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# The Second Circuit Cautiously Expands Walker Process Standing in In re DDAVP

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#### I. INTRODUCTION

n October 2009, the United States Court of Appeals for the Second Circuit became the first appeals court to decide that direct purchasers have standing to assert *Walker Process* claims.<sup>2</sup> In so holding, the court did three interesting things: (1) it retained jurisdiction based on a minor aspect of plaintiffs' claims, despite defendants' arguments that the case belonged in the Federal Circuit because it concerned issues that arose under patent law; (2) it was very cautious in its expansion of antitrust standing for purchasers, limiting it to suits based on patents already held unenforceable due to inequitable conduct; and (3) it held that plaintiffs' antitrust claim was adequately pled, which is arguably inconsistent with the Supreme Court's recent decisions in *Twombly*<sup>3</sup> and *Iqbal*.<sup>4</sup>

#### II. DDAVP: THE DISTRICT COURT OPINION

In 2006, plaintiff direct purchasers filed a class action complaint in the United States District Court for the Southern District of New York against defendants Ferring, who developed and manufactured DDAVP (an anti-diuretic); and Aventis, who marketed and sold DDAVP.<sup>5</sup> Plaintiffs alleged that defendants unlawfully maintained a monopoly by (1) obtaining the patent for DDAVP through fraudulent and inequitable conduct before the Patent and Trademark Office (PTO); (2) improperly listing the patent in the Food and Drug Administration's ("FDA") publication of approved *Referenced Listed Drugs* or "Orange Book;" (3) prosecuting a sham patent infringement litigation in order to delay FDA approval and market entry of generic DDAVP tablets; and (4) filing a sham citizen petition with the FDA in an effort to further delay FDA approval of generic DDAVP tablets (the "sham citizen petition claim").<sup>6</sup>

In *Walker Process*, the Supreme Court had previously held that the enforcement of a patent procured by fraud on the PTO may violate the Sherman Act, provided that the other elements of a

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<sup>&</sup>lt;sup>2</sup> Meijer, Inc. v. Ferring B.V. (*In re* DDAVP Direct Purchaser Antitrust Litig.) (the "DDAVP Second Circuit Opinion"), 2009 U.S. App. LEXIS 22719 (2d Cir. Oct. 16, 2009).

<sup>&</sup>lt;sup>3</sup> Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007).

<sup>&</sup>lt;sup>4</sup> Ashcroft v. Igbal, 129 S. Ct. 1937 (U.S. 2009).

<sup>&</sup>lt;sup>5</sup> Meijer, Inc. v. Ferring B.V. (*In re* DDAVP Direct Purchaser Antitrust Litig.) (the "DDAVP District Court Opinion"), 2007-1 Trade Case. ¶ 75,726, 2006 U.S. Dist. LEXIS 96201 (S.D.N.Y Nov. 2, 2006).

<sup>&</sup>lt;sup>6</sup> *Id.* at \*5 − 6.



Sherman Act claim are present.<sup>7</sup> The *DDAVP* plaintiffs alleged that defendants' fraudulent conduct gave them an illegal monopoly that unreasonably eliminated competition in the market for DDAVP and its generic counterparts.<sup>8</sup> Plaintiffs further claimed that, as a result of the lack of competition, they paid hundreds of millions of dollars more for DDAVP than if competing versions of DDAVP had been available.<sup>9</sup>

The *DDAVP* defendants moved to dismiss, arguing, among other things, that because the direct purchasers were not competitors, plaintiffs lacked standing to assert a *Walker Process* claim. The district court agreed, holding that because the plaintiffs failed to "adequately allege any set of facts that would amount to enforcement, attempted enforcement or threatened enforcement of defendants' patents vis-à-vis the plaintiff," they lacked antitrust standing to assert a *Walker Process* claim.<sup>10</sup>

In a prior article, we examined the district court's reasoning and predicted that the Second Circuit would reverse because the district court had incorrectly denied direct purchasers standing to assert *Walker Process* claims. <sup>11</sup> Because direct purchasers "can clearly be victims of a monopoly obtained by the enforcement of a fraudulently obtained patent, they should have standing to assert a *Walker Process* claim." <sup>12</sup>

#### III. DDAVP: THE SECOND CIRCUIT OPINION

On appeal, plaintiffs argued that the district court erred in dismissing the complaint. Defendants moved to transfer the appeal to the Federal Circuit, arguing that court had exclusive jurisdiction because plaintiffs' claims arose under patent law. The Antitrust Division and the Federal Trade Commission submitted an amicus brief urging reversal, as did the Attorneys General of some 40 states, the District of Columbia and Puerto Rico. The appeal was argued September 15, 2008. Some 13 months later, the Second Circuit reversed.<sup>13</sup>

#### A. Jurisdiction

In deciding whether it had jurisdiction, the Second Circuit acknowledged that the Federal Circuit has exclusive jurisdiction over a case if it "arises under patent law" in so far as "federal patent law creates the cause of action" or "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." The court acknowledged that the first three of plaintiffs' four theories depended on the resolution of a substantial question of federal

<sup>&</sup>lt;sup>7</sup> Walker Process Equip., Inc. v. Food Machinery and Chemical Corp., 382 U.S. 172, 174 (1965).

