06-5525-cv

United States Court of Appeals

for the

Second Circuit

In re DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

ON APPEAL FROM AN ORDER DISMISSING THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

7:05-CV-2237 (CLB) (S.D.N.Y.)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR *AMICI CURIAE* THE AMERICAN ANTITRUST INSTITUTE, AARP, THE CONSUMER FEDERATION OF AMERICA, CONSUMERS UNION, AND FAMILIES USA IN SUPPORT OF PLAINTIFFS-APPELLANTS

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Respectfully submitted,

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Amici Curiae the American Antitrust Institute ("AAI"), AARP, the Consumer Federation of America, Consumers Union, and Families USA respectfully submit this brief, as friends of the Court, in support of Plaintiffs-Appellants ("Plaintiffs"). This case addresses the vitally important legal issue whether overcharged purchasers, when compelled to pay inflated prices as the result of unlawful monopolization effected through the wrongful enforcement of a fraudulently procured patent, have standing to assert monopolization claims under federal antitrust law.[1]

Interests of *Amici Curiae*

As shown below, *Amici Curiae* include various entities having differing interests relating to the issues presented. All of the *Amici Curiae*, however, share a

[1] This brief does not address other issues raised in this appeal, many of which relate more narrowly to particular facts of the case and on which *Amici Curiae* express no opinion. Instead, this brief is limited to the single broad issue of consumer standing, which is a vital legal issue critical to the effective functioning of private antitrust enforcement. *See Reiter v. Sonotone Corp.*, 442 U.S. 330, 344 (1979) (private actions "provide a significant supplement to the limited resources available to [DOJ] for enforcing the antitrust laws and deterring violations"); *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 262 (1972) (In the antitrust laws "Congress encouraged [private litigants] to serve as 'private attorneys general.'").

common interest in protection of the legal rights of overcharged purchasers to pursue claims for monopolization under federal antitrust law against pharmaceutical companies, and other manufacturers, who charge unlawfully inflated prices to purchasers and consumers. *Amici Curiae* strongly believe that the decision of the District Court, which denies antitrust standing to overcharged purchasers for certain patent related antitrust claims, is irreconcilably at odds with axiomatic principles of United States antitrust law and policy. None of the *Amici Curiae* nor their counsel has any financial interest in the outcome of this litigation, nor did Appellants or their counsel make any financial or other contribution toward the preparation of this brief.

The *amici* have two primary concerns. First, this case involves the pharmaceutical industry and a course of conduct that may be used increasingly by brand name pharmaceutical manufacturers to delay the onset of generic drug competition. The filing and enforcement of invalid patents can impose a substantial cost on society and consumers in terms of higher prices, less competition, and less innovation. This is a serious concern in the pharmaceutical industry where there is the opportunity for tremendous consumer savings as over $40 billion in pharmaceuticals are scheduled to go off patent in the next few years. The rule of law adopted by the district court will encourage deceptive and

fraudulent conduct by brand name companies in order improperly to obtain patents and extend patent life.

Second, for antitrust law to function effectively there must be a system of remedies that serves both of two overarching principles: compensation and deterrence. The system of antitrust litigation seeks to enable private plaintiffs to bring suits to compensate them for injuries suffered from unlawful conduct and ensure the violators do not profit from their wrongdoing. The rule of law adopted by the District Court fails to fulfill either of these goals. By limiting suits attacking *Walker Process* violations to competitors, the District Court's decision will provide no compensation for purchasers – who suffer the greatest harm from the illegal conduct. Moreover, by limiting the damages of a wrongdoer, the deterrent effect of private antitrust actions is severely dampened.

1. The American Antitrust Institute

The American Antitrust Institute ("AAI"), which led in the organization of this *amicus curiae* brief, is an independent non-profit education, research and advocacy organization that believes that the national economy is best served by the vigorous enforcement of the antitrust laws. Its mission is to advance the role of competition in the economy, protect customers, and sustain the vitality of the antitrust laws. The Advisory Board of AAI, which serves in a consultative

capacity, consists of prominent antitrust lawyers, law professors, economists, and business leaders. For more information, see www.antitrustinstitute.org.[2]

2. AARP

AARP is a nonpartisan, nonprofit membership organization of over 38 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. AARP conducts research and engages in educational activities and advocacy to increase access to affordable prescription drugs. AARP has carefully tracked and issued reports that closely monitor the pricing actions of the pharmaceutical industry.[3] AARP works to ensure that everyone has access to needed health care and prescription drugs, but prescription drug treatments are particularly important to older persons who have the highest rate of prescription drug use. Persons over 65, although only 13 percent of the population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2 (July 2000). Since generic drugs generally cost much

[2] Although AAI benefits from the advice of its Advisory Board, the decision to file an amicus brief is made by its Board of Directors. Accordingly, the views and positions set forth in this brief are not necessarily the views of any particular members of AAI's Advisory Board. Moreover, members of AAI's Advisory Board who are involved in the litigation have recused themselves from participating in the development of this brief.

