06-5525-cv

IN THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

IN RE DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR THE UNITED STATES AND FEDERAL TRADE COMMISSION
AS AMICI CURIAE SUPPORTING PLAINTIFFS-APPELLANTS

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STATEMENT OF INTEREST

The United States and the Federal Trade Commission have the primary responsibility for enforcing the federal antitrust laws and so have a significant interest in both the substantive and procedural aspects of those laws. This interest includes the proper interpretation of section 4 of the Clayton Act, 15 U.S.C. § 15, which authorizes civil antitrust suits by "any person who shall be injured in his business or property" by an antitrust violation. This case presents a significant issue of first impression in the courts of appeals: whether section 4 authorizes direct purchasers to sue to recover monopoly overcharge damages resulting from maintenance of a monopoly by enforcement of a fraudulently obtained patent. The district court erroneously held that section 4 does not permit such a suit. The United States and the Federal Trade Commission disagree with this ruling and ask the Court not to affirm it. We express no views on the ultimate merits or any other issues in this case. We file pursuant to the first sentence of Federal Rule of Appellate Procedure 29(a).

QUESTION PRESENTED

Whether section 4 of the Clayton Act allows direct purchasers of a patented product to recover damages from overcharges resulting from a monopoly maintained by the enforcement of a patent obtained through intentional fraud on the U.S. Patent and Trademark Office.

STATEMENT

1. Plaintiffs-appellants Meijer, Inc., and others in this putative class action purchased tablets of the anti-diuretic desmopressin acetate under the brand name DDAVP directly from the defendants, Ferring B.V., Ferring Pharmaceuticals, Inc., and Aventis Pharmaceuticals.[1] Consol. Am. Class Action Compl. ¶¶ 2, 9-11, 15 (Am. Compl.) (JA 1-4).[2] The plaintiffs charge that the defendants maintained a monopoly in the United States market for desmopressin acetate tablets in violation of section 2 of the Sherman Act, 15 U.S.C. § 2, and that, as a result, purchasers paid supracompetitive prices for the drug. Am. Compl. ¶¶ 1, 4 (JA 1-2). Specifically, the plaintiffs allege that the defendants enforced a "fraudulently

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[1] Since the ruling under review is the grant of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the complaint's factual allegations are accepted as true and all inferences therefrom are drawn in plaintiffs-appellants' favor for present purposes. *See E& L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 28 (2d Cir. 2006).

[2] JA refers to the Joint Appendix, and SA to the Special Appendix.

obtained" patent[3] on desmopressin tablets to prevent and delay lower-priced generic equivalents of DDAVP from entering the market. Am. Compl. ¶ 3 (JA 2). The enforcement, plaintiffs allege, consisted of improperly listing the patent in the Food and Drug Administration's (FDA) Orange Book and filing and prosecuting patent infringement suits against generic drug makers that applied to market a generic equivalent of DDAVP. *Id.* Under the Hatch-Waxman Act, once the patent was listed in the Orange Book, the filing of infringement suits against the generic drug makers seeking FDA approval to market the drug triggered an automatic 30-month stay of that approval.[4] Am. Compl. ¶¶ 21-35, 88, 98 (JA 6-11, 23, 26).

Defendants' actions, the complaint alleges, "deprived Plaintiffs . . . of access to substantially lower-priced generic versions of desmopressin acetate

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[3] The patent is U.S. Patent No. 5,407,398 (the '398 patent). The alleged fraud rests on Ferring's failure to disclose to the U.S. Patent and Trademark Office its past relationships with several persons who submitted declarations supporting Ferring's contention that a prior patent did not anticipate the invention. Am. Compl. ¶¶ 50-74 (JA 15-20). In an earlier patent infringement suit brought by defendants here against a generic drug maker, that failure was held to be "inequitable conduct" rendering the patent unenforceable. *Ferring B.V. v. Barr Labs., Inc.*, No. 7:02-CV-9851, 2005 WL 437981 (S.D.N.Y. Feb. 7, 2005) (Brieant, J.), *aff'd*, 437 F.3d 1181 (Fed. Cir.), *cert. denied*, 127 S. Ct. 515 (2006).

[4] The plaintiffs also allege that the enforcement of the patent eliminated competition by requiring other drug companies to challenge the '398 patent before obtaining FDA approval, and by causing under Hatch-Waxman a 180-day generic exclusivity period for the first generic applicant who challenged the Orange Book-listed patent. Am. Compl. ¶¶ 39, 83-85, 133 (JA 12, 22, 34).

tablets, thereby causing Plaintiffs . . . to pay supra-competitive prices for DDAVP and its generic equivalents." Am. Compl. ¶ 4 (JA 2). The plaintiffs sustained substantial losses and damage to their business and property in the form of these overcharges, and they seek treble damages for these injuries. Am. Compl. ¶¶ 6, 134 (JA 3, 34).

