

REPORT

CUSTOMERS MAY BE ABLE TO SUE PATENT OWNERS FOR ANTITRUST DAMAGES IN CASES OF FRAUD ON THE USPTO

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I. Introduction

A recent decision by the U.S. Court of Appeals for the Second Circuit has expanded the class of antitrust plaintiffs who can claim monopoly damages in connection with fraudulently obtained patents (known as *Walker Process* suits). In *In re DDAVP Direct Purchaser Antitrust Litigation ("DDAVP")*,¹ the Second Circuit held that direct purchasers (i.e., customers) of a patented drug product have standing to bring antitrust claims against the patentee in cases in which the patent has previously been held unenforceable due to inequitable conduct before the USPTO.

This is the first appellate court to acknowledge the standing of customers to sue a patentee in a *Walker Process* case, and expands in two ways the risk of patentees who are found to have committed inequitable conduct. First, it allows customers, rather than just competitors, to seek damages from a patentee based on the patentee's enforcement of a fraudulently obtained patent. Second, those damages are antitrust damages and, accordingly, can be trebled. Antitrust damages have previously been obtainable by a fraudulent patentee's competitors. However, competitors seldom joined in class action suits brought by plaintiff-oriented law firms, which customers are more likely to do. Thus, the practical risk, in the kinds of cases that may meet all of the antitrust criteria, is larger. This risk can enhance the bargaining position of a competitor who has grounds for alleging inequitable conduct, or provide customers leverage in their purchasing agreements. However, there are many requirements for bringing an antitrust suit, described in more detail below,

and most patentees still have a relatively low risk from antitrust lawsuits.

II. Overview

A more detailed discussion of the *DDAVP* decision and the legal principles involved is provided below. This section provides a summary overview of the legal concepts.

Patents are an exception to the general antitrust laws prohibiting anticompetitive conduct, such as the prohibition on attempts to monopolize a market (Sherman Act, § 2). A lawfully obtained patent permits the patentee to exclude others from practicing the patented invention, regardless of any market monopolization effects.

The Supreme Court's *Walker Process* decision² strips away a patentee's antitrust immunity where (1) the patentee obtained the patent by fraud on the USPTO (the patentee must have done more than merely commit inequitable conduct in obtaining the patent), and (2) the patentee has tried to use the fraudulently obtained patent to exclude competitors from the market. Competitors may thus bring antitrust suits (or assert antitrust counterclaims in a patent infringement suit) in those circumstances. To prevail in a *Walker Process* suit, the competitor must also prove other antitrust elements, including (1) that the patentee has monopoly power in the relevant market and (2) that the invention was sufficiently important to the overall product value that its assertion affected the market enough to cause damages. Due to the difficulty of proving all the required elements, *Walker Process* suits are rarely successful.

¹ Case No. 06-5525-cv, ___ F.3d ___, 2009 WL 3320504 (2d Cir. Oct. 16, 2009) ("*DDAVP*").

² *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

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These stringent rules will also apply to customer suits permitted under the Second Circuit's *DDAVP* decision. Accordingly, the effect of potential customer suits on the bargaining power of a patentee, and on the bargaining power of the patentee's competitors who can make inequitable conduct assertions, will vary depending on many factors. These factors include the strength of the evidence of fraud on the USPTO, the definition of the market for the patented product (e.g., whether the market is carburetors or automobiles), the patentee's market share in that defined market, whether the invention is only an incremental improvement on a multi-component product, and whether the invention is susceptible to roughly equivalent design-arounds.

Only a few trial-level cases have considered whether direct purchasers of fraudulently patented products may maintain a *Walker Process* antitrust suit. Those courts split over whether to allow customer suits. The Second Circuit's *DDAVP* ruling now authorizes customer suits in the Second Circuit, which includes New York state. Neither the Federal Circuit nor the other regional circuits have addressed this issue. Future cases could resolve it differently, which may lead to different rules in different parts of the country or in suits that do or do not include purely patent-based antitrust issues.