<sup>&</sup>lt;sup>8</sup> DDAVP District Court Opinion at \*6.

<sup>&</sup>lt;sup>9</sup> *Id*.

<sup>&</sup>lt;sup>10</sup> Id. at \*21, citing Indium Corp. of America v. Semi-Alloys, Inc., 566 F. Supp. 1344, 1353 (N.D.N.Y. 1983).

<sup>&</sup>lt;sup>11</sup> Aidan Synnott, From Walker Process to In re: DDAVP: Should Direct Purchasers have Antitrust Standing in Walker Process Claims?, GLOBAL COMPETITION POL'Y, November 2008, Release Two, http://globalcompetitionpolicy.org/index.php?&id=1484&action=907.

<sup>12</sup> Id. at 2.

<sup>&</sup>lt;sup>13</sup> Meijer, Inc. v. Ferring B.V. (*In re* DDAVP Direct Purchaser Antitrust Litig.) (the "DDAVP Second Circuit Opinion"), 2009 U.S. App. LEXIS 22719 (2d Cir. Oct. 16, 2009).

<sup>14</sup> Id. at \*11.



patent law, as each theory required that the patent had been fraudulently procured.<sup>15</sup> However, plaintiffs' fourth theory—the sham citizen petition claim—did not turn on a substantial question of patent law, the court held, as it did not rest on whether the patent was validly issued.<sup>16</sup> The Court thereby held that "as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction."<sup>17</sup>

Defendants argued that, because the citizen petition was filed over a year before the patent was deemed unenforceable, plaintiffs could not prove the necessary intent to monopolize without showing that the patent was foreseeably unenforceable, a clear issue of patent law. The court rejected this argument, noting that the patent was deemed unenforceable five months before the citizen petition was rejected and defendants could have withdrawn or modified the petition in the interim. The court concluded that, even though defendants' intent in filing the petition raised questions of patent law, their intent in maintaining it after they lost the infringement litigation did not. Defendants of the patent law, their intent in maintaining it after they lost the infringement litigation did not. Defendants of the patent law, their intent in maintaining it after they lost the infringement litigation did not. Defendants of the patent law, their intent in maintaining it after they lost the infringement litigation did not.

Defendants also argued that jurisdiction properly lay with the Federal Circuit because plaintiffs' sham citizen petition claim was only a minor part of a larger anticompetitive scheme.<sup>21</sup> The Second Circuit held this to be of no moment. The court reasoned that jurisdiction requires courts to focus on claims and not theories and it had jurisdiction as long as any theory could support the claim of Sherman Act violation without raising issues of patent law.<sup>22</sup> That other theories might increase liability, augment damages exposure, and raise issues of patent law was irrelevant to the court. This holding has the potential to dramatically diminish the exclusive jurisdiction of the Federal Circuit over antitrust claims in patent cases.

#### B. Antitrust Standing

On antitrust standing, the Second Circuit held, as we predicted, that direct purchasers should not be automatically precluded from raising *Walker Process* claims. However, the court was cautious in its ruling and concerned about opening the floodgates by extending standing too far. It expressly limited its ruling to cases where the underlying patent has already been found unenforceable due to inequitable conduct and left the question of broader standing for future consideration.<sup>23</sup>

In reviewing *de novo* whether plaintiffs had antitrust standing, the court used a two prong test, requiring plaintiffs to show (1) antitrust injury and (2) that they were proper plaintiffs—i.e., efficient enforcers of the antitrust laws.<sup>24</sup>

<sup>15</sup> *Id.* at \*13.

<sup>&</sup>lt;sup>16</sup> *Id.* at \*14.

<sup>&</sup>lt;sup>17</sup> Id. at \*11 - 12 citing In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 199 (2d Cir. 2006).

<sup>&</sup>lt;sup>18</sup> *Id.* at \*18.

<sup>&</sup>lt;sup>19</sup> *Id*.

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> Id. at \*19.

<sup>&</sup>lt;sup>22</sup> *Id.* at \*20.

<sup>23</sup> Id. at \*32.

<sup>&</sup>lt;sup>24</sup> *Id.* at \*21.

The court held that because plaintiffs allegedly were forced to pay higher prices as a result of defendants' anticompetitive conduct, plaintiffs' injury was "of the type the antitrust laws were intended to prevent." Citing *McCready*, the court found that plaintiffs' injury was "inextricably intertwined' with the anti-competitive effects of defendants' conduct and thus 'flowed from that which makes defendants' acts unlawful." Therefore, the first prong was satisfied.

