Nos. 14-2071, 15-1250

In the United States Court of Appeals for the First Circuit

No. 14-2071

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

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

Plaintiffs – Appellants

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTHCARE & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS INTERNATIONAL UNION OF NORTH

AMERICA LOCAL 35 HEALTH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; WALGREEN CO.; THE KROGER CO.; SAFEWAY INC.; ALBERTSON'S, LLC; HEB GROCERY COMPANY L. P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORTATORIES IRELAND LIMITED; WARNER CHILCOTT COMPANY; ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.

Defendants – Appellees

No. 15-1250

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; END PAYOR PLAINTIFFS; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly

situated; LABORERS' INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; A. F. OF L. BUILDING TRADES WELFARE PLAN; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND,
individually and on behalf of all others similarly situated

Plaintiffs – Appellants

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; ALBERTSON'S, LLC; HEB GROCERY COMPANY. L.P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.

Defendants – Appellees

On Appeal from the United States District Court for the District of Rhode Island

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BRIEF FOR *AMICI CURIAE* CONSUMER ACTION, AARP, UNITED STATES PUBLIC INTEREST AND RESEARCH GROUP, PUBLIC CITIZEN, FAMILIES USA, AND CONSUMERS UNION IN SUPPORT OF PLAINTIFFS-APPELLANTS IN FAVOR OF REVERSAL

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CORPORATE DISCLOSURE STATEMENT

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* Consumer Action states that it is a nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* AARP states the following: the Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) (1993) of the Internal Revenue Code and is exempt from income tax. AARP is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code 1951. Other legal entities related to AARP include AARP Foundation, AARP Services, Inc., Legal Counsel for the Elderly, and AARP Insurance Plan, also known as the AARP Health Trust. AARP has no parent corporation, nor has it issued shares or securities.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* United States Public Interest Research Group ("US PIRG") states that it is nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* Public Citizen states that it is nonprofit, non-stock corporation. It has no parent

corporation and there is no corporation that has an ownership interest of any kind in it.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* Families USA states that it is nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* Consumers Union states that it is nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

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INTEREST OF *AMICI CURIAE*[1]

In accordance with Fed. R. App. P. 29(a), *amici curiae* state that all parties have consented to the filing of this *amicus* brief.

Consumer Action is a national non-profit organization that has worked to advance consumer literacy and protect consumer rights in many areas for over forty years. The organization achieves its mission through several channels, from direct consumer education to issue-focused advocacy. Consumer Action is particularly concerned with ever-growing healthcare costs including rising costs within the pharmaceutical industry.

AARP is a nonprofit, nonpartisan organization with a membership that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as health care, employment and income security, retirement planning, affordable utilities and protection from financial abuse. Since its founding in 1958, AARP has advocated for access to affordable health care, including affordable prescription medications, and for controlling costs without compromising quality. Access to affordable drugs is particularly important to older adults because they have the highest rates

[1] Pursuant to FRAP 29(c)(5), *amici curiae* state that no party's counsel has authored this brief either in whole or in part; that no party or its counsel contributed money that was intended to fund preparing or submitting the brief; and that no person other than these *amici curiae* and their counsel have contributed money intended to fund preparing or submitting the brief.

of prescription drug use due to their higher rates of chronic and serious health conditions.

U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers, through public outreach to advocate for policies and strategies to bring down the high cost of healthcare and prescription drugs. U.S. PIRG's mission is to deliver result-oriented public interest activism that protects consumers, encourages a fair, sustainable economy, and fosters responsive, democratic government. U.S. PIRG regularly advocates before state and federal regulators and legislators on both consumer protection and competition policy issues in the payment system marketplace. U.S. PIRG has been directly involved in prescription drug policy and has been an *amici* in pay-for-delay cases.