[3] *See, e.g.*, AARP, *Rx Watchdog Report*, May 2007, Vol. 4, Issue 4, *available at* http://www.aarp.org/issues/rx_watchdog.

less than their brand-name counterparts, AARP has worked at the state and national levels to increase access to lower cost generic versions of drugs. AARP has filed *amicus curiae* briefs related to several prescription drug antitrust cases. AARP and its members have a significant interest in the question whether consumers have an effective remedy to pursue antitrust claims for damages caused by anticompetitive practices.

3. Consumer Federation of America

The Consumer Federation of America ("CFA") is the nation's largest consumer-advocacy group, composed of over 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations, with more than 50 million individual members. CFA represents consumer interests before federal and state regulatory and legislative agencies and participates in court proceedings. CFA has been particularly active on antitrust issues affecting health care and high technology industries.

4. Consumer Union

Consumer Union is a nonprofit membership organization which provides consumers with independent expert information about goods, services, health, and personal finance. Consumer Union's income is solely derived from the sale of *Consumer Reports* and *ConsumerReports.org*, its other publication and from noncommercial contributions, grants and fees. Consumer Union's products have a

combined paid circulation of approximately 7.3 million consumers. *Consumer Reports* and *ConsumerReports.org* regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare.

5. Families USA

Families USA is a national nonprofit, nonpartisan organization dedicated to achieving high-quality, affordable health care for all Americans. Working at the national, state, and community levels, Families USA has earned a national reputation as an effective voice for health care consumers. Families USA regularly advocates on health care competition issues including the rising prices of pharmaceuticals and publishes an annual survey of antitrust litigation on behalf of pharmaceutical consumers.

Preliminary Statement

In 1965 the Supreme Court in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) (*"Walker Process"*) held that "the maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under Section 2 of the Sherman Act, and therefore subject to a treble damage claims *by an injured party* under Section 4 of

the Clayton Act." *Id*. at 173 (emphasis added).[4] The *Walker Process* opinion could not be clearer in contemplating, consistently with 15 U.S.C. § 15, that antitrust standing extends to "an injured party," *i.e.*, to "*[a]ny person* who shall be injured in his business or property by reason of anything forbidden in the antitrust laws. . . ." *Id.* at 174 n. 2 (quoting this latter language from 15 U.S.C. § 15; emphasis added). The "any person" language in Section 4 of the Clayton Act has consistently been construed broadly by the Supreme Court, and in *Pfizer v. Government of India*, 434 U.S. 308 (1978), was read to include foreign government *purchasers* asserting monopolization claims that rested in part on "fraud upon the United States Patent Office." *Id*. at 310.[5] Nevertheless, in a ruling supported by scant district court precedent and by no appellate precedent whatsoever, the District Court below held that *purchasers* who pay inflated prices

[4] As Justice Harlan's concurring opinion in *Walker Process* makes clear, this is true even when the person maintaining and enforcing the patent is not the person who procured it, so long as the enforcing party "had been enforcing the patent with knowledge of the fraudulent manner in which it was obtained." 382 U.S. at 179 (Harlan, J., concurring).

[5] The antitrust claims in *Pfizer* arose from a finding by the Federal Trade Commission ("FTC") that a patent for tetracycline had been obtained by fraud on the Patent and Trademark Office ("PTO"). *See Charles Pfizer & Co. v. Federal Trade Commission*, 401 F.2d 574, 577 (6th Cir. 1968) (affirming FTC decision). While the Supreme Court in *Pfizer* did not specifically address whether *Walker Process* claims could be brought by purchasers, it is noteworthy that neither the Court nor the pharmaceutical defendants apparently questioned this point.

as a result of the type of monopolization forbidden in *Walker Process* lack "standing" to assert antitrust claims based on such wrongdoing, and that such standing is limited instead only to competitors of the patent holders.

