NOS. 15-2005, 15-2006, 15-2007
UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Nos. 15-2005, 15-2006, 15-2007
IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION
(caption continues on subsequent pages)

On Appeal from the United States District Court
For the District of Massachusetts
Civil Action No. 12-md-02409-WGY

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION IN SUPPORT OF NO PARTY

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Nos. 15-2005
IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; VALUE DRUG COMPANY; BURLINGTON DRUG COMPANY INC.; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and others similarly situated; MEIJER, INC.; MEIJER DISTRIBUTION, INC.,

Plaintiffs-Appellants,

ALLIED SERVICES DIVISION WELFARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 17 HEALTH CARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; FRATERNAL ORDER OF POLICE MIAMI LODGE 20 INSURANCE TRUST FUND; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND; UNITED FOOD & COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; MICHIGAN REGIONAL COUNCIL OF CARPENTERS EMPLOYEE BENEFITS FUND; INTERNATIONAL UNION OF MACHINISTS AND AEROSPACE WORKERS DISTRICT NO. 15 HEALTH FUND; INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 595 HEALTH AND WELFARE FUND; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; SUPERVALU, INC.; HEB GROCERY CO. LP; GIANT EAGLE, INC.; RITE AID CORPORATION; RITE AID HEADQUARTERS CORPORATION; JCG (PJC) USA, LLC; MAXI DRUG, INC., d/b/a Brooks Pharmacy; ECKERD CORPORATION; CVS PHARMACY, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARITEN INSURANCE COMPANY; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.; HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE OF KENTUCKY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC.; CAREPLUS HEALTH PLANS, INC.; CARITEN HEALTH PLAN INC.; CHA HMO, INC.; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN;

HUMANA HEALTHAMERICA LOCAL 345 HEALTH CARE FUND, on behalf of itself and all others similarly situated,

Plaintiffs,

v.

ASTRAZENECA LP; ASTRAZENECA AB; AKTIEBOLAGET HASSLE; RANBAXY PHARMACEUTICALS INC.; RANBAXY INC.; RANBAXY LABORATORIES LTD.,

Defendants-Appellees,d

DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

Nos. 15-2006
IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

ALLIED SERVICES DIVISION WELFARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 17 HEALTH CARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; FRATERNAL ORDER OF POLICE MIAMI LODGE 20 INSURANCE TRUST FUND; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND; UNITED FOOD & COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; MICHIGAN REGIONAL COUNCIL OF CARPENTERS EMPLOYEE BENEFITS FUND; INTERNATIONAL UNION OF MACHINISTS AND AEROSPACE WORKERS DISTRICT NO. 15 HEALTH FUND; INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 595 HEALTH AND WELFARE FUND,

Plaintiffs – Appellants,

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; VALUE DRUG COMPANY; BURLINGTON DRUG COMPANY INC.;

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and others similarly situated; MEIJER, INC.; MEIJER DISTRIBUTION, INC.; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; SUPERVALU, INC.; HEB GROCERY CO. LP; GIANT EAGLE, INC.; RITE AID CORPORATION; RITE AID HEADQUARTERS CORPORATION; JCG (PJC) USA, LLC; MAXI DRUG, INC., d/b/a Brooks Pharmacy; ECKERD CORPORATION; CVS PHARMACY, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARITEN HEALTH PLAN INC.; CARITEN INSURANCE COMPANY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; CAREPLUS HEALTH PLANS, INC.; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.; CHA HMO, INC.; HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE COMPANY OF KENTUCKY; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN; HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.; HUMANA HEALTH COMPANY OF NEW YORK, INC.; HUMANA HEALTH PLAN, INC.; HUMANA HEALTH PLAN OF CALIFORNIA, INC.; HUMANA HEALTH PLAN OF OHIO, INC.; HUMANA HEALTH PLAN OF TEXAS, INC.; HUMANA HEALTH PLANS OF PUERTO RICO, INC.; HUMANA MEDICAL PLAN, INC.; HUMANA MEDICAL PLAN OF MICHIGAN, INC.; HUMANA MEDICAL PLAN OF UTAH, INC.; HUMANA REGIONAL HEALTH PLAN, INC.; HUMANA WISCONSIN HEALTH ORGANIZATION INSURANCE CORPORATION; M.D. CARE INC.; HUMANA INSURANCE COMPANY OF NEW YORK; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 345 HEALTH CARE FUND, on behalf of itself and all others similarly situated,

Plaintiffs,

v.