Founded in 1971, Public Citizen, Inc. is a non-profit consumer advocacy organization with more than 300,000 members and supporters nationwide. Public Citizen advocates before Congress, administrative agencies, and the courts on a wide range of issues, and works for enactment and enforcement of laws protecting consumers, workers, and the public. Public Citizen has a longstanding interest in protecting consumers' ability to obtain affordable prescription drugs. Accordingly, Public Citizen has advocated enforcement of the antitrust laws against brand-name drug manufacturers that seek to exclude generic competition, including by filing an

amicus brief on behalf of former U.S. Representative Henry Waxman in *Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), in which the United States Supreme Court recognized that agreements in which brand-name manufacturers pay generic competitors to delay entry into the market are subject to antitrust scrutiny.

Families USA is a national nonprofit, nonpartisan organization dedicated to achieving high-quality, affordable health care for all Americans. Working at the national level with local and state consumer organizations, 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.

Consumers Union is the policy and advocacy arm of Consumer Reports, an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. Consumers Union has long advocated for policies that promote access to safe, effective and affordable medications, including antitrust enforcement against anticompetitive practices that delay market entry by generic alternatives.

BACKGROUND

Each year, consumers spend ever-increasing amounts on prescription drugs. To combat the high prices of brand-name pharmaceuticals, consumers rely on

access to generic drugs—pharmaceutical substitutes that have the same therapeutic benefits as their brand-name bioequivalents. From 2004 through 2013, generic drugs saved Americans nearly $1.5 trillion, with $239 billion in savings in 2013 alone. GENERIC PHARMACEUTICAL ASS'N, *Generic Drug Savings in the U.S.* 1 (6th ed. 2014), *available at* http://goo.gl/6QUXLK. The savings are largely attributable to the lower cost of generic drugs. Once multiple generic drugs are available to compete with a brand, the cost of a generic drug is typically 80 to 85 percent less than its brand-name equivalent. *See* Food and Drug Administration, *Facts About Generic Drugs* 2, *available at* http://goo.gl/9I0zJg. In recent years, prices for brand-name drugs have continued to climb while prices for their generic counterparts decrease. *See* Stephen Schondelmeyer and Leigh Purvis, *Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2013* (2015), *available at*: http://goo.gl/Cyoc8n *(*finding that "retail prices for 280 generic prescription drugs widely used by Medicare beneficiaries fell by an average of 4.0 percent in 2013, [while] the retail prices for 227 brand name prescription drugs most widely used by Medicare beneficiaries increased by an average of 12.9 percent").

The increasing availability of generic drugs to compete with their brand-name counterparts is due, in part, to a decades-old effort by Congress. Passed in 1984, the Hatch-Waxman Act encourages quick and effective entry of generic

pharmaceuticals into the marketplace once patents on brand-name drugs expire or are found to be invalid. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified as amended at* 21 U.S.C. § 355 (1994). Hatch-Waxman creates "a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term." *Novo Nordisk A/S, et al. v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir., Apr. 14, 2010) (*citing Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002), *rev'd*, 132 S. Ct. 1670 (2012).

As part of this balance, Hatch-Waxman prescribes the process by which generic pharmaceuticals may enter the market and sets forth procedures to resolve patent disputes between branded and generic drug manufacturers. In particular, the Act enables generic companies to file an Abbreviated New Drug Application ("ANDA") that includes a certification that the brand's patent is either invalid or has expired. The Act also allows the brand-name manufacturer to file an infringement lawsuit to contest an assertion of invalidity. U.S.C. §§ 355(j)(2)(A)(vii)(IV), 355(j)(5)(B)(iii). To incentivize generic manufacturers to challenge potentially faulty patents, Hatch-Waxman grants a 180-day period of exclusivity to the first generic manufacturer to file an ANDA, a period during

which no other *generic manufacturer* may sell that drug product. *Id.* at § 355(j)(5)(B)(iv). For the first-filer generic manufacturer, this 180-day period of exclusivity can be worth hundreds of millions of dollars. *See* Shashank Upadhye, *There's A Hole In My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved And Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1301, 1318 (2014) (assuming a hypothetical drug product is worth $1 billion per year, 180-day exclusivity period of the hypothetical generic is valued at $320 million).

