

# The AIPLA Antitrust News

A Publication of the AIPLA Committee on Antitrust Law

January 2010

## **DIRECT PURCHASERS' STANDING TO SUE FOR *WALKER PROCESS* FRAUD**

### ***IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION***

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Deciding a novel issue, the United States Court of Appeals for the Second Circuit recently held that direct purchasers have standing to assert claims of *Walker Process* fraud, at least when a patent has already been found to be unenforceable due to inequitable conduct. *Meijer, Inc. v. Ferring B.V. (In re: DDAVP Direct Purchaser Antitrust Litig.)*, 585 F.3d 677 (2d Cir. 2009) (“*DDAVP II*”). Apparently wary of the potential of expanding the universe of potential patent challengers, the court was careful to limit its holding to the factual scenario before it—one where the plaintiffs challenged an “already tarnished patent.”<sup>1</sup> Because the decision is narrowly crafted, it seems unlikely to cause an explosion in *Walker Process* challenges by purchasers, absent further expansions by other courts in standing to bring *Walker Process* claims.

<sup>1</sup> *DDAVP II* at 691.

## **I. District Court Proceedings**

The case arose when direct and indirect purchasers filed a nationwide class action in federal district court against Ferring, which developed and manufactured antidiuretic desmopressin acetate tablets (“*DDAVP*”), and Aventis, which had an exclusive license to market and sell *DDAVP*.<sup>2</sup> The plaintiffs alleged that Ferring and Aventis had unlawfully monopolized the market for *DDAVP* and its generic equivalents by: (1) procuring the patent for *DDAVP* through fraud or inequitable conduct before the United States Patent and Trademark Office; (2) improperly listing that patent in the Food and Drug Administration’s *Orange Book* to facilitate assertion of patent infringement claims against potential competitors; (3) bringing sham patent infringement litigation to delay FDA approval and market entry of generic desmopressin acetate tablets; and (4) filing a sham citizen petition with the FDA in an effort to further postpone final approval of the generic. Plaintiffs asserted that they and members of the proposed class had paid supra-competitive prices, compared to what they would have paid if competing or generic versions of the drug had been available.

Defendants moved to dismiss the complaint for failure to state a claim, and District

<sup>2</sup> *In re: DDAVP Direct Purchaser Antitrust Litig.*, No. 05 CV 223, 2006 U.S. Dist. LEXIS 96201 (S.D.N.Y. Nov. 2, 2006) (“*DDAVP I*”).

Judge Charles Brieant granted the motion. Although Judge Brieant had determined in an earlier case that Ferring's DDAVP patent was unenforceable due to inequitable conduct before the PTO, he ruled here that the plaintiffs had not alleged fraud with the particularity required by Fed. R. Civ. P. 9(b).<sup>3</sup> In the earlier case, Ferring and Aventis had brought a patent infringement suit against a generic manufacturer, Barr, which had filed an abbreviated new drug application ("ANDA") prior to the expiration of the DDAVP patent.<sup>4</sup> On Barr's motion for summary judgment, Judge Brieant concluded that Ferring's patent was unenforceable because, in obtaining it, Ferring had submitted declarations by scientists without disclosing their connections to Ferring (several had been employed by Ferring or received research funds from it).

In the antitrust case, however, Judge Brieant noted that procuring and enforcing a patent is normally protected from antitrust liability by the First Amendment, though that immunity can be lost through fraud. In the seminal *Walker Process* decision, the Supreme Court held that enforcement of a patent obtained by fraud on the PTO can violate Section 2 of the Sherman Act,<sup>5</sup> as long as the other elements of a Section 2 case are present.<sup>6</sup> But *Ferring I* found only inequitable conduct: fraud imposes a higher

standard of intent and materiality than inequitable conduct (and carries more serious penalties of patent invalidity and potential antitrust treble-damage liability). The direct purchasers had not carried their burden to plead fraud with particularity, requiring dismissal of the antitrust claim.

As an alternative ground for dismissing the antitrust claims, the district court held that the plaintiffs did not have standing to bring a *Walker Process* claim because the patent had not been enforced against them.<sup>7</sup> As customers, they did not allege that they "compete[d] or would have competed with Defendants, nor that they have been sued or threatened with an infringement lawsuit by the Defendants."<sup>8</sup>

Separately addressing Aventis, the district court concluded that the claims against Aventis should be dismissed because the plaintiffs had failed to allege sufficient facts to show that Aventis participated in the prosecution of the DDAVP patent or had knowledge of Ferring's inequitable conduct before the PTO.

## II. Second Circuit Decision

The Second Circuit vacated the district court's decision, deciding four main points: (1) it retained jurisdiction, rejecting defendants' arguments that the appeal belonged in the Federal Circuit because it

<sup>3</sup> *Id.* at \*15.

<sup>4</sup> *Ferring B.V. v. Barr Labs., Inc.*, No. 02 CV 9851, 2005 U.S. Dist. LEXIS 3597 (S.D.N.Y. Feb. 7, 2005) ("*Ferring I*"), *aff'd*, 437 F.3d 1181 (Fed. Cir. 2006) ("*Ferring II*").