ASTRAZENECA LP; ASTRAZENECA AB; AKTIEBOLAGET HASSLE; RANBAXY PHARMACEUTICALS INC.; RANBAXY INC.; RANBAXY LABORATORIES LTD.,

Defendants-Appellees,

TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Nos. 15-2006
IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

WALGREEN CO.; KROGER COMPANY; SAFEWAY INCORPORATED; SUPERVALU, INC.; HEB GROCERY CO. LP; GIANT EAGLE, INC.; RITE AID CORPORATION; RITE AID HEADQUARTERS CORPORATION; JCG (PJC) USA, LLC; MAXI DRUG, INC., d/b/a BROOKS PHARMACY; ECKERD CORPORATION; CVS, INC.,

Plaintiffs – Appellants,

ALLIED SERVICES DIVISION WELFARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 17 HEALTH CARE FUND; LABORERSINTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND; FRATERNAL ORDER OF POLICE MIAMI LODGE 20 INSURANCE TRUST FUND; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND; UNITED FOOD & COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; MICHIGAN REGIONAL COUNCIL OF CARPENTERS EMPLOYEE BENEFITS FUND; INTERNATIONAL UNION OF MACHINISTS AND AEROSPACE WORKERS DISTRICT NO. 15 HEALTH FUND; INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 595 HEALTH AND WELFARE FUND; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; BURLINGTON DRUG COMPANY INC.; MEIJER DISTRIBUTION, INC.; MEIJER, INC.; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and others similarly situated; VALUE DRUG COMPANY; AMERISOURCEBERGEN DRUG CORPORATION; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 345 HEALTH CARE FUND; CARITEN INSURANCE COMPANY; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.;

HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE COMPANY OF KENTUCKY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC.; CAREPLUS HEALTH PLANS, INC.; CARITEN HEALTH PLAN INC.; CHA HMO, INC.; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN; HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.; HUMANA HEALTH COMPANY OF NEW YORK, INC.; HUMANA HEALTH PLAN, INC.; HUMANA HEALTH PLAN OF CALIFORNIA, INC.; HUMANA HEALTH PLAN OF OHIO, INC.; HUMANA HEALTH PLAN OF TEXAS, INC.; HUMANA HEALTH PLANS OF PUERTO RICO, INC.; HUMANA MEDICAL PLAN, INC.; HUMANA MEDICAL PLAN OF MICHIGAN, INC.; HUMANA MEDICAL PLAN OF UTAH, INC.; HUMANA REGIONAL HEALTH PLAN, INC.; HUMANA WISCONSIN HEALTH ORGANIZATION INSURANCE CORPORATION; M.D. CARE INC.,

Plaintiffs,

v.

ASTRAZENECA AB; ASTRAZENECA PHARMACEUTICALS LP; AKTIEBOLAGET HASSLE; RANBAXY INC.; RANBAXY LABORATORIES LTD.; RANBAXY PHARMACEUTICALS INC.,

Defendants-Appellees,

TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.,

Defendants.

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INTRODUCTION

Competition from generic drugs saves consumers hundreds of billions of dollars each year. To encourage generic competition, Congress established a mechanism that enables generic drug manufacturers to challenge patents associated with brand-name drugs. In some cases, parties have settled the resulting patent dispute with an agreement in which the brand-name drug manufacturer pays the generic drug maker to drop its patent challenge and stay off the market. In *FTC v. Actavis, Inc.*, the Supreme Court held that such "reverse payment" agreements create a "risk of significant anticompetitive effects" and must be analyzed under the antitrust rule of reason. 133 S. Ct. 2223, 2237-38 (2013). The Court explained that "the relevant anticompetitive harm" from this type of agreement is that it "prevents the risk of competition." *Id.* at 2236.

In this case, the district court concluded that the jury had found that the challenged reverse payment agreement was "unreasonably anticompetitive under a rule of reason standard." *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107, 125 (D. Mass. 2015). But the court nonetheless held that plaintiffs had failed to establish an antitrust violation. It did so because the jury "was not persuaded" that the parties would have agreed to an earlier entry date but for the reverse payment. *Id.* at 142; *see also id.* at 125 (describing the special verdict).

