UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2008
(Argued: September 15, 2008 Decided: October 16, 2009)
Docket No. 06-5525-cv

In Re: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

MEIJER, INC., MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

ROCHESTER DRUG CO-OPERATIVE, INC., LOUISIANA WHOLESALE DRUG CO., INC.,

Consolidated-Plaintiffs-Appellants,

-- v. --

FERRING B.V., FERRING PHARMACEUTICALS, INC., AVENTIS PHARMACEUTICALS, INC.,

Defendants-Appellees,

-- v. --

VISTA HEALTHPLAN, INC., on behalf of itself and all others, PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of itself and all others, PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND,

Consolidated Plaintiffs.

B e f o r e : FEINBERG, WALKER, and LIVINGSTON, Circuit Judges.

Appeal by Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-operative, Inc., and Louisiana Wholesale

Drug Co., Inc., from the dismissal of their class action antitrust complaint in the United States District Court for the Southern District of New York (Charles L. Brieant, Judge) for lack of standing and failure to state a claim upon which relief can be granted. We hold that the district court erred in dismissing the complaint, because the plaintiffs have antitrust standing and have adequately stated a claim upon which relief can be granted.

VACATED and REMANDED.

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General, Gerald F. Masoudi, Deputy Assistant Attorney General, Robert B. Nicholson, Attorney, on the brief), U.S. Department of Justice, Washington, DC, William Blumental, General Counsel, Federal Trade Commission, Washington, DC, for Amici Curiae United States and Federal Trade Commission.

J. Douglas Richards, Pomerantz Haudek Block Grossman & Gross LLP, New York, NY, for Amici Curiae the American Antitrust Institute, AARP, the Consumer Federation of America, Consumers Union, and Families USA.

Andrew W. Cuomo, Attorney General of the State of New York, Barbara D. Underwood, Solicitor General, Benjamin N. Gutman, Deputy Solicitor General, Jay L. Himes, Chief, Antitrust Bureau, Robert L. Hubbard, Director of Litigation, Antitrust Bureau, of counsel, New York, NY, for Amici Curiae the States of New York, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, and

Wyoming, and the District of Columbia and Puerto Rico.

Margaret M. Zwisler, Charles R. Price, Latham & Watkins LLP, Washington, DC, Diane E. Bieri, Pharmaceutical Research and Manufacturers of America, Washington, DC, Thomas DiLenge, Biotechnology Industry Organization, Washington, DC, for Amici Curiae the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization.

JOHN M. WALKER, JR., Circuit Judge:

This case presents a novel question of standing that lies at the junction of antitrust and patent law. The plaintiffs, direct purchasers of desmopressin acetate tablets (sold under the name DDAVP), filed this class action in the Southern District of New York (Charles L. Brieant, Judge) against the defendants Ferring B.V., Ferring Pharmaceuticals (collectively, "Ferring"), and Aventis Pharmaceuticals ("Aventis"), alleging that Ferring and Aventis abused the patent system to unlawfully maintain a monopoly over DDAVP. Ferring developed, patented, and manufactures DDAVP, and Aventis holds FDA approval for DDAVP tablets as well as a license from Ferring to market and sell the drug. The plaintiffs alleged that Ferring and Aventis inflated the price of DDAVP by suppressing generic competition for the tablets in violation of the antitrust laws. The district court dismissed the suit, concluding that the plaintiffs both lacked

antitrust standing and had failed to state a claim upon which relief could be granted. This appeal followed.

BACKGROUND

The facts that follow are either undisputed or, because they are properly pled, presumed true for the purposes of this appeal at the pleading stage. See Diaz v. Paterson, 547 F.3d 88, 91 (2d Cir. 2008).

DDAVP is an antidiuretic prescription medication used to manage a form of diabetes, excessive urination, excessive thirst, and bed wetting. Ferring developed and manufactures DDAVP and owns U.S. Patent No. 5,047,398 (the "'398 patent"), which claims the compound in tablet form. Ferring filed its application for the '398 patent on December 17, 1985, and the Patent and Trade Office ("PTO") issued the patent on September 10, 1991. Ferring granted an exclusive license to Aventis to market and sell the patented tablets under the DDAVP name. In addition to its license from Ferring, Aventis also holds an approved New Drug Application ("NDA") from the FDA for the tablets. A manufacturer seeking to market a new drug must file an NDA to demonstrate the drug's safety and efficacy.

In 2002, Ferring filed a patent infringement suit against Barr Laboratories, Inc. ("Barr"), which came before the same district judge who later presided over this action. Earlier that year, Barr had filed an Abbreviated New Drug Application ("ANDA")

for a generic version of the compound. An ANDA filing accelerates the approval process for a generic drug by allowing the manufacturer to rely on the safety and efficacy data provided in the NDA for the drug's branded counterpart. As part of the ANDA, Barr filed a certification (called a "paragraph IV certification") stating that the '398 patent was invalid, unenforceable, and/or would not be infringed by Barr's generic product. This filing triggered Ferring's infringement action against Barr pursuant to 35 U.S.C. § 271(e)(2).