Notably, the Second Circuit's decision permits customer suits only if a court has previously ruled that the patent was obtained through inequitable conduct. That limitation greatly limits the number of patents subject to a customer *Walker Process* claim, but may not be adopted by other appellate courts. Similarly, the Second Circuit has allowed suits only by direct purchasers of the product from the patentee, but other courts might allow suits by indirect purchasers farther down the distribution chain. In addition, at least one customer-initiated antitrust suit has been brought based on patent invalidity, rather than inequitable conduct.³ While the viability of such claims is currently unclear, further developments in the law may be forthcoming.

³ A pending district court class action in Pennsylvania brought by indirect consumers of the drug Mirapex asserts antitrust injury based on double patenting invalidity, with no allegations of inequitable conduct during patent prosecution. *In re Mirapex End-Payor Antitrust Litigation*, Civil Action No. 2:09-cv-1044-GLL (W.D. Pa.).

III. Issues Addressed By *DDAVP*

A. General Background

A *Walker Process* claim requires a higher standard of proof than that necessary to show inequitable conduct before the USPTO. For antitrust liability, there must be proof of common law fraud, which requires clear and convincing evidence of (1) a false representation or deliberate omission of a fact material to patentability, (2) made with intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) "but for" which representation or deliberate omission the patent would not have been granted.⁴

Attempted enforcement of the fraudulently procured patent is also required for a *Walker Process* claim, such as bringing or threatening a patent infringement action or, in the case of prescription pharmaceuticals, publishing the compound patent in the Food & Drug Administration (FDA) Orange Book, an official publication listing all drug patents. In addition to the patent-oriented elements of a *Walker Process* action, a plaintiff must be able to allege the other elements of an antitrust case, including antitrust standing. Antitrust standing requires proof of an antitrust injury and a showing that the plaintiff would be an "efficient enforcer" of the antitrust laws, based on a multi-factor evaluation.

In *DDAVP*, the Second Circuit reversed a lower court's dismissal of the case for lack of antitrust standing. In the last five years, four other district courts—in New Jersey, the Eastern District of New York, the District of Columbia, and the Northern District of California—have addressed the issue.⁵ Of these, two courts rejected direct purchaser

⁴ *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998).

⁵ *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.)*, 335 F. Supp. 2d 522, 528-29 (D.N.J. 2004); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 546-47 (E.D.N.Y. 2005) (expressing doubt as to customer *Walker Process* standing), *aff'd on other grounds*, 544 F.3d 1323 (Fed. Cir. 2008); *Molecular Diagnostic Lab. v. Hoffman-LaRoche*, 402 F. Supp. 2d 276, 279-82 (D.D.C. 2005); *In re Netflix*, 506 F. Supp. 2d 308, 314-16 (N.D. Cal. 2007). *See also In re K-Dur Antitrust Litig.*, 2007 WL 5297755 (D.N.J.) (Special Master's Recommendation to deny antitrust standing on a *Walker Process* claim to indirect purchasers).

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standing (D.N.J. and E.D.N.Y.) and two courts permitted it (D.D.C. and N.D. Cal.).

Outside of the *Walker Process* context, direct purchaser antitrust standing has long been recognized, while indirect purchasers are considered to have interests too remote to justify antitrust claims.⁶ Some states, however, permit indirect purchaser suits under state antitrust laws.

B. The *DDAVP* District Court Case

Ferring B.V. and Ferring Pharmaceuticals ("Ferring") developed, patented, and manufactured DDAVP tablets, a prescription-based diuretic compound. During prosecution, Ferring successfully overcame an obviousness rejection by submitting the declarations of five scientific experts. Ferring failed to disclose to the USPTO that four of those five experts had either been employed by Ferring or had received Ferring research funds.