Based on this determination, the district court ruled that the plaintiffs had failed to establish that they suffered an injury (in the form of an overcharge for Nexium), and thus had failed to establish an antitrust violation, which foreclosed any remedy. *Id*. at 141-42. In so doing, the court mistakenly conflated two distinct analyses: the existence of an antitrust violation, which requires a general showing of harm to the competitive process, and the question of antitrust standing, which requires a specific showing by a private plaintiff that, among other things, it suffered an injury-in-fact caused by the violation.[1] *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990); *Sullivan*, 34 F.3d 1091. Appellants may be making the same mistake. *See* Consolidated Brief of Direct Purchaser and End-

[1] *See RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 14 (1st Cir. 2001); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1103 (1st Cir. 1994). The district court referred to this requirement generally as "causation," *Nexium*, 309 F.R.D. at 141, but it is clear that the court's use of the term included two parts: a showing of an injury-in-fact and an injury resulting from the anticompetitive effects found by the jury. In *Sullivan*, this Court referred to this requirement as "causation of injury-in-fact," 34 F.3d at 1103, which we shorten to "injury-in-fact" for purposes of this brief.

The injury-in-fact requirement necessary to establish antitrust standing under the Clayton Act, 15 U.S.C. § 15, may overlap with the parallel requirement necessary to show Article III standing generally. *See* 2A Phillip E. Areeda, Herbert Hovenkamp, Roger D. Blair, & Christine Piette Durrance *Antitrust Law* ¶ 335a at 77 n.7 (4th ed. 2014). Regardless, the injury-in-fact requirement is an aspect of antitrust standing, not of the substantive antitrust violation.

Payor Class Plaintiffs-Appellants, *In re: Nexium (Esomeprazole) Antitrust Litig.*, Nos. 15-2005 et al., at 72-75, 118-22 (1st Cir. Feb. 5, 2016).[2]

This distinction is especially important in the context of reverse-payment agreements, which, as the Supreme Court has explained, harm the competitive process by removing the risk of potential but uncertain competition. *Actavis*, 133 S. Ct. at 2236. That harm occurs regardless of whether a specific purchaser ultimately proves that it suffered injury-in-fact.

The Federal Trade Commission submits this brief to address the district court's legal error in its analysis of the requisite showing for a rule of reason violation. In addition, we seek to clarify that the district court, while correctly acknowledging a difference in the showings required of the FTC and private plaintiffs to obtain relief, erred in suggesting that such difference derives from 15 U.S.C. § 45(n). That provision is limited to FTC claims challenging "unfair … acts or practices," not antitrust claims challenging "unfair methods of competition."

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[2] And at least in the district court, appellees did make that mistake. *See* AstraZeneca's Opp. to Pls.' Mot. for Perm. Injunction, *In re: Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, at 2, ECF No. 1473 (D. Mass. Jan. 26, 2015) ("To establish an antitrust violation under *Actavis*, Plaintiffs had to prove that lawful generic Nexium would have entered the market prior to May 27, 2014 in the absence of the AstraZeneca-Ranbaxy settlement agreement.") Ranbaxy's Opp. to Pls.' Mot. for Perm. Injunction, *In re: Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, at 8-10, ECF No. 1475) (D. Mass. Jan. 26, 2015).

The FTC offers no views regarding the underlying facts of the case or the ultimate merits of the plaintiffs' appeal. Nonetheless, as an antitrust enforcement agency responsible for protecting the public interest, the FTC wishes to ensure that courts properly analyze antitrust violations. The district court's erroneous analysis threatens to impede federal antitrust law enforcement efforts by, in effect, requiring the government to take on additional proof requirements that, under the law, are to be borne only by private plaintiffs. Moreover, this is the first case to be tried under *FTC v. Actavis*. As various other post-*Actavis* cases proceed, the prospect that other courts might repeat the district court's error is of particular concern.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC is an independent federal agency charged with promoting a competitive marketplace and protecting consumer interests. As exemplified by *Actavis*, the Commission has primary responsibility for federal antitrust enforcement in the pharmaceutical industry. It also makes use of its broad statutory authority to gather information directly from market participants to prepare "systematic, institutional stud[ies] of real-world industries and activities."[3]

[3] Miles W. Kirkpatrick et al., Report of the American Bar Association Section of Antitrust Law Special Committee to Study the Role of the Federal Trade Commission, 58 Antitrust L.J. 43, 103 (1989); *see* 15 U.S.C. § 46(b). The Supreme Court and other courts have frequently relied on such FTC studies. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 n.21 (3d Cir. 2015).

Of particular relevance here, the Commission has issued a variety of empirical studies addressing the competitive dynamics of generic substitution for brand-name drugs,[4] and has used its law enforcement authority to challenge patent settlements of the type at issue here.[5] Pursuant to Fed. R. App. P. 29(a), the Commission respectfully submits this brief.

STATEMENT OF THE CASE

A. Generic Drugs

Before marketing a new drug, a pharmaceutical manufacturer must file a "new drug application" ("NDA") with the Food and Drug Administration and obtain FDA approval. 21 U.S.C. § 355(b). A drug approved under the NDA process is often called a "brand-name" drug.