Ferring's suit failed. On summary judgment, the district court found that the '398 patent, rather than having been infringed by Barr, was unenforceable due to inequitable conduct before the PTO by Ferring and its agents. Ferring B.V. v. Barr Labs., Inc., No. 7:02-CV-9851, 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). The Federal Circuit affirmed. See Ferring B.V. v. Barr Labs., Inc. ("Ferring I"), 437 F.3d 1181 (Fed. Cir. 2006).

The inequitable conduct that crippled the '398 patent occurred on the patent's troubled path to approval. In November 1986, PTO examiners rejected certain of the '398 patent's claims as anticipated by or obvious from U.S. Patent No. 3,497,491 (the "'491 patent"), a patent exclusively licensed to Ferring that subsequently expired in 1987. See id. at 1183-84. The Board of Patent Appeals and Interferences ("BPAI") affirmed the examiners'

rejection in September 1990, but on slightly different grounds: relying only on the '491 patent, the BPAI concluded that the '491 patent rendered the '398 patent "obvious" when considered "in light of" a 1973 article written by Ivan Vavra. Id. at 1184. In November 1990, in an effort to persuade the examiners of the '398 patent's novelty, the applicants, two Ferring employees who assigned their prospective patent rights to Ferring, submitted declarations from several scientists stating that the '491 patent and Vavra article did not suggest the '398 patent. Id. at 1185. It turned out, however, that four of the five declarants previously had either "been employed or had received research funds from Ferring," facts that the submissions failed to disclose to the PTO. See id. On the strength of these declarations, the earlier rejection notwithstanding, the PTO issued the '398 patent in September 1991. See id. at 1185, 1188-89. The district judge found this non-disclosure to be inequitable conduct in the Barr litigation, and determined the patent to be unenforceable. See id. at 1194-95.

Upon de novo review, the Federal Circuit held both that the undisclosed affiliations would have been material to the examiners' decision to issue the '398 patent, see id. at 1187-90, and that the evidence suggested that the affiants' previous relationships with Ferring were "deliberately concealed," id. at 1193. The Federal Circuit therefore concluded that the district

court had not abused its discretion in finding inequitable conduct, see id. at 1194-95, rendering the '398 patent unenforceable as against Barr and all other parties.

Less than two months after the Federal Circuit's February 2006 ruling, the direct purchaser plaintiffs filed the instant suit. The plaintiffs argue that the defendants' conduct, in addition to making the '398 patent unenforceable, violated the antitrust laws. They allege that defendants Ferring and Aventis "engaged in an exclusionary scheme" that included (1) "[p]rocuring the '398 patent by committing fraud and/or engaging in inequitable conduct before the PTO," (2) "[i]mproperly listing the fraudulently obtained '398 patent in the [FDA's] Orange Book," thereby enabling patent infringement claims against potential competitors, (3) prosecuting sham infringement litigation against generic competitors, and (4) "filing a sham citizen petition to further delay FDA final approval of Barr's ANDA." Compl. ¶ 144. The plaintiffs claim that the lack of competing, generic versions of DDAVP injured them by forcing them to pay monopolistic prices for the drug.

Ferring and Aventis jointly moved to dismiss the complaint on the basis that, inter alia, the plaintiffs lacked standing to assert their claimed antitrust violations. Aventis separately moved to dismiss the case on the ground that the plaintiffs had not sufficiently alleged misconduct against it. The district

court granted both motions and dismissed the antitrust action. See In re DDAVP Direct Purchaser Antitrust Litig., No. 05 Cv. 2237, slip op. at 15 (S.D.N.Y. Nov. 2, 2006).

The district court acknowledged that, while conduct in obtaining and enforcing a patent is generally protected from antitrust liability by the First Amendment, a patentee loses this immunity and can incur antitrust liability for enforcing a patent if the patent was obtained by fraud on the PTO. See id. at 5-6 (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 173 (1965)). However, the district court held that the plaintiffs failed to plead fraud on the PTO with sufficient particularity, noting that fraud requires a greater showing of culpability than the inequitable conduct that can render a patent unenforceable. See id. at 7-8. The district court concluded that, "[f]or this reason alone, granting the motions to dismiss is appropriate." Id. at 8.

However, "in the interest of completeness," the district court also considered the plaintiffs' standing. Id. As an initial matter, the district court noted the lack of binding precedent "with regard to the specific issue of whether purchaser plaintiffs like those in this case have standing to assert a Walker Process claim." Id. at 10-11. The district court then held that the plaintiffs lacked antitrust standing for their Walker Process claim because the '398 patent had not been

enforced against them, and they were not competitors of Ferring or Aventis. Id. at 11-12 (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005); Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.), 335 F. Supp. 2d 522 (D.N.J. 2004)).