To limit standing to pursue *Walker Process* claims to competitors alone would not adequately remedy the antitrust injuries caused by fraudulently-procured patents. Often, lost profits of competitors who might challenge a patent in court will be far less than the additional profits that the owner of a fraudulently procured patent earns by exploiting his unlawful monopoly. For example, in pharmaceutical cases like the case at hand, a generic challenger to a patent on a brand name drug, even if it succeeds in a patent challenge, is able to earn only a small fraction of the profits that the brand name manufacturer is able to extract from the public by maintaining its monopoly on the drug. Thus, generic challengers generally have far less financial incentive to mount expensive and difficult patent challenges than would the purchasers or consumers who could bring a claim under *Walker Process*. As one leading commentator has recently pointed out, this is particularly true of those generic challengers other than the first so-called "ANDA filer," who do not get the 180-day period of exclusivity provided for by the Hatch-Waxman amendments.[6] From a deterrence standpoint, antitrust challenges under *Walker*

[6] *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006).

Process could not be relied upon adequately to deter fraudulently-procured patents if, as the District Court held in this case, the *only* persons permitted to seek damages and having standing in *Walker Process* antitrust cases were relatively weakly-motivated competitors, whose financial interests in the issue often are vastly smaller than those of purchasers.

These deficiencies of competitors as putative guardians of the interests of purchasers and consumers are further compounded by the fact that competitors often have collateral business relations with patent holders in the same industry, which can act as a strong disincentive to enforcement of the competitors' rights under antitrust laws. By way of illustration, the patent challenger in this case, Barr Laboratories, frequently settles patent litigation against leading brand name drug manufacturers cutting across a wide variety of prescription drugs.[7] Moreover, competitors could not even purport to have standing to recover the same damages, attributed to increased prices, that purchasers can recover under antitrust law. An antitrust recovery by a competitor obviously would compensate only for the

[7] *See* C. Scott Hemphill, *Drug Patent Settlements Between Rivals*: *A Survey*, at 3 (Mar. 12, 2007) attached to Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Hearing on H.R. 1902, May 2, 2007, *available at*: http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf. ("Of the seventeen innovators and eighteen generic firms that are party to the settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlements with respect to eight different drugs.")

competitor's smaller lost profits, and would provide no compensation at all for often much larger and more fundamental injuries to overcharged purchasers. To leave such injuries entirely uncompensated would fail to effectuate the "primary" purpose of Section 4 of the Clayton Act, which is the compensation of injured persons. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 485-86 & n. 10 (1977).

Wholly apart from such considerations of simple logic, however, the District Court's decision is equally wrong as a legal matter under basic antitrust principles, as shown below.

Argument

I. Purchasers Have Antitrust Standing to Assert Monopolization Claims under *Walker Process*.

A. Overcharged Purchasers Have The Foremost Antitrust Standing, Which Is *Superior To* That of Mere Competitors.

It is elementary that the purpose of antitrust law is "'the protection of competition, not competitors.'" *Brunswick*, 429 U.S. at 488 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). Thus, under bedrock antitrust law, the persons who *most* clearly have standing to assert an antitrust claim are purchasers overcharged as a result of an antitrust violation -- *not* competitors who may merely have lost business opportunities. *See Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 530

(1983) ("*AGC*") ("Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices"); *id.* at 538 ("[T]he Sherman Act was enacted to assure customers the benefits of price competition"); *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 476-77, 479 (1982) (antitrust remedies "cannot reasonably be restricted to those competitors whom the conspirators hoped to eliminate from the market"); *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) ("[A]t no time" in the legislative history of the Clayton Act "was the right of a consumer to bring an action for damages questioned."); Phillip E. Areeda, Herbert Hovenkamp and Roger D. Blair, *Antitrust Law* ¶ 345, at 356 (2d ed. 2000) ("Areeda") ("Because protecting consumers from monopoly prices is the central concern of antitrust, buyers have usually been preferred plaintiffs in private antitrust litigation.").[8]

Consumers' standing to obtain redress in monopolization cases under Section 2 of the Sherman Act is just as firmly embedded in the law as their standing to challenge cartel overcharges under Section 1.[9] Although antitrust

[8] *Accord, e.g., Barr Laboratories, Inc. v. Abbott Laboratories*, 978 F.2d 98, 109 (3d Cir. 1992) ("[B]asic economic theory teaches us that the chief benefit of competition is lower prices to consumers."); *Arroyo-Melecio v. Puerto Rican Am. Ins. Co.*, 398 F.3d 56, 72 (1st Cir. 2005) (consumers are "presumptively favored as appropriate plaintiffs to assert antitrust injury").