2. The defendants jointly moved to dismiss the direct purchasers' complaint for failure to state a claim, arguing that the plaintiffs lacked antitrust standing under section 4 of the Clayton Act. Aventis separately moved to dismiss for failure to plead with particularity facts showing Aventis' knowledge of, or involvement in, the alleged fraud on the U.S. Patent and Trademark Office (PTO), as required by Federal Rule of Civil Procedure 9(b).

3. The district court granted both motions. Memorandum and Order (Nov. 2, 2006) (Op.) (SA 1-16). It recognized that under *Walker Process Equipment Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the enforcement of a patent obtained by intentional fraud on the PTO may be the basis for a violation of the Sherman Act and a damages action under the Clayton Act. Op. at 5-6 (SA 5-6). The district court, however, concluded that the direct purchasers' *Walker Process* claim failed here for three reasons. First, based on its findings in the prior infringement action, *see supra* note 3, the court held that the defendants' conduct

did not rise to the level of fraud required by *Walker Process.* *Id.* at 8 (SA 8). Second, the plaintiffs did not plead fraud with the particularity required by Rule 9(b). Op. at 8, 13-15 (SA 8, 13-15).

The district court's third reason was that the plaintiffs are not "'proper' antitrust plaintiffs" and therefore did not have antitrust standing to bring a so-called *Walker Process* claim. *Id.* at 8 (SA 8). The court recognized that the plaintiffs were direct purchasers and that they were harmed by the "monopoly, which kept generic versions of DDAVP off of the market and resulted in overcharges to Plaintiffs." *Id.* at 9 (SA 9). Nonetheless, it concluded that they lacked standing because they did not compete, and would not have competed, with defendants, nor were they sued or threatened with an infringement suit by the defendants. *Id.* at 9-12 (SA 9-12).

ARGUMENT

I. THE PLAINTIFFS HAVE ANTITRUST STANDING

A. Antitrust Standing Is Well Established for Direct Purchasers Seeking Overcharge Damages Caused by an Antitrust Violation

Section 4 of the Clayton Act provides that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor." 15 U.S.C. § 15. The section's dual purpose is "to deter"

violators by "depriv[ing] them of the fruits of their illegality and to compensate victims of antitrust violations for their injuries." *Pfizer Inc. v. Gov't of India*, 434 U.S. 308, 314 (1978) (*Pfizer*) (internal quotation marks and citations omitted). The plaintiffs' complaint on its face fits comfortably within the standing requirements and purposes of section 4 as interpreted by the Supreme Court. The plaintiffs are "persons" within the meaning of the Clayton Act. 15 U.S.C. § 12(a). They directly purchased DDAVP from the defendants. And they sought to recover overcharges resulting from a monopoly allegedly maintained by the defendants through conduct violating the antitrust laws.

It is long-settled section 4 law that direct purchasers such as plaintiffs have antitrust standing to recover overcharges. As the leading commentators have explained: "Because protecting consumers from monopoly prices is the central concern of antitrust, buyers have usually been preferred plaintiffs in private antitrust litigation. As a result, consumer standing to recover for an overcharge paid directly to an illegal cartel or monopoly is seldom doubted." 2 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 345, at 356 (2d ed. 2000); *see* 2 Philip E. Areeda & Donald F. Turner, *Antitrust Law* ¶ 345, at 183 (1978); Earl E. Pollock, *Standing to Sue, Remoteness of Injury, and the Passing-On Doctrine*, 32 *Antitrust L.J.* 5, 7 (1966).

The antitrust standing of direct purchasers seeking to recover overcharges from those who raised price by restraining or monopolizing trade in violation of the Sherman Act was established as early as *Chattanooga Foundry & Pipe Works v. Atlanta*, 203 U.S. 390 (1906). The city of Atlanta, which had purchased water pipe at supracompetitive prices from a member of the pipe cartel (*see Addyston Pipe & Steel Co. v. United States,* 175 U.S. 211 (1899)), sued for treble damages under section 7 of the Sherman Act, the direct and substantively identical (*see Pfizer*, 434 U.S. at 311) predecessor of the current section 4 of the Clayton Act. The Court succinctly explained why the plaintiff had antitrust standing: It had purchased the pipe directly from a cartel member; because of the cartel's violations of sections 1 and 2 of the Sherman Act, the plaintiff paid a supracompetitive price; and the payment of that inflated price injured the city in its property. *Chattanooga Foundry*, 203 U.S. at 395-96.