With little discussion, the district court also rejected the plaintiffs' non-Walker Process claims — the Orange Book listing, the sham infringement litigation, and the sham citizen's petition — on the basis that the defendants had not acted "in subjective bad faith." Id. at 13. Finally, the district court granted Aventis's separate motion to dismiss, concluding that the plaintiffs had failed to sufficiently allege that Aventis was complicit in Ferring's fraud upon the PTO. Id. at 14-15.

The plaintiffs now appeal the district court's decision in its entirety. They argue that the district court erred in dismissing the complaint and, in doing so, violated their due process rights. The defendants moved in this court to transfer the case on the basis that the Federal Circuit has exclusive jurisdiction over this appeal. We reserved decision on that motion.

DISCUSSION

I. Jurisdiction

We disagree that this appeal properly belongs in the Federal Circuit. The Federal Circuit has exclusive jurisdiction over

appeals where the district court's jurisdiction is "based, in whole or in part, on section 1338 of [title 28]," 28 U.S.C. § 1295(a)(1), which in turn gives district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents," id. § 1338(a). Such jurisdiction exists if a case "arises under" patent law, such that "a well-pleaded complaint establishes either [1] that federal patent law creates the cause of action or," as is relevant here, "[2] that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 808-09 (1988). However, "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 under 28 U.S.C. § 1338." In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 199 (2d Cir. 2006). In such a scenario, because "there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." Id. (quoting Christianson, 486 U.S. at 812).

In this case, because the plaintiffs have filed an antitrust suit, patent law does not create the cause of action. The

Federal Circuit's jurisdiction over this case, if it exists, must rest upon the second part of the Christianson test: that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." 486 U.S. at 809. The plaintiffs argue that their right to relief can stand on any one of four different theories: (1) the defendants committed Walker Process fraud in obtaining and securing the '398 patent; (2) the defendants listed the '398 patent in the FDA's Orange Book despite knowing the patent was fraudulently procured and therefore invalid; (3) the defendants, knowing the '398 patent was invalid, prosecuted sham patent infringement litigation against generic competitors in order to delay FDA approval of the competitors' generic DDAVP equivalent; and (4) the defendants filed a sham citizen petition, asking the FDA to require additional testing of a generic DDAVP equivalent (thus delaying its approval) despite knowing that such testing was unnecessary.

The first three of the plaintiffs' four theories plainly "depend[] on resolution of a substantial question of federal patent law," as they all turn on how the '398 patent was procured. In the absence of any fraud, actions taken by Ferring and Aventis in obtaining, maintaining, and enforcing the '398 patent would be exempt from antitrust liability. See Walker Process, 382 U.S. at 177 & n.5; SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1206 (2d Cir. 1981). The plaintiffs' antitrust claim,

under their first three theories, requires that the '398 patent had been fraudulently procured. See Walker Process, 382 U.S. at 177 & n.5. In this context, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent would not have been granted. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). Materiality, justifiable reliance, and but-for causation each implicate the issue of patentability, namely, whether the patent would have been granted in the absence of the fraudulent representations or omissions. Because the first three theories turn on substantial questions of patent law, appellate jurisdiction would lie exclusively with the Federal Circuit if the plaintiffs' success solely depended on one or more of these theories.

The plaintiffs' fourth theory, however, does not turn on a substantial question of patent law. Under this theory, Ferring violated the antitrust laws when it filed a sham citizen petition with the FDA, requesting that the FDA require Barr to conduct extra testing to establish that its generic product was bioequivalent to DDAVP, thereby delaying approval of Barr's ANDA. Generally, under the Noerr-Pennington doctrine, citizen petitions

are immune from antitrust liability in light of the First Amendment. See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961) ("[T]he Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly."); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."); Primetime 24 Joint Venture v. Nat'l Broad. Co., 219 F.3d 92, 99 (2d Cir. 2000) (explaining that "concerted actions before courts and administrative agencies" are generally shielded from the Sherman Act by "the right to petition the legislature") (citing Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510-11 (1972)).

Noerr-Pennington protection is not absolute, however. When petitioning activity "ostensibly directed toward influencing governmental action[] is a . . . sham to cover what is . . . nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified." Noerr, 365 U.S. at 144. This sham exception requires that the petition be "(i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through

the use of the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon.'" Primetime 24, 219 F.3d at 100-01 (quoting Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 60 (1993)).

The plaintiffs claim that the citizen petition was a sham because its sole purpose was "to delay the entry of generic competitors into the market." Compl. ¶ 105. Whether the petition was a sham is an issue independent of patent law; the substance of Ferring's citizen petition did not rest on the issuance or validity of a patent. A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham. BE&K Constr. Co. v. NLRB, 536 U.S. 516, 526 (2002); see also Tamoxifen, 466 F.3d at 213 (citing PRE, 508 U.S. at 60). Administrative petitions, while less susceptible than lawsuits to the sham exception, still carry the potential for antitrust liability. See Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1062 (9th Cir. 1998) (noting that "the exact scope of the sham exception to the Noerr-Pennington doctrine has not always been clear in the administrative context" but finding it applicable to "a sufficiently circumscribed form of administrative authority" that is not "essentially political").