[9] *See* Areeda, *supra*, at 356 ("[c]onsumer standing to recover for an overcharge paid directly to an illegal cartel *or monopoly* is seldom doubted")(emphasis added).

Footnote continues next page …

violations under Section 2 generally are implemented through exclusionary conduct directed in the first instance toward competitors, purchasers who pay inflated prices as a result of such conduct nonetheless have the *foremost* antitrust standing.[10] To take just one prominent recent example, when Microsoft was found in the antitrust suit by the United States to have been a monopolist, its monopolization of the market for Intel-compatible PC operating systems stemmed from conduct that was directed in the first instance at Microsoft's competitors, not at consumers. *See United States v. Microsoft Corp.,* 253 F.3d 34 (D.C. Cir. 2001). The fact that prices charged to purchasers were inflated as a result of that conduct nonetheless gave *purchasers* antitrust standing to sue Microsoft for monopolization, in many subsequent private cases.

This case is squarely controlled by *McCready.* In *McCready*, the defendants argued that since the "goal of the conspirators was to halt encroachment by psychologists into a market that physicians and psychiatrists sought to preserve for

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[10] *See Glaberson v. Comcast Corp.*, Civ. A. No. 03-6604, 2006 U.S. Dist. LEXIS 62672, at *28, 2006 WL 2559479, at *7 (E.D. Pa. Aug. 31, 2006) (Competitor RCN was "not the more direct or 'superior' plaintiff" because "Comcast allegedly acted to restrain competition from RCN in order to gain the ability to charge consumers inflated prices. Plaintiffs were, therefore, the ultimate target of Comcast's anticomptetitive conduct towards RCN."); *New York Citizens Committee on Cable TV v. Manhattan Cable TV, Inc.*, 651 F. Supp. 802, 810 (S.D.N.Y. 1986) ("Consumers have standing when they are injured as a result of a defendant's improper exclusion of competitors from the market").

themselves, McCready's injury [as an overcharged purchaser from the psychologists] is rendered 'remote.'" 457 U.S. at 478-79. The Court decisively rejected that argument, stating that "[t]he availability of the [Clayton Act] § 4 remedy to some person who claims its benefit is not a question of the specific intent of the conspirators. Here *the remedy cannot reasonably be restricted to those competitors whom the conspirators hoped to eliminate from the market*." *Id*. at 479 (emphasis added) The same is true *a fortiori* in this case. The injuries to plaintiffs here are even more "direct" than those of the purchasers in *McCready,* since the purchasers in *McCready* paid higher prices to the excluded psychologists, rather than to the defendant psychiatrists. Here, because the higher prices that plaintiffs paid were paid directly to the defendants themselves, plaintiffs' standing is even simpler and more straightforward than that of the overcharged purchasers who had standing in *McCready*.

Indeed, purchasers who pay an unlawfully inflated price are the *primary* "targets" of practices such as those challenged here, in that unlike mere competitors, they actually *pay* the inflated prices, the collection of which is defendants' root motivation for engaging in the unlawful practices.[11] Conversely,

[11] *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 400-01 (3d Cir. 2000) ("Coumadin purchasers were the target of DuPont's antitrust violation" and "[t]he class members here . . . were 'foreseeable and necessary victims' of DuPont's efforts to exclude the generic drug from the market.").

even when conduct is initially "directed" at a competitor's *customers*, such conduct was recently held to provide antitrust standing to a competitor under *Walker Process*, to the extent that the impact on the customers causes an injury to the plaintiff competitor.[12] Thus, the issue is not at whom the behavior is superficially "directed" (as the District Court opinion here erroneously suggests, *see*, pp. 16-17, below), but rather merely whether the plaintiff suffers a non-speculative injury "by reason of" an injury to competition. 15 U.S.C. § 15; *see also McCready*, 457 U.S. at 479 (the question is "not a question of the specific intent of the conspirators"). Under well-established principles, therefore, the overcharged purchasers in this case have standing to assert their antitrust claims.

That competitors often also have standing to bring antitrust claims does nothing to diminish the antitrust standing of purchasers.[13] Moreover, it is

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[12] *See Hydril Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1350 (Fed. Cir. 2007) ("[A] valid *Walker Process* claim [by a competitor] may be based upon enforcement activity directed against the plaintiff's customers" because "[w]ithout customers, a supplier has no business.").