Prior to 1984, a generic drug manufacturer had to undertake the same NDA process as a brand-name drugmaker. That requirement deterred generic entry because the NDA process is costly and can take many years to complete. To

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[4] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) ("*AG Report*"), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[5] *See, e.g.*, *Actavis*, 133 S. Ct. 2223; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (overruled in relevant part in *Actavis*); Plaintiff Federal Trade Commission's First Amended Complaint for Injunctive Relief, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, ECF No. 40 (E.D. Pa. filed Aug. 12, 2009).

address that concern, Congress enacted legislation in 1984, known informally as the Hatch-Waxman Amendments, that promotes competition while continuing to encourage innovation.[6] The Hatch-Waxman Amendments enable generic manufacturers to use a streamlined process to obtain FDA approval for generic versions of previously introduced brand-name drugs. Specifically, the Amendments allow generic manufacturers to file Abbreviated New Drug Applications ("ANDAs") that rely on brand manufacturers' existing safety and efficacy studies, reducing the costs of generic drug development and expediting the FDA approval process. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), (iv). The Amendments also establish procedures that apply when a company seeks FDA approval to market a generic product before expiration of patents claimed to cover the counterpart brand-name drug. In such cases, the generic applicant must certify in its ANDA that the patent in question is invalid or not infringed by the generic product (or both). This is known as a "paragraph-IV certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see generally Caraco*, 132 S. Ct. at 1677-78.

To expedite resolution of patent disputes arising from ANDAs, the Hatch-Waxman Amendments encourage the brand-name manufacturer to respond to a paragraph-IV certification by promptly suing the generic applicant for patent

[6] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (1984) (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code).

infringement. Such a suit triggers an automatic stay of FDA approval of the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). Correspondingly, the Hatch-Waxman Amendments encourage patent challenges by providing the first-filer of an ANDA containing a paragraph-IV certification with a 180-day exclusivity period that protects the first-filer from competition from other ANDA filers. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 133 S. Ct. at 2229 (internal quotation marks omitted).

B. Proceedings Below

AstraZeneca is the brand-name manufacturer of the blockbuster heartburn drug Nexium. Ranbaxy and others filed ANDAs, along with paragraph-IV certifications, to introduce generic competition to Nexium. To protect its Nexium franchise, AstraZeneca allegedly made reverse payments to three generic manufacturers, including first-filer Ranbaxy, to induce them to abandon their patent challenges and stay out of the market until May 2014.

After a six-week trial, the jury returned a special verdict, which the district court found represented a finding that the challenged settlement with Ranbaxy was "unreasonably anticompetitive":

> By checking "yes" to Questions 1, 2, and 3, the jury indicated that they were convinced that the AstraZeneca-Ranbaxy Settlement Agreement was unreasonably anticompetitive under a rule of reason standard. But by checking "no" at Question 4, the jury indicated they

> could not conclude that Ranbaxy would have agreed to an earlier launch date but for their reverse payment settlement agreement.

Nexium, 309 F.R.D. at 125.

The plaintiffs then filed separate motions for an injunction and a new trial. In July 2015, the district court denied both motions. *Id.* at 142-43. The court recognized that the jury had found that the challenged agreement was "unreasonably anticompetitive" under the "rule of reason." *Id.* at 125. But it nonetheless determined that the plaintiffs had failed to show "the prerequisite antitrust violation" required to obtain an injunction because they had not proved a "causal link between this suspicious agreement and the overcharge harms the Plaintiffs allege." *Id.* at 141-42. In the court's words, "[t]here may have been intent to violate the antitrust laws, and certainly anticompetitive 'effect' from the AstraZeneca-Ranbaxy Settlement Agreement, but the jury could not establish that this *materially caused the overcharges* the Plaintiffs allegedly had suffered as consumers of Nexium." *Id.* at 125 (emphasis added). This showing, the district court held, was a necessary part of proving an antitrust violation. *Id.* at 142.

ARGUMENT

I. IN AN ANTITRUST CASE, VIOLATION AND INJURY-IN-FACT ARE DISTINCT ANALYSES

As the Supreme Court has made clear, "proof of a[n antitrust] violation and of antitrust injury are distinct matters that must be shown independently." *Atl.*

Richfield Co., 495 U.S. at 344 (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 334.2c, at 330 (1989 Supp.)). A burden common to all antitrust plaintiffs, public and private, is to establish that the antitrust laws—whether under the Sherman Act or, in the case of the FTC, the FTC Act—have been violated.[7] To do so, the plaintiff must demonstrate that the challenged restraint tends to suppress, rather than promote, competition. Generally, this requires the plaintiff to establish in the context of a rule-of-reason case that the conduct has an "anticompetitive effect," also known as harm to competition.[8] *See Actavis*, 133 S. Ct. at 2237.