The fact that a single citizen petition may trigger the sham exception does not end our jurisdictional inquiry. Even if Ferring's citizen petition was a sham, "[p]roof of a sham merely

deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." PRE, 508 U.S. at 61. Thus we must determine if any of these elements turn on a question of patent law, in which case the sham petition theory cannot be our basis for jurisdiction.

"[T]o state a claim for monopolization under Section 2 of the Sherman Act, a plaintiff must establish '(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 105 (2d Cir. 2002) (per curiam) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)). The plaintiffs also must demonstrate an antitrust injury and damages. See Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc., 502 F.3d 91, 105 (2d Cir. 2007).

The defendants argue that, because the citizen petition was filed over a year before the '398 patent was ruled unenforceable, the plaintiffs cannot prove the necessary intent to monopolize without showing that the patent was foreseeably unenforceable — an issue that raises questions of patent law. However, the '398 patent became unenforceable almost five months before the FDA rejected the citizen petition. During that time, the defendants were free to "supplement, amend, or withdraw" the petition, 21

C.F.R. § 10.30(g), which at that point they knew to be based upon an unenforceable patent. Even if the defendants' intent when filing the petition raises questions of patent law, their intent in maintaining the petition after they lost the infringement litigation does not. And because the defendants' failure to address the citizen petition after the '398 patent became unenforceable could plausibly constitute a Sherman Act violation, the citizen petition supports a patent-independent theory of liability. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 566 (2007) (suggesting that either "action or inaction" could be plausibly alleged as an antitrust violation).

The failed infringement suit also dooms the defendants' suggestion that the '398 patent's status might impact the potential for antitrust injury from the citizen's petition. If the '398 patent had been valid, Barr's ANDA might have been denied regardless of the citizen petition. But the '398 patent had already been held unenforceable due to inequitable conduct, and the ANDA denial was plainly not inevitable (as evidenced by its ultimate approval). Thus, the plaintiffs' antitrust claim can stand on the citizen petition theory without raising questions of patent law.

Finally, the defendants argue that jurisdiction properly lies with the Federal Circuit because the plaintiffs' citizen petition theory is a minor part of the overall allegations.

Indeed, the plaintiffs themselves see the petition as only a single piece of a larger anticompetitive scheme of which the '398 patent is the linchpin. But the relief sought by the plaintiffs is not tied inextricably to this larger scheme. The plaintiffs simply ask for a judgment declaring the defendants' actions to have violated the Sherman Act. See Compl. 37-38. The question of whether the Federal Circuit has jurisdiction "focuses on claims, not theories, and just because an element that is essential to a particular theory might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." Christianson, 486 U.S. at 811 (internal citations omitted). The defendants stress that the plaintiffs' patent-related theories are essential to the overall relief the plaintiffs seek, because the citizen petition theory covers a time period shorter than the overall allegations, but this fact lacks jurisdictional significance. Focusing on claims, not theories, we have jurisdiction as long as any one of the theories can support the claim without raising substantial questions of patent law. The citizen petition theory satisfies this requirement, and therefore we have jurisdiction over this appeal.

II. Antitrust Standing

The defendants argue that the plaintiffs lack standing to pursue this action. We review questions of standing de novo.

Comer v. Cisneros, 37 F.3d 775, 787 (2d Cir. 1994). In addition to demonstrating Article III standing, an antitrust plaintiff must also establish antitrust standing. See Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc., 467 F.3d 283, 290 (2d Cir. 2006). We analyze antitrust standing under a two-part test: 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," Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977), 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 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.

Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council, 857 F.2d 55, 66 (2d Cir. 1988) (citing Associated Gen. Contractors v. Cal. State Council of Carpenters ("AGC"), 459 U.S. 519, 540-45 (1983)).

In this case, the plaintiffs are purchasers of the defendants' product who allege being forced to pay supra-competitive prices as a result of the defendants' anticompetitive conduct. Such an injury plainly is "of the type the antitrust laws were intended to prevent." Brunswick, 429 U.S. at 489; see

also AGC, 459 U.S. at 530 ("Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices by the giant trusts and combinations that dominated certain interstate markets."). Although the defendants' conduct at issue targeted their competitors, such as Barr, the plaintiffs' claimed injury of higher prices was "inextricably intertwined" with the conduct's anti-competitive effects and thus "flow[ed] from that which makes defendants' acts unlawful." Blue Shield of Va. v. McCready, 457 U.S. 465, 484 (1982) (internal quotation marks omitted). Antitrust injury is therefore present.

As for the "efficient enforcer" factors that bear on whether the plaintiffs are "proper" antitrust plaintiffs, spelled out in Volvo, each favors granting antitrust standing. With respect to the first factor, directness of injury, even though the plaintiffs' injuries were derivative of the direct harm experienced by the defendants' competitors, harming competitors was simply a means for the defendants to charge the plaintiffs higher prices. See id. at 478-79; In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 400-01 (3d Cir. 2000). This factor supports the plaintiffs' standing.