The court considered four factors to determine whether plaintiffs were efficient enforcers of the antitrust laws:

(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 the 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."<sup>27</sup>

The court held that plaintiffs satisfied all four factors and rejected defendants' argument that potential competitors were superior enforcers of the antitrust laws and standing should be limited to them.<sup>28</sup>

Still, the court was concerned that allowing direct purchasers to bring *Walker Process* claims could be an end-run around limitations the courts have placed on standing to challenge the validity of a patent. Defendants argued that giving *Walker Process* standing to the direct purchaser plaintiffs—parties not threatened or likely to be threatened with a patent infringement action—could result in "an avalanche of patent challenges" because direct purchasers would be able to challenge a patent's validity by simply dressing their patent challenge in *Walker Process* clothing.<sup>29</sup> Thus, the court limited its holding to the facts of the case: "purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct."<sup>30</sup> The court declined to rule on the broader question whether purchasers have standing to challenge as yet untarnished patents. This caution raises two concerns which we expect will be aired in future litigation

First, given that "the harm is not the invalid patent, but the use of the invalid patent to establish a monopoly," <sup>31</sup> denying standing to a consumer directly harmed because a monopoly was maintained by a fraudulently obtained patent "create[s] the potential to leave a significant antitrust violation undetected or unremedied." <sup>32</sup>

<sup>&</sup>lt;sup>25</sup> Id. at \*21 - 22 citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).

<sup>&</sup>lt;sup>26</sup> Id. at \*22 citing Blue Shield of Va. v. McCready, 457 U.S. 465, 484 (1982).

<sup>&</sup>lt;sup>27</sup> *Id.* at \*21. These are the factors set down by the Supreme Court in Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 540-45 (1983) and widely referred to as the "Associated" or "AGC" factors.

<sup>&</sup>lt;sup>28</sup> *Id.* at \*22 – 26.

 $<sup>^{29}</sup>$  *Id.* at \*27 – 28.

<sup>30</sup> Id. at \*32.

<sup>&</sup>lt;sup>31</sup> Molecular Diagnostics Labs v. Hoffman-La Roche, Inc., 402 F. Supp. 2d 276 (D.D.C. 2005) (holding that the court in *In re* Remeron Antitrust Litig., 335 F. Supp. 2d 522 (D.N.J 2004), appeared to incorrectly believe that "standing alone, the enforcement of the fraudulently procured patent is the relevant injury in a *Walker Process* claim, hence the court's assertion that a plaintiff must be an actual or potential competitor").

<sup>32</sup> DDAVP Second Circuit Opinion at \*30.



Second, the court's reasoning throughout its opinion is in tension with its holding. The court's holding explicitly gives *Walker Process* standing to direct purchasers to assert fraud in part because competitors may not be incentivized to litigate such issues to conclusion.<sup>33</sup> A competitor may choose to settle for a license or some other relief that does not tarnish the patent. The court was concerned that granting standing to purchasers only after the patent holder loses on a fraudulent procurement claim, "asks too much of the generic competitors and other potential patent challengers."<sup>34</sup> Such entities "may not have the strategic interest or the other resources to start or win such a battle, or who may be presented with strong incentives to settle their challenge."<sup>35</sup> There is no reason to believe the incentives are any greater for competitors to make an inequitable conduct case. It is hard to see any principled support for the limitation in the court's holding.

#### C. The Adequacy of the Pleadings

The Second Circuit also reviewed *de novo* the district court's dismissal of the complaint for failure to state a claim upon which relief may be granted. Contrary to the district court, the Second Circuit held that plaintiffs' claims were adequately pleaded. Although it made token reference to the high pleading standards articulated in *Iqbal* and *Twombly*, the court relied entirely on older cases in analyzing the sufficiency of the pleadings and concluding scienter had been adequately alleged, even if "based on fairly tenuous inferences." Thus, the court recognized that a proper *Walker Process* claim requires a plaintiff to allege fraud, not just inequitable conduct, and that but for the fraud, no patent would have issued. But the court nonetheless held that plaintiffs' allegations of the same facts that supported the inequitable conduct were enough to allege fraud. Additionally, the court found that, although plaintiffs did not directly address patentability in their complaint, plaintiffs sufficiently alleged the "but for causation" required of *Walker Process* claims.

#### IV. CONCLUSION

The court was correct that merely being a direct purchaser plaintiff, rather than a competitor, should not automatically preclude a finding that one has standing to assert a *Walker Process* claim, but its holding is very narrow. As long as direct purchasers can adequately plead their *Walker Process* claims, it is not clear they should be denied the opportunity to have their injuries redressed simply because the underlying patent had not already been tarnished. This is an issue that is destined to play out in the lower courts. This novel issue which lies "at the junction of antitrust and patent law,"<sup>40</sup> remains unresolved.

<sup>&</sup>lt;sup>33</sup> *Id.* at \*30.

<sup>&</sup>lt;sup>34</sup> *Id*.

<sup>&</sup>lt;sup>35</sup> Id.

<sup>&</sup>lt;sup>36</sup> *Id.* at \*36 – 42 (in which the district court cites to such cases as Press v. Chem. Inv. Servs. Corp., 166 F.3d 529, 539 (2d. 1999); and Primetime 24 Joint Venture v. Nat'l Broadcasting Co., 219 F.3d 92, 100-01 (2d. Cir. 2000)).

<sup>&</sup>lt;sup>37</sup> *Id.* at \*37.

<sup>38</sup> Id. at \*36.

<sup>39</sup> Id. at \*38.

<sup>&</sup>lt;sup>40</sup> *Id.* at \*1.