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SECOND CIRCUIT REVIEW

Expert Analysis

Opening Door to Direct Purchasers To Bring 'Walker Process' Claims

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This month, we discuss *In re DDAVP Direct Purchaser Antitrust Litigation*,[1] in which the U.S. Court of Appeals for the Second Circuit addressed the standing of a class of direct purchasers to bring *Walker Process* claims for antitrust liability. In an opinion written by Judge John M. Walker and joined by Judge Wilfred Feinberg and Judge Debra Ann Livingston, the court vacated a decision by the U.S. District Court for the Southern District of New York dismissing plaintiffs' class action antitrust complaint for, inter alia, lack of standing.

In a case of first impression in any appellate court, the court held that direct purchasers have standing to bring a *Walker Process* claim—that is, an antitrust claim premised on defendant's enforcement of a patent obtained by fraudulent means—for patents that are already unenforceable due to inequitable conduct. The court, however, declined to decide whether purchaser plaintiffs per se have standing to raise *Walker Process* claims, leaving for another day the extent of this expansion of standing doctrine.

Procedural History

In September of 1991, after a five-year application process, Ferring, B.V. and Ferring Pharmaceuticals (collectively "Ferring") acquired a patent for DDAVP, an antidiuretic prescription medication used to treat diabetes, excessive urination, excessive thirst, and bed wetting. Ferring subsequently granted Aventis Pharmaceuticals an exclusive license to market and sell the newly patented drug. Aventis, in addition to acquiring the license from Ferring, demonstrated to the Food and Drug Administration (FDA) the safety and efficacy of the drug, and thereby received an approved New Drug Application from the federal agency, which is required to legally market and sell any pharmaceutical.

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More than eight years later, Barr Laboratories Inc. filed an Abbreviated New Drug Application with the FDA, by which it demonstrated its interest in marketing a generic brand of DDAVP. As part of its application, Barr filed a certification that Ferring's patent for DDAVP was "invalid, unenforceable, and/or would not be infringed by Barr's generic product."[2]

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In response to Barr's application, Ferring filed a patent infringement action against Barr in district court. Ferring was unsuccessful in this litigation. District Judge Charles L. Brieant held on summary judgment that the patent for DDAVP was not being infringed by Barr, but rather was "unenforceable due to inequitable conduct before the [Patent and Trademark Office (PTO)] by Ferring and its agents."[3] Specifically, the district court found that Ferring's original application had been rejected by the PTO because the patent examiners concluded that DDAVP was not sufficiently novel to warrant a patent.

It was not until the examiners subsequently considered declarations from several scientists, which directly addressed their concerns, that the PTO granted Ferring a patent for DDAVP. It was later discovered, however, that four out of five of these crucial declarations were written by scientists employed by, or who had received funding from, Ferring. The district court granted summary judgment to Barr on the grounds that the patent had been obtained by inequitable conduct by Ferring in connection with this nondisclosure of the scientists' ties to Ferring, which rendered the patent unenforceable. The district court's holding was upheld by the U.S. Court of Appeals for the Federal Circuit.[4]

Within two months of the Federal Circuit decision, the purchaser plaintiffs (namely, direct purchasers Meijer Inc., Meijer Distribution Inc., Rochester Drug Co-operative Inc., and Louisiana Wholesale Drug Co. Inc.) filed suit against Ferring and Aventis. In their complaint, plaintiffs asserted antitrust law violations, alleging that, among other things, defendants fraudulently obtained the DDAVP patent; improperly listed the patent for DDAVP in the FDA's Orange Book despite knowing the patent was invalid; prosecuted a sham litigation against Barr for patent infringement; and fraudulently delayed the approval of a generic form of DDAVP by filing a citizen petition with the FDA asking the agency to require additional testing of the generic form of the drug while knowing this testing was unnecessary. All of these actions, plaintiffs contended, prevented a generic version of DDAVP from being available to the public, causing the cost of the drug to be artificially inflated in violation of antitrust law.

Ferring and Aventis jointly filed a motion to dismiss the plaintiffs' complaint for lack of standing, and Aventis additionally moved to dismiss on the ground that plaintiffs had not adequately alleged any misconduct on its part. Judge Brieant granted these motions.[5] The district court held that the plaintiffs had not pled fraud with sufficient particularity, holding that plaintiffs were required to plead facts showing more culpability on the part of defendants than the inequitable conduct necessary to render a patent unenforceable.

Although the district court held that the plaintiffs' failure to plead fraud with enough particularity was grounds enough to dismiss

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plaintiffs' claims, it also considered defendants' argument that plaintiffs lacked standing. The court held that the purchaser plaintiffs did not have standing to assert a *Walker Process* claim because the patent had not been enforced against them, and they were not direct competitors of either defendant.

Second Circuit

While the Second Circuit overturned all of the legal bases for the district court's dismissal of the complaint,[6] it is the court's decision concerning plaintiffs' standing to bring a *Walker Process* claim that makes this case noteworthy.