[13] *See McCready*, 457 U.S. at 469 n.4, 474-75 (allowing purchaser of health insurance to challenge boycott by insurer and psychiatrists directed at competitor psychologists, even though the competitor psychologists had maintained their own successful suit, because the psychologists and the purchasers had suffered different injuries); *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1168-70 (3d Cir. 1993) (the presence of competing trucking companies as other victims did not dilute the causal connection between the inflated charges paid by steel company purchasers of transport services and defendants' conspiracy; "other direct victims exist, but their presence does not diminish the directness of the

Footnote continues next page …

particularly unrealistic to suggest that generic competitors should be the *only* ones with antitrust standing in a context such as this one, because competitors here clearly cannot be relied upon to represent the entirely different antitrust interests of consumers and purchasers. "When the plaintiff is a poor champion of consumers, a court must be especially careful not to grant relief that may undercut the proper functions of antitrust." *Ball Memorial Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1334 (7th Cir. 1986). *See also Barr Laboratories*, 978 F.2d at 109 ("'[C]ourts have carefully scrutinized enforcement efforts by competitors because their interests are not necessarily congruent with the consumer's stake in competition'") (quoting *Alberta Gas Chems. Ltd. v. E.I. DuPont de Nemours & Co.*, 826 F.2d 1235, 1239 (3d Cir. 1987)). The injury that purchasers suffer – here, paying inflated prices for DDAVP – is inherently distinct and different in kind from any injury to competitors, who do not purchase from the patent holder and thus do not pay inflated prices to begin with. A competitor case based on enforcement of a patent does nothing from a compensatory standpoint to remedy the entirely different, public injury of inflated prices to purchasers. Thus, to deny

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[purchasing] steel companies' injury"); *Glaberson*, 2006 U.S. Dist. LEXIS 62672, at *26, 2006 WL 2559479, at *7 ("Plaintiff's injuries, which consist of overcharges, are distinct from [the competitor's] injuries, which likely consist of lost profits.") (citation omitted). *See also, U.S. Horticultural Supply, Inc. v. Scotts Co.*, Civ. A. No. 03-773, 2004 U.S. Dist. LEXIS 11859, at *6, 2004 WL 1529185, at *2 (E.D. Pa. Feb. 18, 2004) (there can be more than one proper plaintiff to seek claims based on antitrust violation).

standing to DDAVP purchasers affords no remedy for the *primary* antitrust "wrong" of the inflated prices that the purchasers were compelled to pay.

In suing to recover their damages, the purchasers here, like those in *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 399 (7th Cir. 2000), are not asserting the entirely different rights of competitors, but instead "are asserting their own rights, and thus . . . have standing." It is logically indefensible to suggest, as the District Court's opinion implicitly does, that the rightful interest of purchasers in antitrust enforcement under *Walker Process* would be protected by the possibility of antitrust suits by competitors alone.

B. The Reasoning of the District Court Is Deeply Flawed.

To support its conclusion below, the District Court did not rely on any of the factors articulated by the Supreme Court or by this Court for assessing standing in private antitrust actions. *See* Op. at 10 (quoting *Balaklaw v. Lovell*, 14 F.3d 793 (2d Cir. 1994)). Rather, the Court professed to rest its conclusion primarily on language from *Walker Process* which states that it is "the enforcement of" the patent that creates the antitrust violation, Op. at 12, citing *Walker Process*, 382 U.S. at 174, and reasoned that because "there has been no enforcement of the patent against the customer Plaintiffs," they have no antitrust standing. Op. at 12. This is a *non-sequitur*. The cited language from *Walker Process* merely defines the antitrust violation. It says nothing about who is injured by and should have

standing to sue for that violation, which 15 U.S.C. § 15 makes clear should include "*any person* who shall be injured in his business or property" as a consequence of the antitrust violation (emphasis added). Although the Supreme Court has established limitations on the scope of this "any person" language which can apply when the plaintiff is "*neither a consumer nor a competitor* in the market in which trade was restrained," *AGC*, 459 U.S. at 539 (emphasis added), those limitations do not deny standing to an overcharged purchaser. On the contrary, the Supreme Court clearly established the opposite in *McCready*. *See* pp.12-13, *supra*.