Unfortunately, the billions of dollars of potential earnings at stake in patent litigation has led to anticompetitive conduct within the pharmaceutical industry. When a generic company seeks to challenge a brand-name manufacturer's patent, brand-name and generic manufacturers frequently enter into anticompetitive patent litigation settlements, commonly known as "pay-for-delay" settlements, under which generic manufacturers agree to drop their patent challenges and defer entry into the market until closer to patent expiration, in return for a share of the brand-name manufacturer's monopoly profits. *See generally* FTC, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), *available at* http://goo.gl/OcUsxq. A pay-for-delay settlement has the potential to terminate a genuine patent challenge that might otherwise have opened the marketplace to competition from generic drugs; terminating the challenge allows the brand-name

manufacturer to unnaturally prolong its monopoly on sale of the drug product at the higher brand-name price.

In a pay-for-delay agreement, the brand-name manufacturer can offer many forms of consideration to the generic manufacturer to induce it to delay entry into the marketplace. *See* FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), *available at* http://goo.gl/R6gpZb [hereinafter *Authorized Generics Report*]. Often, the consideration has been a simple cash payment. However, as the Federal Trade Commission ("FTC"), the courts, and the public have heightened their scrutiny of pay-for-delay agreements,[2] cash has become less favored as the form of "payment" in these kinds of settlements. In 2013, the FTC found that of 29 potential pay-for-delay settlements involving drugs with approximately $4.3 billion in annual sales, only 14 involved monetary compensation. *See* FTC, *Overview of Agreements Filed in FY 2013* (2014), *available at* https://goo.gl/klWjw8.

Other settlements highlighted by the FTC involved a range of valuable consideration paid by brand-name to generic manufacturers. The compensation

[2] *See* Press Release, FTC, FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics (May 28, 2015), *available at* https://goo.gl/AjtTXx (FTC settled with Cephalon after FTC challenged over $300 in monetary payments paid to delay generic competition with the Cephalon drug Provigil).

offered by brand-name to generic manufacturers in these cases included: (1) "side deals" involving production, marketing, or distribution rights to other products, (2) acceleration clauses ensuring that the settling generic company would be the first generic entrant regardless of other generic companies' attempts to invalidate a patent, and (3) no-authorized-generic agreements ("no-AG agreements") wherein the brand-name manufacturer agrees not to market its own generic version of the drug to compete directly with the first-filer during the 180 days of exclusivity.[3] *Id.*

In 2013, the Supreme Court issued its landmark decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013). In *Actavis*, the Court made clear that pay-for-delay schemes involving brand-name and generic drug manufacturers are subject to rule of reason antitrust scrutiny requiring a court to consider multiple factors concerning the pay-for-delay agreement, including "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 2237. Nowhere in *Actavis* did the Supreme Court state that the "payment" at issue *must* be in the form of cash or other liquid monetary assets to be scrutinized under the antitrust laws. *Id.*

[3] *Amici curiae* will further discuss no-AG agreements, acceleration clauses, and side-deals in Section III.

SUMMARY OF THE ARGUMENT

In this case, the district court misconstrued the *Actavis* decision as applying "solely to *monetary* settlements." *In re Loestrin 24 FE Antitrust Litigation*, No. 13-2472, slip op. at 26 (D. R.I. Sept. 4, 2014) [hereinafter Loestrin Opinion]. Limiting *Actavis* in that manner would empower brand manufacturers to continue to engage in anticompetitive pay-for-delay settlements by providing the generic manufacturers with equally valuable consideration other than monetary payments to refrain from competition. Here, while there was no monetary payment, Warner Chilcott Company, LLC ("Warner"), the brand-name manufacturer of Loestrin 24 Fe ("Loestrin 24"), persuaded the generic manufacturers, Watson Pharmaceuticals, Inc., ("Watson") and Lupin Pharmaceuticals, Inc. ("Lupin"), to end their patent litigation against Warner and entered into "Exclusion Payment Agreements." As an inducement, Warner offered valuable consideration to Watson and Lupin that included: (1) a "no-authorized," or "no-AG" agreement; (2) an acceleration clause; and (3) side deals. *See* Loestrin Opinion at 10.