A government plaintiff that demonstrates an antitrust violation is generally entitled to appropriate relief, whereas a private plaintiff must make an additional showing that it suffered an injury-in-fact (actual or threatened) caused by the anticompetitive conduct in order to prevail. *See Cal. v. Am. Stores Co.*, 495 U.S. 271, 295-96 (1990) (contrasting the Government's entitlement to relief upon proving an antitrust violation with the requirement that private plaintiffs show "threatened harm or damages").

This difference in standards is due to the statutory structure of the antitrust laws. The federal government enforces the substantive antitrust laws directly. *See*,

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[7] *See FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (noting that "unfair methods of competition" under the FTC Act encompasses all practices that violate the Sherman Act and the other antitrust laws).

[8] Part II below addresses the relevant harm to competition in reverse-payment cases.

e.g., 15 U.S.C. § 45(a)(2). In contrast, private plaintiffs derive their authority to bring suit from Section 4 or 16 of the Clayton Act, and must satisfy the additional burdens imposed by those provisions. *See* 15 U.S.C. §§ 15, 26. This distinction is rooted in public policy. The interest of private plaintiffs is to remediate an injury they have suffered or may suffer. The interest of the government is to "prevent and restrain" violations of the antitrust laws along with the attendant social costs such violations can cause. *See* 2 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 303, at 62 (4th ed. 2014) (quoting 15 U.S.C. § 25).

A. Showing Injury-in-Fact Is Not Necessary to Establish Anticompetitive Effect

The Supreme Court and this Court have long recognized that a showing of injury-in-fact is not necessary to establish that a challenged agreement has an anticompetitive effect and thus violates the antitrust laws. Instead, the analysis focuses on whether an agreement "promotes competition or … suppresses competition." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 691 (1978). Of course, anticompetitive effects *can* be established by demonstrating an actual increase in prices or decrease in output, because those effects reveal the underlying anticompetitive character of the agreement. *See Sullivan*, 34 F.3d at 1097. But even where an actual price increase is not proven, antitrust law precludes "actions that harm the competitive process." *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.); *see also Town*

of Concord, Mass. v. Boston Edison Co., 915 F.2d 17, 21-22 (1st Cir. 1990) (Breyer, J.) (holding that an agreement has anticompetitive effects when it "obstructs the achievement of competition's basic goals—lower prices, better products, and more efficient production methods").

Thus, the Supreme Court has condemned restraints because they "impede[d] the ordinary give and take of the marketplace," *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 692, or were "likely enough to disrupt the proper functioning of the price-setting mechanism of the market … even absent proof that [they] resulted in higher prices." *Ind. Fed'n of Dentists*, 476 U.S. at 461-62. Rather than focusing on whether a challenged agreement has injured a specific party, the Court has focused on "the principal tendency of a restriction" to interfere with competition. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999); *see also Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) (to determine whether restraint violates the rule of reason, courts should examine "the nature of the restraint and its effect, actual or probable").

The *en banc* D.C. Circuit decision in the *Microsoft* monopolization case illustrates this principle, holding that proving an antitrust violation does not require showing that the conduct at issue caused specific harm that would not have occurred in a reconstructed but-for world. The D.C. Circuit explained that the antitrust violation analysis does not "turn on a plaintiff's ability or inability to

reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct" because "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical … development in a world absent the defendant's exclusionary conduct." *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (citing 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651c, at 78 (1996)). Instead, to establish a violation (as opposed to injury-in-fact), a plaintiff need only show that "as a general matter the [defendant's conduct] is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power," viewed "at the time [the defendant] engaged in the anticompetitive conduct." *Id.* As the court explained, "to some degree, 'the defendant is made to suffer the uncertain consequences of its own undesirable conduct.'" *Id.* (quoting 3 Areeda & Hovenkamp, *Antitrust Law* ¶ 651c, at 78).

B. To Obtain Relief, Private Plaintiffs Must Establish Both an Antitrust Violation and Injury-in-Fact

Although proof of injury-in-fact is not necessary to establish an antitrust violation, it is generally necessary for a private plaintiff to prove injury-in-fact in order to obtain relief. The Supreme Court and this Court have explained that to establish antitrust standing (which includes injury-in-fact) a private plaintiff must demonstrate a causal connection between the antitrust violation and an injury that it actually sustained. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S.