As to the second factor, motivation, the defendants argue that their competitors are the parties most motivated to enforce the antitrust laws, because the competitors were most directly

impacted by the alleged anticompetitive behavior. They note that we declined to find antitrust standing in Paycom in part because the plaintiff there was "not an entity whose self-interest would most 'motivate [it] to vindicate the public interest in antitrust enforcement.'" 467 F.3d at 294 (quoting AGC, 459 U.S. at 542) (alteration in original). But this argument overlooks the fact that the Paycom court asked if the plaintiff was an entity most motivated by self-interest, not the entity most motivated by self-interest. See id. The second factor simply looks for a class of persons naturally motivated to enforce the antitrust laws. "Inferiority" to other potential plaintiffs can be relevant, but it is not dispositive. See Andrx Pharms., Inc. v. Biovail Corp., Int'l, 256 F.3d 799, 816 (D.C. Cir. 2001). Even if the competitors might be the most motivated, the plaintiffs are also significantly motivated due to their "natural economic self-interest" in paying the lowest price possible. See Daniel v. Am. Bd. of Emergency Med., 428 F.3d 408, 444 (2d Cir. 2005) (internal quotation marks omitted).

Moreover, the defendants' competitors, unlike the plaintiffs, would be seeking lost profits, not overcharges. Lost profits are the difference between the competitive price and what the competitors' costs would have been, while overcharges are the difference between the defendants' supra-competitive price and the competitive price. Denying the plaintiffs a remedy in favor

of a suit by competitors would thus be "likely to leave a significant antitrust violation undetected or unremedied." AGC, 459 U.S. at 542; see also Andrx Pharms., 256 F.3d at 817 (noting that lost profits and overcharges are distinct injuries). The second factor supports standing.

Turning to speculativeness, the third factor, the defendants argue that the plaintiffs' allegations rest upon tenuous assumptions about the beneficial effects of generic competition. The assumptions are not as speculative as the defendants suggest. That no other manufacturer would have obtained a patent on the drug is a fair assumption, we think, given that "[t]he reluctance of the PTO to issue the '398 patent was evident" in advance of the defendants' inequitable conduct. Ferring I, 437 F.3d at 1186. And that generic manufacturers would have decided to compete for DDAVP sales is self-evident: manufacturers sought approval for generic DDAVP when the '398 patent was still enforceable. It may be difficult to account precisely for the likely effects of generic competition, but we have little doubt that those effects can be sufficiently estimated and measured here. See Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 499 (2d Cir. 2004) (listing literature analyzing generic drug competition). This is especially so when "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which

his own wrong has created." Bigelow v. RKO Radio Pictures, 327 U.S. 251, 265 (1946). Like the first two factors, the third factor supports the plaintiffs' antitrust standing.

As for the fourth factor, the potential for duplicative recovery, the difference between lost profits and overcharges is again relevant. Even assuming some overlap between lost profits and overcharges (as could occur if generic manufacturers charged more than the competitive price), the two are conceptually different measures that we think can be fairly apportioned in order to avoid duplicative recoveries. See Andrx Pharms., 256 F.3d at 817. This factor also supports the plaintiffs' antitrust standing.

In sum, then, although the relative weight given to each factor is imprecise, see, e.g., Daniel, 428 F.3d at 443, the plaintiffs would be efficient enforcers under any formulation. What complicates the standing question, however, is the centrality of the alleged Walker Process fraud to the plaintiffs' case. Walker Process claims are based on a fraudulently obtained patent, and are typically brought as counterclaims in patent infringement suits: the plaintiff claims the defendant infringed his patent, and the defendant responds that the patent was invalid as fraudulently obtained, and that the plaintiff's enforcement efforts violate Walker Process. See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1067 (Fed. Cir.

1998). If a patent is valid, a Walker Process claim cannot stand.

Outside of an infringement suit counterclaim, a patent's validity can be challenged only by a party (1) producing or preparing to produce the patented product, and (2) being threatened or reasonably likely to be threatened with an infringement suit. See, e.g., Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 862 (Fed. Cir. 1987). As purchasers of DDAVP, the plaintiffs do not satisfy these requirements and cannot directly challenge the '398 patent's validity. As the district court noted, whether the plaintiffs have standing to bring their Walker Process claim, when a court has yet to find the '398 patent fraudulently obtained, is a question of first impression.