<sup>5</sup> 15 U.S.C. § 2, barring monopolization and related conduct.

<sup>6</sup> *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 173 (1965).

<sup>7</sup> *DDAVP I* at \*21, *citing Indium Corp. of America v. Semi-Alloys, Inc.*, 566 F. Supp. 1344 (N.D.N.Y. 1983) (dismissing *Walker Process* claim where no facts were alleged that would amount to enforcement, attempted enforcement, or threatened enforcement of defendant's patent against the plaintiff).

<sup>8</sup> *Id.* at \*15.

involved issues of patent law; (2) it cautiously extended antitrust standing to open *Walker Process* fraud claims to purchasers, provided that the patent had previously been held unenforceable for inequitable conduct; (3) it held that plaintiffs' antitrust claims were adequately pled; and (4) it refused Aventis's separate arguments for dismissal, determining that a plausible claim had been stated against it.

*Jurisdiction Properly Lies In The Second Circuit Rather Than The Federal Circuit If Even A Minor Non-Patent Theory Supports The Claim*

As to jurisdiction, the Second Circuit determined that although three of the plaintiffs' four claims turned on patent law, the fourth claim – whether Ferring's filing of a citizen petition before the FDA was a sham – did not because it did not rely on the issuance or validity of the patent.<sup>9</sup> While the sham petition claim constituted only a single – and frankly quite derivative and minor – piece of the overall case, “as long as any one of the theories can support the [Sherman Act] claim without raising substantial questions of patent law” it could serve as a basis for jurisdiction outside of the Federal Circuit.<sup>10</sup> In other words, if a plaintiff asserts even a minor theory to support a claim that is independent of patent

<sup>9</sup> *DDAVP II* at 685-87. Defendants argued that because the citizen petition had been filed more than a year before the DDAVP patent was held unenforceable, plaintiffs would have to show that the patent was foreseeably unenforceable to prove the necessary intent to monopolize. The Second Circuit responded that defendants knew the patent was unenforceable nearly five months before the FDA rejected the citizen petition, yet failed to supplement, amend, or withdraw the petition. *Id.* at 687.

<sup>10</sup> *Id.* at 690.

law, jurisdiction will remain in the Second Circuit. While unlikely to be overturned, the Second Circuit's retention of jurisdiction was fairly aggressive. If other circuits adopt this approach, it could decrease the Federal Circuit's exercise of exclusive jurisdiction over antitrust claims in patent cases.

*Purchasers' Standing To Bring A Walker Process Claim Against A Tarnished Patent*

While the Second Circuit held that direct purchasers were not automatically barred from asserting *Walker Process* claims, it tailored its holding to the facts of the case, wary of overextending the antitrust standing doctrine. First, the court examined the traditional questions of antitrust standing: whether the plaintiffs had suffered antitrust injury and whether they satisfied the four factors to be an efficient enforcer of antitrust law.<sup>11</sup> After relatively straightforward analysis, the court determined that the plaintiffs met both criteria.

The interesting wrinkle came in the court's analysis of *Walker Process* fraud. Normally a patent's validity can be challenged only by a party that both produces (or is preparing to produce) the patented product and that is being threatened (or reasonably likely to be threatened) with an infringement suit. Purchaser plaintiffs would not satisfy those requirements and could not directly challenge the patent.<sup>12</sup> Should that preclude them from being able to raise a *Walker*

<sup>11</sup> *Id.* at 688-89, relying on *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977), and *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 540-45 (1983).

<sup>12</sup> *Id.* at 690.

*Process* claim when the underlying patent had not been found to be fraudulently obtained? The court held no.

Defendants argued that a party should only have *Walker Process* standing if it would also have standing to challenge the patent's validity. They warned that otherwise parties who could not directly challenge a patent's validity could do so by simply bringing the patent challenge under the guise of a *Walker Process* claim, resulting in an "avalanche of patent challenges" and increasing the costs of defending and enforcing patents.<sup>13</sup> There were two salient issues for the defendants: the risk of expanding the pool of potential patent challengers and the threat of treble damages liability from a patent found to be fraudulently procured, which could diminish the incentives in the patent system favoring innovation.

The Second Circuit held that "purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct."<sup>14</sup> Importantly, it expressly declined to decide whether "purchaser plaintiffs per se have standing to raise *Walker Process* claims," noting that because the patent was already sullied, plaintiffs could obtain "antitrust standing without altering the typical limits on who can start a challenge to a patent's validity."<sup>15</sup>

The court's reasoning interweaves several threads. For one thing, the Supreme Court did not shy away from letting antitrust liability affect the patent system in the