477, 486, 489 (1977) (explaining injury requirement and noting that antitrust laws include "statutory prohibition[s] against acts that have a potential to cause certain harms" and statutory authority for "damages action[s] intended to remedy these harms"); *RSA Media, Inc.*, 260 F.3d at 14. To satisfy these requirements, private plaintiffs seeking monetary relief must show actual damages, while those seeking only an injunction must show "threatened loss or damage." *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 113 (1986) (to access the "complementary remedies for a single set of injuries" provided by the Clayton Act—*i.e.*, monetary relief and injunctive relief—a private plaintiff must demonstrate damages or the "threatened loss or damage of the type the antitrust laws were designed to prevent") (internal quotation marks omitted); *see also* 2A Areeda et al., *Antitrust Law* ¶ 335b, at 78 ("[T]he plaintiff must show that this threatened injury would be caused by the alleged antitrust violation and that this threatened injury would constitute 'antitrust injury' if it actually occurred.").[9] This showing of injury-in-fact is analytically separate from—and required in addition to—the showing of

[9] Plaintiffs seeking damages must also quantify the amount of damages. *See Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 543-44 (1983); *Gallant v. BOC Grp. Inc.*, 886 F. Supp. 202, 209 (D. Mass. 1995).

anticompetitive effects necessary to establish the underlying antitrust violation.[10] Indeed, if it were otherwise, the injury-in-fact inquiry would itself be largely redundant: Establishing an actual price increase would simultaneously show an anticompetitive effect and an overcharge injury.

In holding that injury-in-fact was a necessary element of the underlying violation, the district court relied primarily on an erroneous interpretation of *Sullivan v. National Football League*. *See Nexium*, 309 F.R.D. at 140-41.[11] This Court's analysis in *Sullivan*, however, actually illustrates the distinction between antitrust violations and injury-in-fact. *Sullivan* concerned an antitrust challenge to an NFL rule barring public ownership of football teams. The former owner of the New England Patriots claimed that this restriction on ownership eligibility violated

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[10] *Atlantic Richfield*, 495 U.S. at 344 ("proof of a[n antitrust] violation and of antitrust injury are distinct matters that must be shown independently") (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 334.2c, at 330 (1989 Supp.)); *see Volmar Distribs., Inc. v. N.Y. Post Co.*, 825 F. Supp. 1153, 1161 n.5 (S.D.N.Y. 1993) (*Atlantic Richfield* is "clear … that the antitrust injury requirement exists separate and apart from the substantive requirements of the Sherman Act.").

[11] The other cases cited by the district court are similarly consistent with the well-established distinction between violation and injury. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969) (court of appeals holding that "failure to prove the fact of injury barred injunctive relief" was "unsound"); *Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 169 (3d Cir. 1984) ("[I]f plaintiff fails to establish a causal relationship between its financial difficulties and defendants' *antitrust violations*, its case must fail." (emphasis added)); *Foremost-McKesson, Inc. v. Instrumentation Lab., Inc.*, 527 F.2d 417, 418 (5th Cir. 1976) (citing *Zenith Radio* and noting that plaintiff must demonstrate that "the illegality" caused it injury).

the Sherman Act because it prevented him from selling his team to the highest bidder.

This Court began by analyzing whether this type of restraint was anticompetitive. *Sullivan*, 34 F.3d at 1096-97. It noted that anticompetitive effects are "*usually* measured by a reduction in output and an increase in prices in the relevant market." *Id.* at 1097. But it explained that "an action [also] harms the competitive process 'when it obstructs the achievement of competition's basic goals—lower prices, better products, and more efficient production methods.'" *Id.* (quoting *Town of Concord*, 915 F.2d at 22). Despite no evidence of higher prices and thin evidence of any competition for the sale of NFL teams, the Court nevertheless concluded that the NFL rule harmed competition because the agreement excluded *potential* purchasers, thereby "making the relevant market unresponsive to consumer preference." *Id.* at 1101.

The Court then separately examined whether Sullivan had "suffered damages from an antitrust violation and [whether] there is a causal connection between the illegal practice and the injury." *Id.* at 1103. It found sufficient evidence that, in the absence of the NFL's rule, Sullivan could have sold the team to the public for substantially more money and therefore had suffered an injury. *Id.* at 1106. *See also Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of R.I.*, 883 F.2d 1101, 1105-06 (1st Cir. 1989) (reviewing decision

finding a violation of Section 2 of the Sherman Act, but awarding no monetary or injunctive relief, and concluding that on appeal the court must "deal first with the merits of the jury's finding of antitrust liability" before deciding whether an injunction was appropriate). Consistent with long-established Supreme Court precedent, this Court's *Sullivan* opinion treated antitrust violation and injury-in-fact as distinct analyses.[12]