Subsequent decisions reaffirmed the antitrust standing of direct purchasers. In *Georgia v. Evans*, 316 U.S. 159, 162 (1942), the Court held that states that purchased directly from the defendants had the same standing to sue as injured persons under section 4 "which is available to other purchasers who suffer through violation of the Act." In *Pfizer*, 434 U.S. at 310, 319, the Court held that, like a private person or a state, a foreign government that had directly purchased goods

from a cartel had standing to sue under section 4. And in *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339-42 (1979), the Court unanimously rejected an argument that a direct purchaser of price-fixed hearing aids may sue under section 4 only if the purchaser is engaged in a commercial venture, and held that a direct purchaser who is an actual user has equally clear antitrust standing. Direct purchaser standing is thus at the center of what the Court has called the "'expansive remedial purpose'" of section 4. *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 472 (1982), quoting *Pfizer*, 434 U.S. at 313.

Notwithstanding that "expansive remedial purpose," the Supreme Court has held that section 4 is not to be read literally and does not "encompass every harm that can be attributed directly or indirectly to the consequences of an antitrust violation." *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 529 (1983) (*AGC*). Most importantly, in *Brunswick Corp. v. Pueblo Bowl-O-Mat*, 429 U.S. 477, 489 (1977), the Court held that section 4 permits recovery only for antitrust injury, which the Court defined as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful," adding that injury giving rise to standing "should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation."

In addition, the courts have long held that section 4 does not permit recovery for "indirect, remote, and consequential" injuries.[5] *Loeb v. Eastman Kodak, Co.* 183 F. 704, 709 (3d Cir. 1910) (denying standing to shareholders); *see G.K.A. Beverage Corp. v. Honickman*, 55 F.3d 762, 766-77 (2d Cir. 1995) (denying standing to distributors for a soft drink bottler that allegedly was the target of exclusionary conduct); *Southwest Suburban Bd. of Realtors, Inc. v. Beverly Area Planning Ass'n*, 830 F.2d 1374, 1378 (7th Cir. 1987) ("Merely derivative injuries sustained by employees, officers, stockholders, and creditors of an injured company do not constitute 'antitrust injury' sufficient to confer antitrust standing."). Rather, damage recovery is available under section 4 only when the injuries complained of were proximately caused by the antitrust violations. *AGC*, 459 U.S. at 532-34, 540-43; *McCready*, 457 U.S. at 476-78.

This Court has reduced the analysis of *AGC* to a two-part test for standing: 1) whether there is antitrust injury; and 2) whether other factors, mainly directness of injury and identifiability of that injury, prevent the plaintiff from being an efficient enforcer of the antitrust laws. *Balaklaw v. Lovell*, 14 F.3d 793, 797 & n.9

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[5] Moreover, injuries to indirect purchasers from the passing-on of overcharges do not give rise to damages claims under section 4. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977); *Kansas v. Utilicorp United Inc.*, 497 U.S. 199 (1990).

(2d Cir. 1994); *see Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 290-91 (2d Cir. 2006). Section 4 requires that the plaintiff be "an efficient enforcer," rather than "the most efficient enforcer," and the possibility that the generic drug makers may also have antitrust standing—though they have not brought antitrust suits—does not detract from the current plaintiffs' standing under section 4 to recover for their antitrust injuries. *See Molecular Diagnostics Labs. v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 281 (D.D.C. 2005). The recovery by direct purchasers would not duplicate the recovery by competitors because each group suffers direct, but distinct injuries with non-overlapping measures of damages. The direct purchasers' damages are the overcharges they paid, measured as the difference between the monopoly price and the but-for price, while competitors' damages are their lost profits, measured as the difference between that but-for price and their costs.

None of the limitations on the application of section 4 poses an obstacle to recovery in this case. Assuming, *arguendo*, the underlying merit of the plaintiffs' claims, they plainly suffered antitrust injury when they paid prices elevated by the monopoly illegally maintained by enforcing a fraudulently obtained patent. And the injuries suffered by plaintiffs were proximately caused by the allegedly unlawful conduct.

