14-4624-CV

In the United States Court of Appeals
for the Second Circuit

State of New York

Plaintiffs-Appellee,

v.

Actavis, PLC, and
Forest Laboratories, LLC.,

Defendants-Appellants.

On Appeal from United States District Court
for the Southern District of New York
(The Honorable Robert W. Sweet)

BRIEF FOR *AMICI CURIAE*
AFSCME – DISTRICT COUNCIL 37 HEALTH AND SECURITY PLAN, COMMUNITY CATALYST, CONSUMER ACTION, CONSUMERS UNION, FAMILIES USA, PUBLIC CITIZEN, SERGEANTS BENEVOLENT ASSOCIATION OF THE POLICE DEPARTMENT OF THE CITY OF NEW YORK HEALTH AND WELFARE FUND, AND UNITED STATES PUBLIC INTEREST RESEARCH GROUP IN SUPPORT OF PLAINTFF- APPELLEE

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CORPORATE DISCLOSURE STATEMENT

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* AFSCME - District Council 37 Health & Security Plan ("the DC 37 Plan") 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* Community Catalyst 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* Consumer Action 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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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

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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* Sergeants Benevolent Association of the Police Department of the City of New York Health and Welfare Fund 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* 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.

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JURISDICTIONAL BASIS TO FILE

Amici curiae file this brief pursuant to Fed. R. App. P. 29 and 2nd Cir. L.A.R. 29. All parties have consented to the filing of this Brief for *Amici Curiae* AFSCME – District Council 37 Health and Security Plan, Community Catalyst, Consumer Action, Consumer Union, Families USA, Public Citizen, Sergeants Benevolent Association of the Police Department of the City of New York and Health and Welfare Fund, and United States Public Interest Research Group in Support of Plaintiff-Appellee.

INTEREST OF AMICI CURIAE[1]

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 raising costs within the pharmaceutical industry.

Community Catalyst, Inc. is a national non-profit organization committed to building consumer and community voice in health care. The organization has

[1] Pursuant to FRAP 29(c)(5) and 2d Cir. L.R. 29.1, *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.

worked to promote expanded access to needed medicines while also challenging deceptive, fraudulent, or illegal promotional drug industry practices that inflate drug costs. They built a nationwide coalition comprised of 130 organizations in 36 states and the District of Columbia, with a combined membership of over 13 million people, including consumer, senior, labor and other advocacy organizations, and union benefit plans. Members of this coalition became active participants in over 30 class action lawsuits, including litigation concerning the deceptive advertising of Nexium, and pay-for-delay agreements concerning Cipro and Provigil.

Consumers Union is the policy and action 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.

AFSCME District Council 37 Health and Security Plan ("the DC 37 Plan") is a public sector union-sponsored, self-funded health and welfare benefit plan, which provides a generic-based prescription drug benefit for covered New York City municipal workers, retirees and their families. The DC 37 Plan provides supplemental health benefits, including a prescription drug benefit, for over

303,000 covered participants in every state in the United States. Because it has limited resources to pay for the prescription drug benefit, the DC 37 Plan has and continues to participate in various cases aimed at lowering or controlling the cost of prescription drugs. See its amicus brief in *William H. Sorrell, et al., v. IMS Health, Inc., et al.* No. 10-779 131 S.Ct. 2653 (2011); *New England Carpenters Health Benefits Fund et al. v. First DataBank, Inc. and McKesson Corporation*, CA No. 1:05-CV-11148-PBS (United District Court for the District of Massachusetts); *Vista Healthplan, Inc., et al., v. Cephalon, Inc.,* et al., No. 06-Civ-01833 (pending in the U.S.D.C. for the E.D. on PA).

Contributions towards funding DC 37 Plan benefits are bargained for with various municipal employers, including The City of New York, various authorities and corporations and quasi-public institutions. The employer contributions the DC 37 Plan receives to fund its prescription drug benefit have not kept pace with the cost of providing this prescription drug benefit. Currently, due to the unprecedented ever-escalating cost of providing this important benefit, the DC 37 Plan is now operating at a deficit and soon may have to curtail or severally limit the prescription benefit it provides to its participants. The instant product hopping scheme forces both the financially strapped DC 37 Plan to pay for costly brand drugs in lieu of the less expensive generic equivalents while also forcing low wage workers and retirees to pay a higher co-pay for the branded drug.

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.

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 name-brand manufacturers pay generic competitors to delay entry into the market are subject to antitrust scrutiny. Product hopping schemes such as the one at issue in this case are, similarly, an obstacle to the fulfillment of the policies underlying federal laws

that seek to benefit consumers by speeding the introduction of generic drugs in order to reduce prescription drug prices.

Sergeants Benevolent Association of the Police Department City of New York Health and Welfare Fund ("SBA") is the certified exclusive bargaining representative for health related benefits of all sergeants in the Police Department of New York City. SBA partners with an alliance of labor unions, in the non-profit coalition True Health Benefits, with approximately 56,000 overall participants. SBA has a vested interest in access to affordable generic pharmaceuticals for its members and consumers in general.