This valuable consideration goes beyond anything that could have been obtained by the generic manufacturers had they won the patent case. Absent the Exclusion Payment Agreements, consumers would have gained access to generic Loestrin 24 soon after September 2009, when Watson received final FDA approval for its generic. *See* Loestrin Opinion at 12. Instead, both generic companies

received non-monetary consideration worth millions of dollars and Warner continued to reap monopoly profits on Loestrin 24—totaling $1.75 billion from 2006-2012. *Id.*

Pay-for-delay agreements, whether for cash or some in-kind payment, subvert marketplace competition and have a negative impact on consumers. First, pay-for-delay schemes directly harm consumers because these agreements deny access to more affordable generic alternatives. Second, as demonstrated in other court decisions, a "payment" that can be considered anti-competitive under *Actavis* includes more than monetary payment. Finally, the specific types of valuable consideration offered by Warner to Watson and Lupin serve to prevent generic market entry and harm consumers by stifling competition.

ARGUMENT

I. Consumers Are Harmed By Anticompetitive Pay-For-Delay Schemes.

Anticompetitive pay-for-delay schemes, such as the Warner agreements at issue in this case, cause significant and unnecessary delays in consumer access to less costly generic medications. In 2014, Americans spent $374 billion on prescription medications, a 13 percent increase from the previous year. Bill Berkot, *U.S. Prescription Drug Spending Rose 13 Percent in 2014: IMS Report*, REUTERS (Apr. 14, 2015 12:01 AM), http://goo.gl/0kzYli. Although pharmaceutical cost increases may be due to a number of factors, the added

expense of brand-name medications contributes significantly to the high cost of prescription drugs. *See* Jordan Rau, *Brand-Name Medicines Dominate Medicare's $103 Billion Drug Bill*, NPR.COM (May 1, 2015, 9:30 AM), http://goo.gl/biS04u (finding that brand-name drugs are the "among the most expensive" for the federal government's Medicare prescription benefit "costing more than $1 billion each in 2013"). The high cost of brand-name drugs can create significant financial burdens for consumers. *See* Bill Walsh, *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*, AARP at 3 (2009), *available at* http://goo.gl/9w3Q0T (finding that high drug costs can cause consumer to "forgo basic living expenses").

Higher costs associated with brand-name pharmaceuticals, in some cases, cause consumers to forgo treatment altogether, leading to other health-related problems. In 2012, *Consumer Reports* found that 18 percent of consumers *with* prescription drug coverage declined to fill their medications due to cost, while 45 percent of consumers *without* prescription drug coverage did not fill a prescription due to cost. *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point*, Consumer Reports (2012), available at http://goo.gl/idey3l. Forgoing a prescribed drug regimen can have disastrous health implications for consumers.

In fact, 30 to 50 percent of all treatment failures are likely attributable to non-adherence to medications. Thomas H. Wroth and Donald E. Pathman,

Primary Medication Adherence in a Rural Population: The Role of the Patient-Physician Relationship and Satisfaction of Care, 19 J. AM. BOARD FAM. MED. 478, 478 (2006). Approximately 125,000 patients die each year as a result of not adhering to medications. *Medication Adherence—Improving Health Outcomes*, AMER. COLL. PREV. MED. at 6 (2011), *available at* http://goo.gl/Y0hGk8. Moreover, failed prescription adherence has a direct cost to the American health care system: an estimated $100 to $289 billion a year is spent on re-hospitalizations and physician visits that would not otherwise be needed. Centers for Disease Control and Prevention, *Medication Adherence* (2013), *available at* http://goo.gl/PJFqkw.

In this case, Warner's anticompetitive conduct delayed consumer access to less costly generic medications for almost five years—a significant length of time. Warner's valuable non-monetary consideration offered to both Watson and Lupin prevented consumer access to less costly medications. The settlement offends the public policy intent of Hatch Waxman, and wrongfully prolonged the patent due to an anticompetitive settlement, which resulted in consumers unnecessarily paying hundreds of millions more for brand-name Loestrin 24 than they otherwise should have.

II. Limiting The *Actavis* Decision To Monetary Payments Contradicts The Supreme Court's Reasoning In Holding That Pay-For-Delay Settlements Are Subject To Rigorous Antitrust Scrutiny Because Of Their Anticompetitive Effects.