In 2002, Barr Pharmaceuticals sought to enter the DDAVP generics market, and Ferring sued Barr for patent infringement. At trial, the district court found the patent unenforceable due to inequitable conduct based on the failure to disclose to the USPTO the relationship of the experts. That finding was upheld on appeal by the Federal Circuit in 2006, which found the declarations submitted by Ferring "absolutely critical" to overcoming the initial rejection during prosecution.⁷

Soon after, direct purchasers of the patented product brought a class action antitrust suit against Ferring and Ferring's exclusive licensee, Aventis. The suit alleged that defendants' exclusionary conduct included fraudulently procuring the patent, improperly listing DDAVP as a patented product in the Orange Book, pursuing sham litigation against generic drug manufacturers like Barr, and submitting an unfounded citizens' petition to the FDA to make Barr do more safety testing with the intent to delay regulatory approval of Barr's generic alternative to DDAVP.

⁶ *E.g.*, *Chattanooga Foundry v. Atlanta*, 203 U.S. 390 (1906) (approving direct purchaser standing); *Illinois Brick v. Illinois*, 431 U.S. 720 (1977) (denying indirect purchaser standing).

⁷ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

The district court dismissed the complaint, holding that the plaintiffs lacked antitrust standing because they lacked standing to challenge patent validity. Plaintiffs appealed to the Second Circuit. The Federal Trade Commission and the U.S. Department of Justice filed an *amicus* brief urging that the antitrust laws authorize direct purchaser suits "resulting from maintenance of a monopoly by enforcement of a fraudulently maintained patent."

The Second Circuit, acknowledging that the case presented "a novel question of standing that lies at the junction of antitrust and patent law," reversed the trial court decision and remanded for further proceedings.

C. Second Circuit Analysis

1. Appellate Jurisdiction

The Second Circuit first addressed whether it could even consider the appeal, because complaints wholly "arising under" the patent laws are heard exclusively by the Court of Appeals for the Federal Circuit. Although most of the alleged monopoly-generating conduct involved use of Ferring's patent, one aspect—the sham citizens' petition to the FDA—did not involve a patent question, at least after the patent had been held unenforceable. This non-patent claim permitted the Second Circuit to assess the merits of the entire complaint on appeal.

2. Antitrust Standing

a. Antitrust Injury And Other Factors

Next, the Second Circuit determined that direct purchasers of DDAVP tablets suffered "antitrust injury" of the "type that the antitrust laws were intended to prevent." Because the defendants' conduct had excluded generic competition, market prices were above what generic drug manufacturers would have charged.

The court went on to analyze the reasons why customers in this setting were "efficient enforcers" of the antitrust laws, applying the factors deemed relevant by the Supreme Court:⁸

⁸ *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 540-45 (1983), as characterized in *Volvo North America Corp. v. Men's International Professional Tennis Council*, 857 F.2d 55, 66 (2d Cir. 1988).

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- (1) *directness of injury* – the court found direct economic injury because it was alleged that customers had paid above-generic prices;
- (2) *motivation to vindicate the public interest* – the court rejected defendants' argument that antitrust standing should be limited to the "most motivated" class (i.e., competitors), finding the overcharged customers to be "significantly motivated";
- (3) *nonspeculative injury* – the court felt that estimating the precise effects that would have resulted from earlier generic competition might be difficult, but was feasible; and
- (4) *nonduplicative recovery* – the court considered the direct purchasers' damages to be distinct from the market losses suffered by competitors, and that allocation was possible, if needed.

b. Policy Considerations

Defendants argued that antitrust standing for a *Walker Process* claim should not be recognized as to persons unable to challenge the validity of the underlying patent.⁹ Customers of the patentee are unable to challenge the validity of patents directly because they are not infringers and can be neither sued nor threatened by patent holders. Defendants urged that opening the *Walker Process* field to customer suits would have a chilling effect on the innovation underlying patents, given the risk that patent enforcement might lead to frequent assertions of treble damage antitrust liability for patentees.