The defendants acknowledge that Walker Process standing might be warranted for a purchaser when a patent has already been held to have been fraudulently procured. But the defendants urge us to hold that, when dealing with a patent not yet found to be fraudulently obtained, a party has Walker Process standing only if that party also has standing to challenge the patent's validity. They argue that giving Walker Process standing to the plaintiffs, who cannot directly challenge the '398 patent's validity, could result in an avalanche of patent challenges, because direct purchasers otherwise unable to challenge a patent's validity could do so simply by dressing their patent

challenge with a Walker Process claim. It would be relatively easy, the defendants argue, for these purchasers to allege an antitrust injury, as patent protection inherently leads to supra-competitive prices. See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."). Given that Walker Process fraud converts this fundamental feature of the patent system into a potential antitrust violation, the defendants contend that finding purchaser standing could significantly increase the costs of defending and enforcing patents by greatly expanding the universe of potential challenges. They insist that "[i]f the threat of treble damage liability . . . were imbedded in the minds of potential patent holders as a likely prospect . . . , the efficacy of the economic incentives afforded by our patent system might be severely diminished." SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1206 (2d Cir. 1981).

Walker Process itself, of course, reflects a willingness to let antitrust liability impact the patent system. However, the defendants argue that Walker Process is the product of the Supreme Court's careful balancing of antitrust and patent policies, a balance which should not be upset and under which Walker Process plaintiffs must be independently able to first prove the patent's fraudulent procurement. Yet the language of

Walker Process does not necessarily suggest such a limit:

> While one of [the claim's] elements is the fraudulent procurement of a patent, the action does not directly seek the patent's annulment. The gist of Walker's claim is that since Food Machinery obtained its patent by fraud it cannot enjoy the limited exception to the prohibitions of § 2 of the Sherman Act, but must answer under that section . . . to those injured by any monopolistic action taken under the fraudulent patent claim. Nor can the interest in protecting patentees from 'innumerable vexatious suits' be used to frustate the assertion of rights conferred by the antitrust laws.

382 U.S. at 176 (emphasis added). To be sure, the Walker Process Court also noted that allowing antitrust recovery "accord[ed]" with the "long-recognized procedures" that controlled how parties could challenge a patent's validity, 382 U.S. at 176-77, thereby suggesting that the Court may not have envisioned expanding the universe of potential patent challengers.

Nonetheless, we are reluctant to embrace the defendants' position because we are wary of creating the potential "to leave a significant antitrust violation undetected or unremedied." AGC, 459 U.S. at 542. As the defendants would have it, direct purchasers would be able to recover antitrust damages from a fraudulent patentee only after that patentee first loses on a fraudulent procurement claim. This asks too much of the generic competitors and other potential patent challengers, who may not have the strategic interest or the resources to start or win such a battle, or who 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. See C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1616 (2006) (noting how "an innovator has an especially strong incentive to pay to neutralize . . . potential competition" when a generic manufacturer first files an ANDA).

Although settlements between patent holders and generic manufacturers that delay generic entry into the market may themselves invite antitrust liability, a plaintiff must be able to show the settled litigation to have been a sham in order to succeed. See Tamoxifen, 466 F.3d at 208-09 ("In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."). A purchaser seeking to challenge the settlement by showing the underlying infringement litigation to be a sham would need to attach antitrust liability to the patent enforcement efforts — a move that would raise the same standing issues presented by this case. Thus, not only are there strong potential settlement incentives, but these settlements could be shielded from purchaser attack.

The difference between inequitable conduct and fraud also

bears on the question. Inequitable conduct is a lesser showing than fraud, but is sufficient to render a patent unenforceable. A generic competitor interested simply in selling its product may not value the higher showing of fraud enough to pursue it, especially if the competitor's antitrust damages would be minor or difficult to prove. Again, relying on generic competitors to lead the antitrust charge may ask too much of them.

On the other hand, we do not pass lightly over the defendants' objections to expanding the universe of patent challengers. The risk of disturbing the incentives for innovation dictates that we tread carefully. As a result, we decline to decide whether purchaser plaintiffs per se have standing to raise Walker Process claims. In this case, the plaintiffs are challenging an already tarnished patent. We are able to grant them antitrust standing without altering the typical limits on who can start a challenge to a patent's validity. We therefore hold only that purchaser plaintiffs have standing to raise Walker Process claims for patents that are already unenforceable due to inequitable conduct. The district court erred by concluding to the contrary.

III. Was the Antitrust Claim Adequately Pled?

Granting standing to the plaintiffs does not resolve this appeal, because the district court also concluded that the plaintiffs had failed to state a claim. "We review the district

court's dismissal of a complaint for failure to state a claim de novo, accepting as true all facts alleged in the complaint and drawing all inferences in favor of the plaintiff . . . ." Faulkner v. Beer, 463 F.3d 130, 133 (2d Cir. 2006) (internal quotation marks omitted). "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009). We believe that the plaintiffs meet this standard for their antitrust claim under each of their four theories.

Walker Process fraud, the plaintiffs' first theory, requires:

> (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 the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.

Nobelpharma, 141 F.3d at 1069-70. A fraudulent omission, which "can be just as reprehensible as a fraudulent misrepresentation," can be sufficient to "support a finding of Walker Process fraud." Id. at 1070.