The decision below, by restricting the Supreme Court's decision in *Actavis* to purely monetary settlements, contradicts the Court's holding that some pay-for-delay agreements are anticompetitive. The reasons for the Supreme Court's holding apply regardless of whether the "payment" that stifles competition is in cash. "[I]f the if the settlement involves the patent holder's sacrifice of something with greater value to it than its own prospective litigation costs, it is reasonable to presume that the patent holder is paying for some protection from competition." Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, __ RUTGERS L. REV. __ (forthcoming 2015), *available at* http://goo.gl/EUhm2E.

In laying the groundwork for future court decisions analyzing patent settlement agreements under federal antitrust law, the Supreme Court in *Actavis* set out an open-ended framework to ensure that antitrust scrutiny could be appropriately applied beyond the facts of the *Actavis* case. Thus, the Court required that pay-for-delay settlements be individually scrutinized under a "rule of reason" analysis. *Actavis*, 133 S. Ct. at 2237. Along with considering any potential procompetitive justifications of a settlement, courts must consider "its size, its scale in relation to the payor's anticipated future litigation costs, its

independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* These factors do not relate solely to monetary payments but instead are applicable to the full gamut of potential valuable consideration that brand-name manufacturers might offer to the potential generic competitors.

District courts have determined that the *Actavis* decision applies to patent settlement cases involving non-monetary payments. *See In re Niaspan Antitrust Litig.*, No. 13-md-2460, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014) ("To read *Actavis* as … limited [to monetary payments] would be particularly anomalous in the context of antitrust law, in which 'economic realities rather than a formalistic approach must govern.'") (quoting *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005)); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 391-92 (D. Mass. 2013) ("Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment."). Likewise, the Supreme Court of California, while holding that cash payment settlements in a pay-for-delay deal involving the drug ciprofloxacin were anticompetitive, also recognized that cash payments have become a "relic" as a form of consideration in pay-for-delay settlements. *In re Cipro Cases I and II*, 2015 Cal. LEXIS 2486 at *32 n.11 (May 7, 2015). The *Cipro* court noted that it

"need not define precisely what noncash forms of consideration will qualify, but courts... should not let creative variations in the form of consideration result in the purchase of freedom from competition escaping detection." *Id.* at *32-33 n.11.

The arrangements at issue here between Warner, Watson, and Lupin to delay competitive entry of generic drugs in return for valuable consideration thwart Hatch-Waxman's goal of "get[ting] generic drugs into the hands of patients at reasonable prices—fast," *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991), just as effectively as if they involved cash payments. The district court wrongly limited *Actavis* to monetary pay-for-delay settlements.

III. The Specific Agreements At Issue In This Case Delay Generic Entry And Raise Costs To Consumers.

From a consumer's perspective, it makes no difference what specific form the "payment" in a pay-for-delay agreement takes—only whether such payment is an effective inducement to engage in anticompetitive conduct, in light of the factors articulated by the Supreme Court in *Actavis*. Although not in the form of cash, each type of "payment" in this case is such an inducement and had the effect of contributing to the maintenance of high brand-name prices for Loestrin 24.

A. No-Authorized Generic Clauses Are Valuable Consideration For Generic Manufacturers And Raise Costs For Consumers.

A no-AG agreement is an anticompetitive technique used to entice a delay in entry from generic manufacturers, which eliminates competition, diminishes

consumer options, and raises costs. Typically, during a first-filer generic manufacturer's 180-day exclusivity period, the brand-name manufacturer can introduce its own authorized generic into the market to compete with the generic manufacturer. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). This competition significantly diminishes the profits the first-filer can expect. However, under a no-AG clause, such as Warner offered Watson, the brand-name manufacturer agrees not to sell an authorized generic version of the product during the 180-day exclusivity period after the generic manufacturer eventually enters the market. Thus here, for the 180 days prior to the termination of Warner's Loestrin 24 patent, consumers would only have a choice between brand-name Loestrin 24 and Watson's generic substitute.[4]