The decision below also seems to rest in part on a rationale "that non-infringing consumers of potential products have no cause of action *to invalidate a patent*. . . ." Op. at 11 (emphasis added) (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp 2d 516 (E.D.N.Y 2005)). However, to view the claims asserted here as claims "to invalidate a patent" flies squarely in the face of *Walker Process* itself. The basis on which the Supreme Court reversed the Seventh Circuit in *Walker Process* was that the rule that "only the United States may sue to cancel or annul a patent" did *not* apply because "Walker counterclaimed *under the Clayton Act, not the patent laws*," and that contrary to the Seventh Circuit's views in that case, a monopolization claim for damages based on "the maintenance and enforcement of" a wrongfully-procured patent "*does not directly seek the patent's annulment*." 382 U.S. at 175-76 (emphasis added). *See*

also Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F. 3d 1341, 1349 (Fed. Cir. 2004) (recognizing that *Walker Process* claims are "*antitrust* claims premised on the bringing of a patent infringement suit") (emphasis added, citation omitted), *rev'd in part on other grounds*, 546 U.S. 394 (2006).

Thus, antitrust plaintiffs who pursue monopolization claims under *Walker Process* do *not* seek "to invalidate a patent," as the District Court erroneously assumed. Instead, plaintiffs here assert an *antitrust* claim for recovery of damages based on injuries that they suffered by paying inflated prices for DAAVP, as a consequence of the "maintenance and enforcement" of Ferring's wrongfully-procured DDAVP patent. The inflated prices that plaintiffs paid provide them with standing under the most elementary antitrust principles. Thus, the court in *Molecular Diagnostics Labs. v. Hoffman-LaRoche, Inc.*, 402 F. Supp. 2d 276, 281 (D.D.C. 2005) correctly reasoned that when a claim under *Walker Process* is "[v]iewed properly as an *antitrust* claim, there is little reason to think that standing requirements for *Walker Process* claims differ from standing requirements in more conventional antitrust actions," and that purchasers therefore have antitrust standing.

The District Court relied for authority principally on the prior decision in *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D. N.J. 2004). In *Remeron*, however, the court reached a then-unprecedented conclusion denying antitrust

standing *to purchasers* by erroneously relying on language taken out of context *from competitor cases*, principally including *Carrot Components Corp. v. Thomas & Betts Corp.*, 229 U.S.P.Q. (BNA) 61 (D. N.J. 1986).[14] However, in a competitor case like *Carrot Components*, unlike a purchaser case, it is often doubtful whether a competitor plaintiff who is not threatened with patent enforcement has suffered any "antitrust injury," or whether the competitor's goal instead is merely to seek to use the antitrust laws as a competitive weapon when *competition* was not injured by the challenged conduct.[15] Unless a plaintiff-competitor who claims to compete

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[14] Additional non-purchaser cases cited either by the District Court or in *Remeron* include *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704 (9th Cir. 2003), *Indium Corp. of America v. Semi-Alloys, Inc.*, 591 F. Supp. 608 (N.D.N.Y. 1984) and *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003). However, standing of purchasers to assert *Walker Process*-type claims was neither presented as an issue, nor was it addressed in *Bourns*, *Indium* or *Asahi*. In *Bourns*, in stating that "[o]nly an actual competitor or one ready to be a competitor can suffer antitrust injury," 331 F.3d at 711, all the court was saying is that *in a competitor case*, a competitor who neither competes nor intends to compete lacks antitrust injury. Because Bourns "did not have the intent and preparedness to be a competitor," *id.*, he lacked standing. But Bourns was not a purchaser. His lack of standing does nothing to show a lack of standing for purchasers, which was not at issue. Likewise in *Indium*, the court held only that *when a competitor is the plaintiff,* the competitor must have been "ready, willing and able" to compete in order to have a cognizable antitrust injury. 591 F. Supp. at 614. In *Asahi*, the court held merely that since the inclusion of a supplier in a patent infringement case between competing manufacturers had no possible anticompetitive effect, the supplier itself had no antitrust standing.