The court began its analysis by outlining the requirements for antitrust standing, which is separate and distinct from Article III standing. Generally, to establish antitrust standing, a plaintiff must show

> (1) antitrust injury, which is injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful, and (2) that he is a proper plaintiff in light of four efficient enforcer factors:
> (1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.[7]

Evaluating each of these factors, the court held that plaintiffs had clearly alleged an antitrust injury by pleading that they had been forced to purchase products that were excessively priced due to the alleged illegal behavior of the defendants. Specifically, the court found that (1) plaintiffs were directly injured by the harm defendants caused to competitors; (2) plaintiffs were of a class of people motivated to enforce antitrust laws, and the fact that defendants' competitors may have more motivation was not dispositive; (3) the alleged injury was far from speculative, as demonstrated by the fact that manufacturers of a generic brand of DDAVP attempted to enter the market while the patent was still pending; and (4) there was no potential for duplicative recovery, since the damages asserted by the direct purchaser class were for overcharges, and the damages that could potentially be asserted by competitors were for conceptually distinct lost profits. The court thus concluded that, "although the relative weight given to each factor is imprecise, the plaintiffs would be efficient enforcers under any formulation."[8]

After concluding that the plaintiffs had antitrust standing, the court addressed whether direct purchaser plaintiffs have standing to bring a *Walker Process* claim based on a patent that had not yet been determined to have been fraudulently obtained. In *Walker Process Equip. Inc. v. Food Mac. & Chem Corp.,*[9] the U.S. Supreme Court held that a defendant could incur antitrust liability for enforcing a patent if that patent was obtained by fraud on the PTO. To establish such a claim, a plaintiff must demonstrate:

> (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, (5) injury to the party deceived as a result of his reliance on the misrepresentation.[10]

The plaintiff must then show that monopolization occurred as a result of the enforcement of the fraudulently obtained patent.

As the Second Circuit noted, since the validity of a patent is central to a *Walker Process* claim, such claims generally are brought as counterclaims to patent infringement suits. In *In re DDAVP Direct Purchaser Antitrust Litigation*, however, the plaintiffs brought the *Walker Process* claim independent of a patent infringement case, and for a patent that was not already found to have been obtained through fraud. Furthermore, plaintiffs in this matter did not have standing to directly challenge the validity of the underlying DDAVP patent because, under well-established law, only parties who produce, or plan to produce, a patented product, or who have been threatened with or reasonably believe they will be threatened with an infringement suit, have standing to challenge a patent's validity.

> While the court declined to hold that direct purchasers always have standing to bring 'Walker Process' claims, the decision cautiously acknowledges the possibility that the law may shift in that direction.

Invoking the time-honored floodgates argument, defendants asserted that the court should hold that unless the patent at issue has already been found to be fraudulently obtained, plaintiffs who do not have standing to challenge the patent should also not have standing to bring a *Walker Process* claim. In particular, defendants argued that any contrary result would allow plaintiffs who otherwise would not have standing effectively to challenge patents under the guise of an antitrust claim.

The court, while acknowledging the policy interests implicated by defendants' argument, was reluctant to hold that direct purchasers could never bring a *Walker Process* claim absent a prior finding that the patent was fraudulently procured. The court feared that this holding would "leave a significant antitrust violation undetected or unremedied" because direct competitors often do not have the desire, resources, or wherewithal to argue that a patent was fraudulently obtained.[11]

As the court explained, although the standard for demonstrating a patent was fraudulently obtained is much higher than the standard for demonstrating a patent was obtained through inequitable circumstances, from the point of view of a competitor, the results for each claim are the same—the patent is held to be invalid, and the competitor can then market a generic brand of the product.

Recognizing, however, "[t]he risk of disturbing the incentives for innovation," the court articulated a need to "tread carefully" in expanding the universe of patent challengers.[12] Accordingly, the court declined to determine whether direct purchaser plaintiffs per se had standing to bring a *Walker Process* claim. Rather, the court expressly limited its holding to the standing of direct purchasers bringing *Walker Process* claims based on patents that have already been deemed unenforceable due to defendants' inequitable conduct.

Conclusion

In *In re DDAVP Direct Purchaser Antitrust Litigation*, the Second Circuit opened the door for direct purchaser plaintiffs to assert antitrust claims against companies using certain invalid patents to monopolize the market. While the court declined to hold that direct purchasers always have standing to bring *Walker Process* claims, the decision cautiously acknowledges the possibility that the law may shift in that direction. It will be interesting to see how it develops.

1. Docket No. 06-5525-cv, 2009 WL 3320504 (2d Cir. Oct. 16, 2009).
2. Id. at *1.
3. Id.
4. *Ferring B.V. v. Barr Labs. Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).
5. *In re DDAVP Direct Purchaser Antitrust Litig.*, No. 05 C. 2237, slip op. at 15 (SDNY Nov. 2, 2006).
6. The Second Circuit also addressed arguments by appellants that only the Federal Circuit, and not the Second Circuit, had jurisdiction to hear the appeal, and that the district court also had erred in finding the antitrust claim was not adequately pleaded, particularly as to defendant Aventis. These issues are not addressed in this column.
7. *In re DDAVP Direct Purchaser Antitrust Litig.*, 06-5525-cv, 2009 WL 3320504, at *7 (internal citations omitted).
8. Id. at * 8.
9. 382 U.S. 172, 173 (1965).
10. *Nobelpharma AB v. Implant Innovations Inc.*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998).
11. *In re DDAVP Direct Purchaser Antitrust Litig.*, 06-5525-cv, 2009 WL 3320504, at *8 (internal citations omitted).
12. Id. at 11.

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