This arrangement benefits the generic manufacturer by increasing its sales and profits during that period, but harms consumers because the lack of generic competition keeps the price higher than it otherwise would be. Moreover, generic manufacturers are typically willing to agree to longer delays before entering the market where a pay-for-delay settlement includes a no-AG provision. According to the FTC, while cash-only pay-for-delay settlements delay generic entry by an

[4] Even though Watson had forfeited its 180 days of market exclusivity because it failed to obtain tentative FDA approval within 30 months, Warner's No-AG promise gave Watson the same exclusivity during its first 180 days on the market that it could have received under the Hatch-Waxman Act.

average of 17 months, pay-for-delay settlements incorporating no-AG agreements delay generic entry by an average of 37.9 months. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, *supra* at 2; *see also Authorized Generics Report*, *supra* at vi. Overall, a no-AG agreement has the effect of substituting one monopoly (the brand-name drug) with another (the first generic to file an ANDA) for a period of time.

Watson and other generic firms find a no-AG clause an attractive form of consideration because the introduction of a brand manufacturer's authorized generic is a serious competitive threat to the generic manufacturer's profits during the 180-day exclusivity period. *See* FTC Brief As *Amici Curiae* at 1, *In re: Effexor XR Antitrust Litigation*, No. 3:11-cv-05479 (D.N.J., Aug. 12, 2012) (noting that a generic manufacturer relying on a no-AG agreement found it "lucrative" and that its revenues would increase "when it does not face competition from an AG during its exclusivity period."). In fact, according to the FTC, entry by an authorized generic during the period of exclusivity lowers estimated revenue of the first-filer by 40 to 52 percent. *Authorized Generics Report*, *supra* at 33. Given that other generics often enter the market at the end of the 180 days and drive prices downward, a generic manufacturer has a strong interest in maximizing its profit during the exclusivity period.

And keeping the authorized generic out of the marketplace means consumers ultimately pay higher prices. According to the FTC, drug markets containing an authorized generic competitor have "wholesale generic prices that are 7-14 percent lower than prices without authorized generic competition." *Authorized Generics Report*, *supra* at ii. The highest price drop for generic medications occurs when the *second* generic medication is introduced. Entry of a single generic drug, as seen during the period of exclusivity, offers only a marginal price change, or roughly six percent less than the brand drug. Food and Drug Administration, *Generic Competition and Drug Prices*, http://goo.gl/uKFPAQ (last visited June 14, 2015). However, the introduction of a second generic competitor, such as an authorized generic, can lower prices to nearly *half* the brand-name drug's cost. *Id.*

Given the lucrative nature of no-AG agreements particularly during the period of exclusivity, generic manufacturers often insist on including them in pay-for-delay settlements. In 2012 and 2013, 23 pay-for-delay agreements included no-AG provisions. *See* FTC, *Overview of Agreements Filed in FY 2013* (2014), *available at* https://goo.gl/klWjw8; *see also* FTC, *Overview of Agreements Filed in FY 2012* (2013), *available at* https://goo.gl/cJxmWA.

In this case, along with other anticompetitive provisions, the agreement between Warner and Watson delayed Watson's entry from as early as September 2009, until January 2014, at which time Watson would still enter as the sole

generic drug. Loestrin Opinion at 10. According to publicly available information and calculations by Appellants, the no-AG provision, while not a cash payment, had a monetary value for Watson of over $41 million. *See* Brief for Appellants American Sales Company, LLC And Rochester Drug Co-Operative, Inc. at 48, *In re Loestrin 24 FE Antitrust Litigation*, No. 13-2472 (D. R.I. June 9, 2015). Most importantly, each month of this settlement, by delaying competition between brand-name and generic version of the drug, forced consumers to pay higher prices than they would have absent this agreement.