A party "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The plaintiffs argue that they have pled each element with sufficient specificity. They alleged a series of "highly material" omissions, without which "the '398 patent

would not have issued." Compl. ¶ 74. The Federal Circuit agreed on the "high[] material[ity]" of the omissions when it found the '398 patent unenforceable. Ferring I, 437 F.3d at 1194. The Ferring I litigation also addressed the third element of intent, as the district court found "clear and convincing evidence of an intent to mislead the examiners." Ferring B.V., 2005 WL 437981, at *9. Reliance and injury, the fourth and fifth elements, are straightforward here: the PTO was justified in relying on the information the defendants provided, and injury is a "matter of course whenever the other four elements are met." Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1361 (Fed. Cir. 2004), rev'd on other grounds, 546 U.S. 394 (2006). Thus, the plaintiffs contend the district court's dismissal on the pleadings was erroneous.

The defendants respond that the district judge's rejection of the plaintiffs' claim must be affirmed because he was also the district judge in the initial infringement litigation, in which he held the '398 patent unenforceable. The defendants argue that the judge's involvement in both cases enabled him to validly conclude that his previous findings could not support a claim of fraudulent procurement in the instant case. This is a logical non sequitur. The district judge could be correct in determining that inequitable conduct occurred and yet mistaken that such conduct did not amount to fraud. Moreover, the defendants'

argument ignores the distinction between findings and pleadings. Even if the district judge was correct that the earlier record did not show fraud, the record in this case could be different following discovery.

The defendants contend that simply adding a conclusory allegation of fraud to the previous findings is inadequate to meet the plaintiffs' obligation to "allege facts that give rise to a strong inference of fraudulent intent." Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir. 1995). We are, however, "lenient in allowing scienter issues to withstand summary judgment based on fairly tenuous inferences," because such issues are "appropriate for resolution by the trier of fact." Press v. Chem. Inv. Servs. Corp., 166 F.3d 529, 538 (2d Cir. 1999). The same holds true for allowing such issues to survive motions to dismiss. The district court found "an intent to deceive" in the patent litigation. Ferring B.V., 2005 WL 437981, at *9. Granting the plaintiffs all favorable inferences as we must on a motion to dismiss, and given that the omissions at issue occurred repeatedly over a period of years, this intent is sufficient to plausibly support a finding of Walker Process fraud.

The defendants next argue that the plaintiffs must allege evidence of intent distinct from the omission itself. While a false or clearly misleading statement can permit an inference of deceptive intent, a misrepresentation in the form of an omission

is more likely to be innocent and cannot support Walker Process fraud without "evidence of intent separable from the simple fact of the omission." Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1347 (Fed. Cir. 2007). The issue in the initial infringement litigation was inequitable conduct, not Walker Process fraud. Moreover, the district court in that litigation correctly noted that high materiality could overcome a lesser showing of intent. Ferring B.V., 2005 WL 437981, at *9; see Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1380-81 (Fed. Cir. 2001). While such balancing is impermissible with Walker Process claims, we think the plaintiffs' allegations are nonetheless sufficient. Dippin' Dots concerned findings, not pleadings, see 476 F.3d at 1341-42; even if the district court's findings in the Ferring I litigation could not satisfy Dippin' Dots, the plaintiffs' pleadings could plausibly lead to additional findings that would satisfy Dippin' Dots, which is all that is required at this stage of the litigation.

The defendants additionally argue that the allegations of materiality are insufficient. Specifically, they contend that the plaintiffs do not dispute the '398 patent's patentability on the merits or claim that, but for the alleged fraud, no patent could have been issued to anyone. For antitrust purposes, whether a patent could be issued matters more than who would possess it; if a patent could still "have been issued to

someone," its market power would still have been concentrated (properly) in one party. Brunswick Corp. v. Riegel Textile Corp., 752 F.2d 261, 265 (7th Cir. 1984). As a result, Walker Process fraud must concern a material issue of patentability; otherwise, a patent would have issued regardless of any fraud, and potential plaintiffs would have suffered the same monopoly effects (but legitimately).

Although the plaintiffs do not address patentability directly in the complaint, the issue is implicit in their allegations. The defendants' allegedly fraudulent affidavits were attempts to explain away prior art. The Federal Circuit found them "absolutely critical" to the defendants' overcoming the patent application's initial rejection. Ferring I, 437 F.3d at 1189. Whether or not these declarations, if accompanied by full disclosure, would have resulted in an enforceable patent is debatable, but we think that, at the pleading stage, the fact of non-disclosure is sufficient to properly allege materiality. Overall, then, the plaintiffs have sufficiently alleged Walker Process fraud to survive the defendants' motion to dismiss on the pleadings.