*Walker Process* decision itself. For another, purchasers and competitors have different strategic interests and would seek remedies for different injuries (overcharges and lost profits, respectively). Therefore, the defendants' proposal would leave a significant antitrust violation potentially undetected and unremedied because it makes purchasers dependent on parties that can bring a direct patent challenge—largely generic competitors—to bring and win a fraudulent procurement claim before the purchasers could pursue their own claims. This, the court worried, "asks too much of the generic competitors."<sup>16</sup> Such competitors "may not have the strategic interest or the resources to start or win such a battle, or ... may be presented with strong incentives to settle their challenge by patent holders seeking not only to preserve their patent's enforceability, but also to avoid potential *Walker Process* liability."<sup>17</sup>

Furthermore, to be able to sell its products, a generic competitor need only show inequitable conduct to obtain a determination of patent unenforceability. Accordingly, a generic competitor can likely achieve its major goal without attempting the higher showing of fraud. Together, to the Second Circuit, these factors create a substantial risk that limiting *Walker Process* standing to those who could challenge the patent directly could leave purchasers out in the cold, and an antitrust violation unremedied. Interestingly, although the court was sensitive to the divergent interests of purchasers and competitors, it did not seem concerned that the potential for

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<sup>13</sup> *Id.* at 690.

<sup>14</sup> *Id.* at 691-92.

<sup>15</sup> *Id.* at 691.

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<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

reverse-payment settlements and strategic interests might also reduce incentives for competitors to bring and fully litigate inequitable conduct claims. To the contrary, the court made inequitable conduct a prerequisite of purchaser *Walker Process* standing.

### *Plaintiffs' Pleading Was Adequate To Survive Dismissal On Each Antitrust Theory*

The plaintiffs stated a claim sufficient to survive a motion to dismiss on each of the antitrust theories, according to the Second Circuit. Defendants argued that plaintiffs' addition of a conclusory allegation of fraud to the previous findings on inequitable conduct did not satisfy their burden to adequately allege facts giving rise to a strong inference of fraudulent intent. The court disagreed, stating that the allegations of fraudulent intent would suffice even if based on "fairly tenuous inferences."<sup>18</sup> The court acknowledged that, to state a *Walker Process* claim, a plaintiff has to allege both fraud and that but-for the fraud the patent would not have issued, which entails raising a material issue of patentability. Surprisingly, the court concluded that the plaintiffs' pleading of patentability sufficed where the "issue [was] implicit in their allegations" (but not directly addressed).<sup>19</sup> Oddly, the court here referenced findings on intent and materiality from *Ferring I* and *II*, but disregarded Judge Briant's opinion that the record in the patent case would not have supported a determination of fraud nor that

the patent would have issued but-for Ferring's omissions before the PTO.<sup>20</sup>

### *Licensee Kept In the Case*

Finally, the Second Circuit rejected Aventis's separate request that it be dismissed. While the district court gave no credence to the idea that Aventis would pay to license a patent that it knew to be unenforceable, the Second Circuit believed that serious questions had been raised about the patent's validity when Aventis filed its NDA and *Orange Book* listing. Yet, plaintiffs alleged, Aventis undertook no investigation of the patent's validity. Moreover, Aventis and Ferring had a long-standing relationship. This was enough to create a "plausible inference of knowledge and liability" and to state a plausible monopolization claim.<sup>21</sup>

## III. Implications

Despite the courts' view that the antitrust standing question here is one of first impression, in other contexts, direct purchasers are the darlings of antitrust standing. They almost enjoy a presumption of standing to challenge anticompetitive conduct.

Cognizant of the need to tread lightly, the Second Circuit took pains to limit its holding to the specific factual scenario before it. By its terms, this decision at most only modestly expands *Walker Process* standing. Although the case seems unlikely to serve as a springboard for a large number of future suits by direct purchasers, it may

<sup>18</sup> *Id.* at 693, quoting *Press v. Chem. Inv. Servs. Corp.*, 166 F.3d 529, 538 (2d Cir.1999).

<sup>19</sup> *Id.*

<sup>20</sup> *DDAVP I* at \*14.

<sup>21</sup> *DDAVP II* at 695.

affect the incentives of patent holders and exclusive licensees facing claims of inequitable conduct, making settlement more attractive. The court correctly distinguished between the interests of purchasers and competitors, but it failed to note that those interests continue to diverge with respect to inequitable conduct claims. The court has made purchaser standing dependent on successful inequitable conduct claims by generic competitors, but that may also “ask too much” of the generic competitors.

Another troublesome aspect of this case is the potentially long time gap for such claims to come to light. Approximately 18 years elapsed between the grant of the patent in 1991 and the determination that the antitrust claims were non-dismissible in 2009. Potential *Walker Process* claims by purchasers could lurk for years while inequitable conduct claims wind their way

through the courts, and then spring to life. The decision does not clarify what event starts the clock for the four-year statute of limitations on private antitrust actions, nor what triggers the right of a purchaser to sue.

Finally, the decision raises some questions for exclusive licensees of patented goods. While the allegations of fraud and wrongdoing against Aventis seemed fairly remote, the case indicates that a licensee might face litigation and possibly antitrust liability if it had reason to know about the alleged fraud or inequitable conduct and failed to independently investigate the patent’s validity. Accordingly, licensees will have one more reason to be proactive when potential issues arise regarding the validity of a patent that they have licensed.