B. Acceleration Clauses Eliminate The Incentive For Subsequent Filers To Litigate For Earlier Entry.

The acceleration clause in the agreement between Warner and Watson served as another means of maintaining higher prices for Loestrin. Although acceleration of generic entry is typically procompetitive, acceleration clauses in pay-for-delay settlements actually are crafted to benefit settling generic companies to the detriment of competition and consumers.[5] An acceleration clause is a provision in a settlement agreement between a brand-name manufacturer and settling generic company, usually the first-filer, that allows the generic company to accelerate its entry date if *another* generic company is going to be able to enter the market, through litigation or settlement, *before* the date agreed upon in the

[5] By reducing incentives for earlier entry, the acceleration clauses in fact work to decelerate generic entry; the adjective "acceleration" really does not apply.

settlement. *See* Michael Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 37 (2014). The acceleration clause can either set the new date of entry at a time that guarantees the settling generic company a period of exclusivity, or it can set the date of entry at the same time as the other generic company can enter.

Acceleration clauses serve two functions, both of which hinder competition. First, an acceleration clause operates as an insurance policy for the settling generic company. A first-filer takes several risks from settling with a brand-name manufacturer and delaying its generic entry. For one, a first-filer may lose its valuable 180-day exclusivity period granted by the Hatch-Waxman Act due to the agreement and a later filer who successfully litigates to defeat the brand-name manufacturer's patent could enter the market before the settling generic manufacturer. Carrier, *supra* at 39. If this occurs, the generic manufacturer would also lose any benefits of the settlement agreement that depend on exclusivity, such as the benefits of the no-AG clause.[6] Acceleration clauses guard against these risks to ensure that the settling generic companies receive the value they bargained for in return for delaying entry.

Second, and equally important, an acceleration clause removes the incentive for other generic companies to challenge the validity of the brand-name patent,

[6] Here, the acceleration clause guaranteed Watson the same exclusivity that it forfeited under the Hatch-Waxman Act.

because it guarantees that the settling generic either will keep the exclusivity period or will enter at the same time as any other generic company is able to. In drafting Hatch-Waxman, Congress found it helpful to incentivize the challenge of weak and invalid patents by granting successful first-filers a 180-day exclusivity period that can be worth hundreds of millions of dollars.

Acceleration clauses ensure that no other generic manufacturer, even if its own costly challenge proved successful, could enter the market before the settling generic company and thereby obtain the 180-day exclusivity period for itself. As noted by the FTC, "the effect of [the acceleration] clause [is] to make it less attractive for each successive generic company to continue to litigate or enter at risk because [the acceleration] clause would automatically permit each generic company that had settled to compete without any risk with any non-settling generic company." Complaint at 16, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D. Pa. Aug. 11, 2009). As a result, the acceleration clause removes an essential motivation for others to challenge weak and invalid patents, thus ensuring that the pay-for-delay settlement succeeds in prolonging the life of the patent.

Much like no-AG agreements, acceleration clauses are quite common in pay-for-delay settlements. In 2009, the Chief Executive Officer and Chairman of generic manufacturer Apotex, Inc., Dr. Bernard C. Sherman, said acceleration clauses had become "a standard component of every contract today." *The*

Protecting Consumer Access to Generic Drugs Act of 2009: Before Subcomm. on Commerce, Trade, & Consumer Protection of Energy & Commerce Comm., 111th Cong. 11 (2009) (testimony of Dr. Bernard C. Sherman, Chief Exec. Officer, Apotex, Inc.). The increased usage of acceleration clauses in pay-for-delay settlements reflects their valuable consideration as insurance to generic settlers and their effectiveness in prolonging the brand-name manufacturer's monopoly. Consumers pay the higher prices that result from delayed generic entry. Absent these agreements, generic drugs would enter the market sooner and reduce prices through meaningful competition.

C. Side Deals As Part Of Pay-For-Delay Settlements Are Valuable Consideration To Generic Manufacturers In Return For Delaying Entry.

"Side deals" between brand-name manufacturers and generic manufacturers likewise serve as valuable consideration to generic manufacturers in return for delaying generic entry. When used as part of a pay-for-delay agreement, side deals are consummated in connection with or at the same time as settlement of the patent litigation and typically involve some ostensibly "unrelated" product licensing or manufacturing agreement benefiting the generic manufacturer. *See* Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 632 (2009).