II. UNDER *ACTAVIS*, THE ANTICOMPETITIVE EFFECT OF A REVERSE PAYMENT IS THAT IT PREVENTS THE RISK OF COMPETITION

The distinction between anticompetitive effect and injury-in-fact is particularly important in the context of a reverse-payment agreement. Under *Actavis*, the "relevant anticompetitive harm" from a large and unjustified reverse payment is that it "prevent[s] the *risk* of competition." 133 S. Ct. at 2236 (emphasis added); *see also King Drug Co. of Florence*, 791 F.3d at 404, 412; *In re*

[12] Other courts have likewise recognized antitrust violations despite plaintiffs' inability to show injury. For example, in a series of decisions, the Seventh Circuit affirmed a jury's antitrust liability verdict and the district court's resulting injunction, *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406 (7th Cir. 1995), while rejecting plaintiffs' damages claims, *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 152 F.3d 588 (7th Cir. 1998). In *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 695-99 (D. Md. 2000), a district court found sufficient evidence that the defendant's exclusive supply agreement violated sections 1 and 2 of the Sherman Act, but found insufficient evidence of both injury and causation because intervening events—including FDA action—would have prevented the plaintiff from entering the market regardless of the defendants' unlawful conduct. The court made clear that the causation and injury requirements were "[i]n addition to proving violation of the antitrust laws." *Id.* at 696.

Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 755 (E.D. Pa. 2014). By holding that the plaintiffs could not establish an antitrust violation without showing that the reverse payment caused an actual overcharge, the district court misconstrued both the established antitrust principles described above and the teaching of *Actavis* itself.

In *Actavis*, the Supreme Court explained that a large reverse payment can "induce the generic challenger to abandon its claim with a share of [the] monopoly profits that would otherwise be lost in the competitive market." 133 S. Ct. at 2235; *see also id.* at 2236 (noting that a firm without market power is unlikely "to pay large sums to induce others to stay out of its market" (internal quotation marks omitted)). The likelihood that a reverse payment will have this effect depends upon its size, its independence from services received, and the lack of any other convincing justification. *Id.* at 2237. The Court explained further that if the basic reason for the payment is "a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.*

Appellants contend that "[i]n reverse payment cases, the anticompetitive effect—maintain[ing] supracompetitive prices—is accomplished by delaying generic competition," and, indeed, that "[n]o one … [has] identified any possible anticompetitive effects other than delay." Consolidated Br. of Direct Purchaser and

End-Payor Class Plaintiffs-Appellants at 118-19 (quotation mark omitted), 121. But the *Actavis* opinion never uses the word "delay" to describe the anticompetitive harm of a reverse payment. To the contrary, it makes clear that a reverse payment can violate the antitrust laws if it induces the generic to abandon its patent challenge and stay out of the market regardless of whether the generic would actually have otherwise entered the market sooner than permitted by the agreement. *Id.* at 2235; *see also id.* at 2231 (noting that the patent "may or may not be valid, and may or may not be infringed"); *id.* at 2234 ("The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.").

Indeed, the Court recognized that paying a generic competitor to drop its patent challenge is anticompetitive even if that challenge were likely to fail:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.

Id. at 2236. The anticompetitive effect of an unlawful reverse payment therefore occurs at the moment the agreement is entered. The antitrust violation is distinct from the actual injury—such as an overcharge to a specific plaintiff—it may

subsequently cause. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003); *see also Polk Bros., Inc. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985) ("A court must ask whether an agreement promoted enterprise and productivity at the time it was adopted."); *Microbix Biosystems*, 172 F. Supp. 2d at 694 ("[A]nti-competitive conduct is determined as of the time the conduct occurred, not thereafter.").

As the California Supreme Court further observed in a reverse-payment case brought under state law, "[e]very case involves a comparison of a challenged agreement against a prediction about—a probabilistic assessment of—the expected competition that would have arisen in its absence. Every restraint of trade condemned for suppressing entry involves uncertainties about the extent to which competition would have come to pass." *In re Cipro Cases I & II*, 61 Cal. 4th 116, 150 (2015) (applying parallel state-law provision). But "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." *Id.* (quoting 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 220 (3d ed. 2012)); *see also Sullivan*, 34 F.3d at 1100 (in assessing harm to competition, "evidence of actual, present competition is not necessary as long as evidence shows the potential for competition exists"); *Microsoft Corp.*, 253 F.3d at 79.