The Second Circuit rejected the defendants' argument. The court considered the focus of *Walker Process* not to be on the validity of the patent, but on the use of a fraudulently obtained patent to monopolize a market. The court reasoned that customers are among those injured by the monopolization, and so should be among those permitted a

⁹ Invalidating a patent is a necessary element of a *Walker Process* claim, as part of establishing that the applicant's fraudulent conduct in the USPTO was the "but for" cause of the patent's issuance. If the thing concealed from the USPTO was not significant enough to invalidate the patent, then the patent was not fraudulently obtained, as it would have issued even absent the misconduct. (In the latter case, the patent itself may still be unenforceable for inequitable conduct.)

remedy. In addition, the court was concerned whether such a remedy would be likely if customers were allowed to sue only after a successful *Walker Process* suit by a competitor. Competitors frequently do not pursue fraud claims, being satisfied with the lesser evidentiary showing needed to establish unenforceability based on inequitable conduct. Moreover, in the ANDA pharmaceutical context (like *DDAVP*), generic drug companies challenging patents often drop their suits and agree to remain out of the market, in exchange for a payment by the patentee.

Defendants did, however, persuade the appeals court to allow direct purchaser suits only where there has been a previous finding of inequitable conduct, resulting in an "already tainted patent."

3. Appellate Disposition

After finding standing, the court went on to find that plaintiffs' pleadings otherwise met the necessary standards. Accordingly, the dismissal of the plaintiffs' claims was vacated, and the case was remanded to the district court. A petition for rehearing and rehearing en banc to the Second Circuit was filed on October 30, but has not yet been decided.

IV. Recommendations

A. Patent Applicants and Patentees

Patentees asserting patents against which inequitable conduct claims may be or have been made should be aware of the *Walker Process* claim possibility, and be prepared with counterarguments both on the *Walker Process* elements and on the antitrust elements generally. The best defense, however, remains a full-disclosure policy in patent prosecution:

1. Be sure to disclose all potentially material information to the USPTO during prosecution of a patent. Material information may include but is not limited to:
 - a. prior art publications and patents;
 - b. copending patent applications and issued patents that may raise double patenting issues (whether or not they are "prior art");

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- c. uses or offers for sale in the United States prior to the U.S. filing date;
 - d. office actions from related patent applications (see also our October 9, 2009 Special Report entitled "The U.S. Duty Of Disclosure As Applied To U.S. And Foreign Office Actions");
 - e. available translations or English-language counterparts of the above (see also our April 1, 2003 Special Report entitled "Are JPO Website Computer-Generated Translations 'Readily Available'? Must They Be Submitted With Information Disclosure Statements?");
 - f. any experimental results that are inconsistent with results presented to the USPTO in an application or during prosecution;
 - g. information affecting the credibility of evidence submitted to the USPTO (e.g., a relationship of a declarant to the assignee);
 - h. lack or loss of entitlement to claimed small entity status;
 - i. any other information that a patent examiner might consider important in deciding whether to allow a patent application.
2. Ensure that all disclosed information is considered of record by the patent examiner before issuance of the patent.
 3. Take care to avoid making any misrepresentations to the USPTO, regarding the invention, the prior art, or any other matter (e.g., entitlement to small entity status), and directly address any inconsistent representations or accidental misstatements.

B. Alleged Infringers

Those accused of infringing a patent should carefully investigate whether inequitable conduct positions are available. If so, in settlement negotiations (privately or before the court) they should consider pointing out the expanded potential risk to the patentee: not just of losing the patent, but also of paying treble damages. Discovery should be focused on all aspects of the disputed patent's prosecution, and any material misrepresentation or omission that is uncovered should be addressed during litigation and in settlement negotiations. If the evidence is sufficient and there is support for the antitrust elements, a *Walker Process* claim should be considered.

C. Direct Purchasers

In most cases, the proof problems and the minor amount of damages at issue make antitrust claims unattractive for individual customers. But in a sole-supplier setting, or on a product with substantial margins, the appropriate case may justify filing a complaint, or joining a proper class action.

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