgia agreed and dismissed the lawsuit. The FTC appealed.

On appeal, the Eleventh Circuit surveyed its prior decisions addressing pay-for-delay settlements, which taken collectively 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." This is because the patent holder, prior to a finding of invalidity or non-infringement, has the right to exclude others from entering the market consistent with the scope and duration of the patent. So long as a pay-for-delay settlement does not create restrictions beyond the patent holder's potential power to exclude, there presumably has been no adverse effect on competition.

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Notwithstanding the prior jurisprudence, the FTC urged the Eleventh Circuit to adopt a rule that "an exclusion payment is unlawful if, viewing the situation objectively as of the time of settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date" under the terms of the settlement. The Eleventh Circuit rejected this request outright. The Court noted that given its plain meaning, a patent holder's claim of infringement that is "likely" to fail is just as likely to succeed 49 times out of 100. Given the high-stakes nature of patent litigation, a patent holder with nearly 50-50 odds of winning its case is motivated to settle. Likewise, one challenging a patent who has a better chance of prevailing has just that, a chance, not a certainty. As stated by the Eleventh Circuit, "[r]ational parties settle to cap the cost of litigation and to avoid the chance of losing." When both sides of the dispute have a substantial chance of winning and losing, it is reasonable for them to settle. Indeed, as noted by the Court, "[w]hen hundreds of millions of dollars of lost profits are at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."

The Eleventh Circuit further noted that the FTC's approach would require a determination after-the-fact of how likely the patent holder was to succeed had it not settled its infringement lawsuit. According to the Court, this is "too perilous an enterprise to serve as the basis for antitrust liability and treble damages." The FTC's proposal would require the parties and the court to sift back through what often amounts to "mountains of evidence" to evaluate the likelihood of the patent holder's success in the underlying litigation. Doing so would burden the legal system and discourage settlement. And a retrospective prediction of the outcome of an already settled case is unlikely to be reliable, as the parties to the prior suit are now aligned by virtue of their settlement. Consequently, the generic competitor no longer has the same incentive to vigorously attack the patent in issue. Finally, the Eleventh Circuit noted that the FTC's approach—which would require the Eleventh Circuit and other non-specialized circuit courts to adjudicate patent issues on appeal—is inconsistent with Congress' decision to grant exclusive appellate jurisdiction over patent cases to the United States Court of Appeals for the Federal Circuit.

The FTC argued that if its proposal of looking back to decide the likely outcome of the previously settled patent infringement litigation was not adopted by the Eleventh Circuit, patent holders and potential competitors would forego patent litigation and instead divide among themselves the stream of monopoly profits even in those situations in which it is more likely than not that the patent would be found invalid or not infringed. According to the FTC, this will result in a lack of competition and higher prices to the end consumer of prescription drugs. The Eleventh Circuit disagreed with the FTC's "ominous forecast," stating that if the patent is actually vulnerable to attack, several other generic companies who are not party to the pay-for-delay agreement will attempt to enter the market and challenge the patent. As more and more generic manufacturers file their own paragraph IV certifications challenging the patent, the patent holder's monopolistic profits will come under continued attack and, presumably, eventually dry up.

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The decision in *Watson Pharmaceuticals* reaffirms that so long as the anticompetitive effects of a pay-for-delay settlement do not extend beyond the scope of the exclusionary potential of the patent, the settlement should withstand an antitrust attack by the FTC in the Eleventh Circuit.[4] However, given the FTC's propensity to continue challenging such settlements, we likely have not heard the last word on this issue. The ball is squarely back in the FTC's court at this point in time.

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1. Paddock partnered with Par Pharmaceuticals Companies, Inc., which agreed to share the costs of litigation with Paddock in exchange for part of the profits from Paddock's generic AndroGel product if that product gained final approval from the FDA.
2. Because Watson filed its ANDA before Paddock, it was eligible for the 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv).
3. *See* 15 U.S.C. § 45(a)(1) (banning "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce").
4. It bears mentioning that in the Sixth Circuit and the District of Columbia Circuit, pay-for-delay agreements are *per se* unlawful under the Sherman Act. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)*; In re Andrx Pharms., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799 (D.C. Cir. 2001). The Second and Federal Circuits, like the Eleventh Circuit, have held that pay-for-delay agreements are neither *per se* unlawful nor unreasonable restraints on competition so long as they fall within the exclusionary scope of the patent. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). The issue of whether pay-for-delay agreements violate antitrust law is presently before the Third Circuit. *See In re K-Dur Antitrust Litig.*, Case No. 10-2077, United States Court of Appeal for the Third Circuit.