Accordingly, lower courts applying *Actavis* have understood that they do not need to determine what would have happened in the absence of a reverse payment to establish that it violates the antitrust laws. The Third Circuit held that *Actavis* does not "require allegations that defendants could in fact have reached another, more competitive settlement" because "the anticompetitive harm is not *certain* consumer loss through higher prices, but rather the patentee's avoidance of the risk of competition." *King Drug Co. of Florence*, 791 F.3d at 410. Similarly, another court observed that "[t]he anticompetitive harm is not that the patent surely would have been invalidated if not for the settlement, and that a generic therefore surely would have entered the market sooner," but "that the reverse-payment settlement seeks to prevent the risk of competition." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (internal quotation marks omitted). And the California Supreme Court in the *Cipro* case determined that a reverse payment could be anticompetitive even though the brand's patent had subsequently been upheld. 61 Cal. 4th at 159 ("Likewise, consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid.").

III. THE DISTINCTION BETWEEN VIOLATION AND INJURY-IN-FACT HAS IMPORTANT PUBLIC POLICY IMPLICATIONS

As the foregoing discussion illustrates, long-established antitrust principles (and the rationale of the *Actavis* decision) contradict the district court's conclusion

that showing an injury-in-fact is necessary to prove an antitrust violation. This error is not merely academic; it has significant implications for government antitrust enforcement. Because the FTC, along with the Department of Justice, enforces the substantive antitrust laws directly, it need not show a specific injury as a private plaintiff would. *See California v. Am. Stores Co.*, 495 U.S. at 295-96 ("In a Government case the proof of the violation of law may itself establish sufficient public injury to warrant relief."); 2 Areeda & Hovenkamp, *Antitrust Law* ¶ 303, at 61. It can "sue anyone who violates the antitrust laws" and obtain an injunction to block an anticompetitive agreement or conduct. *Zoellner v. St. Luke's Reg'l Med. Ctr., Ltd.*, 937 F. Supp. 2d 1261, 1266 (D. Id. 2013) (citing *Glen Holly Entm't Inc. v. Tektronix Inc.*, 352 F.3d 367, 371 (9th Cir. 2003)).

The distinction between public and private suits is intentional, reflecting the strong public law enforcement interest in allowing the government to redress conduct when "the reasonably anticipated consequence" is a "statutorily prohibited injury." 2 Areeda & Hovenkamp, *Antitrust Law* ¶ 303, at 61. The leading antitrust treatise offers a useful analogy:

> [T]he state can interdict drunken driving even when it has caused no injury at all in the particular case. Its power results from the fact that drunken driving is known to have harmful consequences and it is less socially costly to arrest the driver before rather than after those consequences occur. The private plaintiff's interest, by contrast, is purely remedial.

Id. at 62. The public interest in governmental policing of conduct that threatens harm to the competitive process upon which the U.S. economy depends is no less weighty. *See United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972) ("Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise.").

The district court did recognize that the FTC, as a government enforcer, faces requirements that differ from those of private plaintiffs. *Nexium*, 309 F.R.D. at 141. The difference, as discussed above, derives from the FTC's authority to enforce the antitrust laws. *See* 15 U.S.C. § 45(a)(2). The district court, however, erroneously attributed this distinction to Section 5(n) of the FTC Act (15 U.S.C. § 45(n)). That section governs the Commission's authority over "unfair … acts or practices," not its distinct authority to stop "unfair methods of competition." *See* H.R. Rep. No. 103-617 at 12 (1994) (Conf. Rep.), *as reprinted in* 1994 U.S.C.C.A.N. 1795, 1798 (noting that 15 U.S.C. § 45(n) codifies the Commission's Policy Statement on Unfairness (appended to *Int'l Harvester Co.*, 104 F.T.C. 949, 1070, 1072 (1984)), which specifically does not apply to "unfair methods of competition"). Accordingly, it is irrelevant to a case the FTC would bring under *Actavis* because the *Actavis* case alleges only "unfair methods of competition."

Moreover, the court's reliance on 15 U.S.C. § 45(n) incorrectly suggests that the FTC bears the burden of showing in an antitrust case that "a defendant's action is likely to cause injury." *Nexium*, 309 F.R.D. at 141 (quoting Ian Simmons, Kenneth R. O'Rourke & Scott Schaeffer, *Viewing FTC v. Actavis Through the Lens of Clayton Act Section 4,* Antitrust, Vol. 28, No. 1 (2013)). But, as discussed above, the FTC bears no burden to show an injury-in-fact (either actual or likely) from anticompetitive conduct.

CONCLUSION

Whatever outcome it reaches on the merits, this Court should clarify that showing an antitrust violation does not require proof of injury-in-fact.

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