B. Direct Purchasers Are Not Deprived of Standing Merely Because Their Monopoly Maintenance Claim Rests On *Walker Process*

The century-old body of Supreme Court and court of appeals antitrust standing law is not made inapplicable by the plaintiffs' allegations that the monopoly was maintained by enforcing a fraudulently obtained patent. Nor do these allegations transform plaintiffs' antitrust claim into a patent claim. If a seller unlawfully maintains a monopoly whether by enforcing a fraudulently obtained patent or engaging in some other form of exclusionary conduct and that seller charges direct customers supracompetitive prices as a result, these customers suffer core antitrust injuries. And thus they have antitrust standing to make an antitrust claim and seek damages for the antitrust violation, regardless of what form the exclusionary conduct took or whether it violated patent or some other law.

The district court largely ignored this body of antitrust standing law: the court cited little of it and applied none. Op. at 10 (SA 10) (citing the two-part *Balaklaw* test, *supra* p. 9, but not applying it). Rather, the district court tersely, but mistakenly, rested its holding on two recent district court decisions in *Walker Process* suits—one of which did not even rule on section 4 standing and the other of which ignored settled antitrust standing law. Op. at 11-12 (SA 11-12) (citing *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514

(E.D.N.Y. 2005) (*Cipro*), and *In re Remeron Antitrust Litigation*, 335 F. Supp. 2d 522 (D.N.J. 2004) (*Remeron*)). The district court also erroneously seemed to share the defendants' dissatisfaction with the balance between antitrust and patent law struck in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

1. Whatever the merits of the *Cipro* decision, the claims addressed there rest on different factual and legal theories. The *Cipro* plaintiffs' federal antitrust challenge was based on an allegedly anticompetitive agreement settling an infringement suit between a patentee and its competitors and did not include an allegation that the patent was obtained by intentional fraud on the PTO. The district court in *Cipro* concluded that the plaintiffs failed to show any anticompetitive effect beyond the scope of the patent. 363 F. Supp. 2d at 541. The only *Walker Process*-type claims in *Cipro* were brought by indirect purchasers under state law, and those claims were held preempted by federal patent law. 363 F. Supp. 2d at 542-43. While patent law may be relevant to whether fraud was perpetrated on the PTO, antitrust standing under section 4 of the Clayton Act is a question of federal antitrust law independent of patent law. *See Unitherm Food Systems, Inc. v. Swift Eckrich, Inc.*, 375 F.3d 1341, 1349 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006); *see also Walker Process*, 382 U.S. at 176.

The court in *Remeron* based its conclusion that direct purchasers lacked antitrust standing on its misreading of two district court cases holding that an actual or potential competitor did not have standing to bring a *Walker Process* claim unless it was excluded from the market by the defendant's unlawful conduct. *Remeron*, 335 F. Supp. 2d at 529 (citing *Carrot Components Corp. v. Thomas & Betts Corp.*, 229 U.S.P.Q. 61, 64 (D.N.J. 1986); *Indium Corp. of Am. v. Semi-Alloys Inc.*, 566 F. Supp. 1344 (N.D.N.Y. 1983) (*Indium I*); and *Indium Corp. of Am. v. Semi-Alloys Inc.*, 591 F. Supp. 608, 614-15 (N.D.N.Y. 1984) (*Indium II*)). These cases have nothing to do with direct purchaser antitrust standing. They stand for the proposition that standing under section 4 requires a causal relationship between the allegedly unlawful acts and the plaintiff's injury. *See Carrot Components*, 229 U.S.P.Q. at 64 (*Walker Process* claim cannot be based on enforcement that caused no "detriment" to plaintiff); *Indium I*, 566 F. Supp. at 1352-53 (*Walker Process* claim requires a causal link between injury and patentee's enforcement conduct); *Indium II*, 591 F. Supp. at 614-15 (amended complaint alleged sufficient causal link).

A causal relationship is, of course, required for *Walker Process* damages claims, just like other section 4 claims; as we observed above, the antitrust violation must be the proximate cause of the plaintiffs' injuries, *see supra* p. 9.

The causation requirement does not, however, dictate that only plaintiffs against whom the fraudulently obtained patent was enforced have standing to make a *Walker Process* claim. In *Hydril Co. v. Grant Prideco LP*, 474 F.3d 1344, 1350 (Fed. Cir. 2007), for example, the court of appeals held that "a valid *Walker Process* claim may be based upon enforcement activity directed against the plaintiff's customers" if that enforcement causes the plaintiff the kind of harm that the antitrust laws were intended to prevent. While competitors failing to allege that enforcement caused them injury (as in *Carrot Components* and *Indium I*) cannot state a *Walker Process* claim, competitors alleging that the enforcement against their customers caused them antitrust injury (as in *Hydril*) can state a claim. Similarly, purchasers alleging that enforcement against the defendants' competitors caused the purchasers' injury in the form of overcharges have standing to recover for those overcharges. *Cf. McCready*, 457 U.S. at 478-79 (finding antitrust standing for purchaser of psychological services foreseeably injured by exclusionary conduct directed at psychologists).