[15] Such skepticism with regard to the standing of *competitor* plaintiffs is the basic reason for the venerable adage that the purpose of antitrust law is "to protect competition, not competitors." *See Brooke Group, Ltd. v. Brown & Williamson*

Footnote continues next page …

with a patent holder actually would have produced an infringing product -- and also had a reasonable apprehension that an infringement suit might be brought against it – a competitor as such would suffer no antitrust injury. In contrast, *purchasers* suffer antitrust injury *by being forced to pay inflated prices*. Whether a purchaser is "ready to compete in the marketplace" has no sensible bearing on a purchaser's antitrust injury. Thus, in *Glaberson*, the requirement that a competitor be "ready, willing and able" to compete was *inapplicable* in an overcharge case brought by purchasers, because the purchaser plaintiffs were "not competitors of Comcast and *the standards that courts impose upon competitors to ensure that their injury is not speculative are not applicable to the determination of [purchasers'] antitrust standing."* 2006 U.S. Dist. LEXIS 62672, at *25 n. 5, 2006 WL 2559479, at *7 n.5 (emphasis added). In other words, as differently stated in *Molecular Diagonostics*, language from competitor cases like *Carrot Components* (and other competitor cases cited in footnote 14 above) is "limited to the facts of [those cases], and [does] not purport to establish a rule of general applicability"

Tobacco Corp., 509 U.S. 209, 225 (1993)("Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws. . . ."); *Unitherm*, 375 F.3d at 1362 ("It is widely recognized that an antitrust plaintiff must allege more than simply that the defendant's wrongful behavior directly damaged the plaintiff's business, but also that the accused behavior stifled competition") (citations omitted).

that can properly be applied out of context in purchaser cases like this one. *Molecular Diagnostics*, 402 F. Supp. 2d at 280.

Apart from reliance on stray language from inapposite competitor cases, the *Remeron* decision "cites no controlling precedent, nor offers any compelling justification for its conclusion." *Molecular Diagnostics*, 402 F. Supp. 2d at 280. The District Court's reasoning here with regard to claims under *Walker Process*, which rests squarely on the foundation of *Remeron*, is equally defective.

C. To Apply Conventional Antitrust Standing Principles to Monopolization Claims under *Walker Process* Does Not Conflict with United States Patent Policy.

As shown above, conventional antitrust standing principles are irreconcilable with the conclusion of the District Court denying antitrust standing under *Walker Process.* Given that the District Court's holding is so squarely at odds with basic antitrust principles, we anticipate that Appellees may attempt to justify it primarily by reference not to *antitrust* policy, but instead to federal *patent* policy. However, Justice Harlan's concurrence in *Walker Process* makes clear that far from having only cramped or limited application in the *Walker Process* context, "antitrust remedies *should be allowed room for full play."* 382 U.S. at 180 (Harlan, J. concurring; emphasis added). As Justice Harlan stated, "that *private suits* may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by

deliberate fraud, *cannot well be thought to impinge upon the policy of the patent laws to encourage innovations and their disclosure*." *Id*. at 179-80 (emphasis added). This statement applies by its terms to all "private suits" -- not only to competitor cases. As Justice Harlan's opinion clearly states, there can be no argument that permitting purchaser redress in *Walker Process* cases will chill desirable activity when a *Walker Process* claim requires a showing of deliberate fraud.

Even if *Walker Process* itself had not made this clear, deliberate fraud in the procurement of patents still could not reasonably find any shelter under federal patent policy. In *Precision Instruments Mfg. Co. v. Automotive Maint. Mach. & Co.*, 324 U.S. 806 (1945), the Court wrote that "[a] patent by its very nature is affected with a public interest. . . . The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds *free from fraud*. . . ." *Id*. at 816 (emphasis added). PTO rules recognize this anti-fraud policy by imposing a duty of candor on all patent applicants. *See* 37 C.F.R. 1.56 (every person "associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability"). Nevertheless, in the Manual of Patenting Examining Procedure ("MPEP"), the

PTO makes clear that it will not even attempt to police compliance with this rule, stating that

> the Office does not investigate and reject original or reissue applications under 37 CFR 1.56. Likewise, the Office will not comment upon duty of disclosure issues which are brought to the attention of the Office in original or reissue applications except to note in the application, in appropriate circumstances, that such issues are no longer considered by the Office during its examination of patent applications.

MPEP 2010. The PTO explains that it does not enforce the duty of candor because courts, rather than the PTO, are better equipped to deal with such issues in private litigation. *Id*. In light of this posture, it is clear that the PTO itself can provide no effective solution to issues raised by fraudulently procured patents.