We likewise conclude that the sham litigation claim has been adequately alleged. In order to state a claim for sham litigation, the plaintiffs need to allege that "the litigation in question is: (i) 'objectively baseless,' and (ii) 'an attempt to

interfere directly with the business relationships of a competitor through the use of the governmental process . . . as an anticompetitive weapon.'" Primetime 24 Joint Venture v. Nat'l Broadcasting Co., 219 F.3d 92, 100-01 (2d Cir. 2000) (citing Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993)). Based on the same facts alleged to sustain a Walker Process claim, we find that in the circumstances of this case, the plaintiffs' allegations are also sufficient to make out a sham litigation claim. The defendants effectively concede as much. See Brief of Defendants-Appellees Ferring B.V. and Ferring Pharms. at 38 ("[A] sham litigation claim here not only requires proof that defendants defrauded the PTO, but also that they knew their misconduct before the PTO had rendered the patent invalid. . . . [Plaintiffs'] 'sham' litigation allegation is thus substantively duplicative of their patent fraud claim . . . .").

The plaintiffs also may proceed on their Orange Book claim. The defendants all but concede that the plaintiffs would have a basis for contending the Orange Book listing was fraudulent if the '398 patent is found to have been fraudulently procured. See id. at 41 ("[T]he allegations regarding the Orange Book listing are – like the sham litigation claims – purely derivative of the underlying claim that the '398 patent was fraudulently procured."). Indeed, the Orange Book listing's validity flows

from the patent's validity. Having determined that the Walker Process and sham litigation theories are still in play, we similarly conclude that the plaintiffs have adequately alleged that the defendants improperly listed the '398 patent in the FDA's Orange Book.

The final theory is the plaintiffs' citizen petition theory, which, as we have explained, stands apart from the '398 patent's validity. The district court dismissed this theory on the basis that it concerned petitioning activity protected by the First Amendment. Id. To reach this conclusion, the district court presumably reasoned that the plaintiffs could not plausibly show the petition to be a sham, i.e., objectively and subjectively baseless, a proposition with which we disagree. The FDA found that the citizen petition "had no convincing evidence" and lacked "any basis" for its arguments. Compl. ¶ 115 (internal quotation marks and emphasis omitted). In the Ferring I litigation, the district court suggested that the petition might have been "nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise transactional costs for Barr." Ferring B.V., 2005 WL 437981, at *17. Together, these findings indicate the plaintiffs could plausibly show the citizen petition to have been a sham.

Finally, the defendants contend that the citizen petition

cannot give rise to antitrust liability because it could not have impacted the FDA's decision, as the FDA ultimately rejected the petition. But this ignores the possibility that the sham petition caused a delay in generic competition, a possibility reinforced by the fact that the FDA approved the generic drug on the same day that it rejected the petition. See 21 C.F.R. § 10.35(d)(1) (enabling a stay of FDA action after the filing of a petition). Whether the '398 patent was valid on the date the petition was filed is immaterial to this theory's success, because the plaintiffs can plausibly show the patent to have been fraudulently procured. It may turn out at trial that this petition was not a sham, or that the FDA's approval of the generic drug was not delayed by the petition, but the possibility that the petition was a sham, and that it impacted the FDA's decision, is sufficiently plausible to defeat the motion to dismiss.

Overall, the plaintiffs have stated an antitrust claim upon which relief may be granted. Based on the pleadings, each of their four theories could plausibly succeed. The district court erred by concluding to the contrary.

IV. Can Aventis Be Kept in the Case?

The district court also granted Aventis's separate motion to dismiss, concluding that the plaintiffs had not alleged fraud with sufficient particularity to satisfy Rule 9 of the Federal

Rules of Civil Procedure. "Although Rule 9(b) permits knowledge to be averred generally, plaintiffs must still plead the events which they claim give rise to an inference of knowledge." Devaney v. Chester, 813 F.2d 566, 568 (2d Cir. 1987). In a case involving multiple defendants, plaintiffs must plead circumstances providing a factual basis for scienter for each defendant; guilt by association is impermissible. See id. This can consist of allegations as to who "possessed . . . knowledge" of the fraud, "when and how they obtained [that] knowledge," or even why they "should have known" of the fraud. Id. The district court concluded that the plaintiffs fell short of this standard. We disagree.

In the district court's view, "[t]hat Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason." In re DDAVP, slip op. at 15. However, we find the plaintiffs' allegations plausible, and sufficient to survive a motion to dismiss on the pleadings. At the time Aventis filed its NDA and listed DDAVP in the Orange Book, the '398 patent's validity was already in question with the patent having been rejected twice, and the PTO having raised concerns of bias. See Ferring I, 437 F.3d at 1190. Yet, the plaintiffs assert that Aventis apparently made no effort to independently investigate and attest to the validity of the '398 patent. Rule 9(b) requires only the circumstances of fraud to be stated with

particularity; knowledge itself can be alleged generally. Especially considering the long-standing relationship between Aventis and Ferring, the plaintiffs have adequately stated circumstances that give rise to a plausible inference of knowledge and liability. At this early stage, the plaintiffs need only state a plausible claim of monopolization, and they have alleged enough for their suit against Aventis to proceed.

Because the dismissal as to both Ferring and Aventis was in error, we have no cause to address the plaintiffs' claim that their due process rights were violated.

CONCLUSION

For the foregoing reasons, we VACATE the district court's dismissal of the plaintiffs' case and REMAND for further proceedings.