2. The defendants may argue that allowing antitrust suits by direct purchasers would amount to private suits to cancel patents based on fraud, despite the rule that only the United States can sue to cancel a patent for fraud on the patent office, *United States v. American Bell Telephone Co.*, 128 U.S. 315, 369-70 (1888).

This argument has no logical connection to section 4 and boils down to a disagreement with *Walker Process.* In that case, the Supreme Court made clear that the lack of statutory authority for a private suit to cancel a patent on the basis of fraud does not bar "those injured by monopolistic actions taken under the fraudulent patent claim" from bringing an antitrust action seeking damages "under the Clayton Act, not the patent laws." 382 U.S. at 176. "While one of [the antitrust action's] elements is the fraudulent procurement of a patent, the action does not directly seek the patent's annulment." *Id.* Denying standing because of the rule that private parties cannot sue to cancel a patent commits the error the court of appeals made, and the Supreme Court corrected, in *Walker Process*. *See Food Machinery & Chemical Corp. v. Walker Process Equipment, Inc.*, 335 F.2d 315, 316 (7th Cir. 1964); *Walker Process*, 382 U.S. at 175-76.

3. The defendants may also argue that allowing direct purchasers to sue in cases like this will lead to litigation against patent holders that may retard the research and development stimulated by the patent system. *See* Defendants' Reply Memorandum at 1-2 (JA 233-34); *Cipro,* 363 F. Supp. 2d at 541-42. Patents obtained by fraud and used to maintain a monopoly, however, undermine both the patent system and the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain."

Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969); *see Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid").

Moreover, the factual reliability of defendants' prediction is open to serious question. *Walker Process* "deal[s] only with a special class of patents, *i.e.*, those procured by intentional fraud," not "honest mistake" amounting to a mere "technical fraud." 382 U.S. at 176-77; *cf. Walker Process*, 382 U.S. at 180 ("[T]his private antitrust remedy should not be deemed available to reach § 2 monopolies carried on under a nonfraudulently procured patent.") (Harlan, J., concurring). The need to plead with particularity and prove a knowing and intentional fraud on the PTO may discourage many direct purchasers from bringing *Walker Process* claims and defeat most of those who do. *See* Fed. R. Civ. P. 9(b); *see, e.g., Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346-48 (Fed. Cir. 2007). This may explain why *Walker Process*-type claims by direct purchasers, while not unheard of before *Remeron*—the direct purchasers in *Pfizer*, for example, alleged that defendants engaged in "fraud upon the United States Patent Office" to monopolize the market for broad spectrum antibiotics, 434 US. at 310—are rare.

Lastly, the defendants' concern cannot "be used to frustrate the assertion of

rights conferred by the antitrust laws." *Walker Process*, 382 U.S. at 176. As Justice Rehnquist pointed out in his concurrence in *Sonotone*, "the problem, if there is one, is for Congress and not for the courts." 442 U.S. at 346; *id.* at 344-45 (rejecting argument that under section 4 only commercial (as opposed to non-commercial) direct purchasers should be allowed to sue because otherwise there would be a costly increase in litigation).

CONCLUSION

The dismissal of the *Walker Process* claim should not be affirmed on the basis that the plaintiffs lack antitrust standing as direct purchasers to bring such a claim.

Respectfully submitted.

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May 25, 2007

CERTIFICATION OF COMPLIANCE
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1. I James J. Fredricks, certify that this brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 32(a)(7) and 29(d) because it contains 3852 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), as counted by the WordPerfect 10 word processor program used to prepare it.

2. I, James J. Fredricks, further certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using the WordPerfect 10 word processor program in 14-point Times New Roman.

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James J. Fredricks

CERTIFICATE OF SERVICE

I, James J. Fredricks, certify that I caused two copies of the accompanying BRIEF FOR THE UNITED STATES AND THE FEDERAL TRADE COMMISSION AS AMICI CURIAE SUPPORTING PLAINTIFFS-APPELLANTS to be sent via overnight Fedex service and an electronic copy of this brief in pdf format to be sent via email on the 25th of May, 2007, to each of the following:

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