Even if PTO examination rules could be revised to embrace questions of fraud and inequitable conduct, such a change would be pointless and ineffectual in any event in light of structural limitations of the PTO. Forty years ago, this Court recognized "the practical inadequacy of existing remedies for improperly procured patents." *Chas. Pfizer & Co. v. Davis-Edwards Pharmacal Corp*., 385 F.2d 533, 538 (2d Cir. 1967). More recently, in October 2003, the Federal Trade Commission issued an exhaustive study of competition and patent law in October 2003, in which it concluded, after holding extensive hearings on the subject for nearly a year, that "questionable patents" are a very serious problem and that

"existing means for challenging questionable patents are inadequate."[16] Patent examination in the PTO is conducted in an entirely *ex parte* process by examiners who have no laboratory facilities, and thus no ability independently to confirm the truth of representations made by patent applicants to the PTO.[17] This is one of the primary reasons offered by the PTO in the MPEP itself as to why it does not consider issues of fraud or inequitable conduct. *See* MPEP 2010. Moreover, estimates of the time permitted for an examiner to reach a decision on each patent application range from 8 to 25 hours, but all commentators seem to agree that it is "very short."[18] Testimony given by PTO directors reports that "these inadequate time frames create a stressful work environment and are cited in the agency's exit surveys as a primary reason that examiners leave the agency."[19] As a result, the PTO has "difficulty competing with the private sector to attract and retain staff with the high degree of scientific, technical, and legal knowledge required to be

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[16] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (October 2003) ("2003 FTC Report"), Executive Summary pp. 5, 8 (*available at*: www.ftc.gov/os/2003/10/innovationrpt.pdf).

[17] 2003 FTC Report, Executive Summary p. 9; Ch. 1 p. 27; Ch. 5 pp. 6-10.

[18] 2003 FTC Report, Executive Summary p. 10; Ch. 5 p. 5.

[19] GAO Testimony, Intellectual Property, Improvements Needed to Better Manage Patent Office Automation and Address Workforce Challenges, p. 18, GAO-05-1008T (Sept. 8, 2005) (*available at*: www.gao.gov/new.items/d051008t.pdf).

patent examiners."[20] Furthermore, "examiners told us they have to contend with a highly stressful work environment and work voluntary overtime to meet their assigned quotas," examiners "do not have time to conduct high-quality reviews of patent applications," and "[e]xaminers told us that voluntarily working overtime to meet quotas is common at USPTO, and they find it demoralizing not to have enough time to do a good quality job."[21] Even forty years ago, it was recognized that such circumstances make it "nearly impossible to filter out invalid patents prior to their issuance." Note, *Improperly Procured Patents: FTC Jurisdictional and Remedies Power*, 77 Harv. L. Rev. 1505, 1507 (1964) (*cited in Chas. Pfizer & Co.*, 385 F.2d at 538). That reality has become even more pronounced over the years, as "[p]atent applications have doubled in the last twelve years and are increasing at about 10% per year." 2003 FTC Report, Executive Summary p. 9. This has recently been described as an "unprecedented explosion." *Id*., Ch. 5 p. 4.

In view of these realities, in order to protect the public from the very real injuries caused by fraudulently procured patents and resulting monopolies, the only

[20] *Id.* at 1.

[21] GAO Report to Congressional Committees, Intellectual Property, USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain, pp. introduction, 5, 29, GAO-05-720 (June 2005) (*available at*: www.gao.gov/new.items/d05720.pdf).

recourse under existing legal machinery is private litigation.[22] As shown above, however, to limit such private litigation to competitors alone would leave the distinct antitrust interests of purchasers unrepresented and unprotected and would fail adequately to deter fraudulent patent procurement. Accordingly, effective antitrust and patent policy, in addition to established law, requires that fraudulent procurement of patents be subject to challenge by *purchasers* under *Walker Process.*

[22] When private litigation directly challenges a patent under the patent laws, it has long been observed that large proportions of the challenged patents are found to be invalid. As early as 1964, it was observed that the "majority of litigated patents are found invalid." Note, *supra*, 77 Harv. L. Rev. at 1508. More recently, studies have found that "45-46% of all patents litigated to final results are held invalid." 2003 FTC Report, Ch. 5 p 6. In contexts like this one, "[d]ata show that generic applicants have had nearly a 75 percent success rate in pharmaceutical patent infringement litigation." Remarks of FTC Chair Deborah P. Majoras, p. 14 (May 16, 2007)(*available at*: www.ftc.gov/speeches/majoras/051607ACI_Pharma.pdf).

Conclusion

The decision of the District Court with regard to antitrust standing under *Walker Process* should be vacated, and the case should be remanded to the District Court for further proceedings.

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