Side deals are non-monetary payments in pay-for-delay schemes that harm consumers who are ultimately affected by delayed generic entry and are forced to pay higher prices for a longer time. While it might be possible that *some* unrelated generic services offered in side deals are justified, courts should be suspicious of their usage, particularly in the context of a patent settlement. "[T]he absence of brand-generic deals outside of [a pharmaceutical] settlement is a strong reason to suspect that the deals are used to pay for delay." Hemphill, *supra* at 669. According to former FTC Chairman Jon Leibowitz, side deals have been "observed in settlements that restrained generic entry, but *virtually never* in settlements that did not." Jon Leibowitz, Comm'r, FTC, Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution (Jan. 17, 2007), *available at* https://goo.gl/386BcV (emphasis added).

Moreover, given the heightened scrutiny facing pharmaceutical patent litigation settlement, the parties "have ample reason" to use complex side deals "to conceal [the side deal's] genuine nature," — valuable consideration paid to the generic manufacturer to prevent generic entry. Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013). These side deals are also valuable to both parties involved. For example, in another case brought in the Eastern District of

Pennsylvania, allegedly as part of an overall "pay-for-delay" agreement, the brand-name manufacturer and the would-be generic manufacturer entered into an agreement to co-promote certain drugs. The royalty fees involved in that agreement were worth $45 million in its first year to the generic while the brand-name manufacturer kept its market monopoly. Complaint at ¶ 86, *In re Niaspan Antitrust Litig.* No. 2:08-cv-2141 (E.D. Pa. 2014). Therefore, courts must "use common sense when scrutinizing this type of compensation." Carrier, *supra* at 48.

Here, as part of the pay-for-delay scheme, Warner utilized a number of side deals with both Watson and Lupin involving Warner-patented drugs other than Loestrin 24. Warner agreed to pay Watson "annual fees and a percentage of net sales" for Warner's hormone therapy product Femring and the "exclusive right to earn brand sales" on the oral contraceptive drug Generess Fe. Loestrin Opinion at 11. Additionally, Warner granted Lupin a license to market Warner's oral contraceptive Femcon Fe, and the right to sell a generic version of Warner's anti-inflammatory medication Asacol 400. *Id.* at 12. According to the limited publicly available information, the side deals offered by Watson are potentially worth millions of dollars. Complaint for Direct Purchasers at ¶ 165, *In re Loestrin 24 FE Antitrust Litigation*, No. 13-2472 (D. R.I. Dec. 6, 2013). This valuable consideration for both generic manufacturers was provided as part of the litigation settlements, even though the parties could not have obtained the rights to these

drugs if they had won the Loestrin 24 patent litigation. *See Actavis*, 133 S. Ct. at 2236 (discussing the need for "legitimate justifications" for the settlement).

Here, there are no apparent procompetitive justifications for Warner's side deals with the generic manufacturers. Common sense indicates that Warner offered Watson and Lupin significant side deals involving considerable value for unrelated drugs to induce them to forgo entry of generic Loestrin 24 until 2014. These valuable deals served one purpose: ensuring that Warner continued to obtain monopoly profits for Loestrin 24 by effectively sharing the wealth with those who would otherwise be its competitors.

CONCLUSION

The district court's interpretation of the decision in *Actavis* is incorrect, contrary to the antitrust laws, and harmful to consumers. While some patent settlements between brand-name and generic pharmaceutical manufacturers may not violate antitrust laws, a court must make a determination as to whether such an agreement is anticompetitive based on the factors articulated by the Supreme Court in *Actavis*, regardless of the form of payment. If the lower court's decision is upheld, drug manufactures will continue to concoct anticompetitive pay-for-delay settlements that, while avoiding direct cash payments to generic filers, have the same effect of keeping prices artificially high at the consumer's expense. As a result, consumers will wait longer for and pay for more for generic medications, a

direct contradiction to the purpose and intent of the Hatch-Waxman Act. For the foregoing reasons and those stated in the brief of the Plaintiffs-Appellants, *amici curiae* respectfully urge this Court to reverse the district court's decision.

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 5,601 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that, on this 16th day of June, 2015, I filed the foregoing Brief for Amici Curiae in Support of Plaintiffs-Appellants with the Clerk of the United States Court of Appeals for the First Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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