U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers, through public outreach to advocate for affordable health care 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.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

For the last decade, health care consumers have paid ever-increasing prices for prescription medications. As of 2013, consumer spending on pharmaceuticals topped $329.2 billion. Press Release, IMS Institute for Healthcare Informatics, IMS Health Study: Spending Growth Returns For U.S. Medicines in 2012 (Apr. 15, 2014).[2] By 2018, Americans will spend $1,400 per capita on pharmaceuticals, up $300 from 2013. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, GLOBAL OUTLOOK FOR MEDICINES THROUGH 2018 at 1 (2014). One reason for high costs is the usage of brand name medications. According to AARP, between 2006 and 2013, retail prices for 140 brand name drugs increased by an average of 113 percent. Stephen W. Shondelmeyer and Leigh Purvis, *AARP: Rx Price Watch Report* at 1 (Nov. 2014).[3]

In order to get more affordable alternatives in the face of rising drug prices, payors and consumers rely upon access to generic versions of brand name drugs. When offered, generic alternatives cost 80 to 85 percent less than their brand name counterparts. *See Facts About Generic Drugs*, FDA.gov, http://www.fda.gov /drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understanding

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[2] *Available at* http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=d58b8b5776165410VgnVCM10000076192ca2RCRD.

[3] *Available at* http://www.aarp.org/content /dam/aarp/ppi/2014-11/rx-price-watch-report-AARP-ppi-health.pdf.

genericdrugs/ucm167991.htm (last visited Feb. 18, 2015). In 2013 alone, usage of generic pharmaceuticals saved Americans $239 billion. Generic Pharmaceutical Association, *Generic Drug Savings in the U.S. Sixth Annual Edition: 2014* at 1.[4]

Congress has long recognized the clear consumer benefits that result from generic drug competition and entry into the market at the expiration of a brand name drug's patent. To help achieve those benefits, Congress passed the Hatch-Waxman Act in 1984. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)) [hereinafter Hatch-Waxman Act]. The Act serves a dual purpose: (1) to ensure a brand name manufacturer has meaningful patent protection for the life of its patent; and (2) to ensure that once the patent expires or is found invalid, consumers could benefit from the immediate availability of generic substitutes of the innovator drug. *See Examining the Senate and House Versions of the Greater Access to Affordable Pharmaceuticals Act: Hearings Before the Senate Committee on the Judiciary*, 108th Cong. (Aug. 1, 2003) (Stmt. of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration).[5]

Generic entry requires that the generic manufacturer submit an Abbreviated New Drug Application with the Food and Drug Administration ("FDA")

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[4] *Available at* http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf.

[5] *Available at* http://www.fda.gov/newsevents/testimony/ucm115033.htm.

demonstrating that the generic is a "bioequivalent" to the brand name drug that is already approved. 21 U.S.C. § 355(j). Under this abbreviated process, the Hatch-Waxman Act accelerates FDA review process and reduces costs to the generic manufacturer.

States have also been concerned with the high costs of pharmaceuticals and have exercised their own authority to complement the goals of the Hatch-Waxman Act. Most states have instituted "generic substitution laws" designed to promote lower cost competition and implement the goals of the Hatch-Waxman Act. When presented with a prescription that has a brand equivalent, the laws permits a pharmacist, unless a physician or patient directs otherwise, to switch patients to the lowered price AB-rated drug. *See* Brief for Federal Trade Commission as *Amicus Curiae* at 11, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co.*, No. 2:12-cv-03824-PD (E.D. Pa. Dec. 13, 2012). Using generic substitution laws, states have saved payors, including consumers, their insurers, and the federal government, billions of dollars. *See generally* William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, HEALTH AFF'S 2010; 29(7): 1383-1390 (finding that certain types of generic substitution laws could lead to $100 million in savings for Medicaid on just three brand name drugs).

Of course, generic entry has a direct effect on a brand name drug's profitability. According to the IMS Institute for Healthcare Informatics, when a

patent loses exclusivity the brand name manufacturer also loses roughly 80 percent of its market share within just six months. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE U.S. at 3 (2011).[6] In response, brand name manufacturers have created elaborate strategies to circumvent the purpose and intent of both the Hatch-Waxman Act and state substitution laws in order to eliminate generic competition and maintain monopoly profits. Such actions are the antithetical to Congress's intent under the Hatch-Waxman Act: "Congress sought to get 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). Both public and private parties have responded to these strategies by filing lawsuits under the competition laws and have generally met with success in courts.[7]

An anticompetitive strategy known as "product hopping" is now affecting Alzheimer's patients. Alzheimer's is a progressive brain disease that slowly eliminates an individual's memory, thinking skills, and his or her ability to perform everyday tasks. *Alzheimer's Disease Fact Sheet*, NATIONAL INSTITUTE ON AGING, http://www.nia.nih.gov/alzheimers/publication/alzheimers-disease-fact-sheet (last visited Feb. 18, 2015). Currently, five million Americans suffer from this

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[6] *Available at* http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf.

[7] For example, in 2013, the Supreme Court found that one such strategy, known as "pay-for-delay" settlements, can be anticompetitive. *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

debilitating disease, and experts anticipate that as many as 16 million people will have Alzheimer's by 2050. *Fact Sheet March 2014*, ALZHEIMER'S ASSOCIATION, http://www.alz.org/alzheimers_disease_facts_and_figures.asp (last visited Feb. 18, 2015). In fact, Alzheimer's disease is the sixth leading cause of death in America. *Id.* Alzheimer's is also the most costly disease in the United States. In 2014, the Alzheimer's Association found that Americans spent an estimated $214 billion on caring for and treating Alzheimer's patients. *Id.*

While there is no cure for Alzheimer's, some patients may treat their symptoms with a variety of different drugs for different "phases" of the disease. Brand name Namenda IR (whose generic name is memantine), made by Forest Laboratories, is used to treat moderate-to-severe Alzheimer's disease. Generic competition to Namenda IR will begin in July 2015 under license, with significant generic competition expected to follow when the patent expires later in the year. Op. at 6, *New York v. Actavis*, No. 14-7473, (S.D.N.Y. Dec. 11, 2014), Docket No. 80 (hereinafter "Op."). In response, Forest utilized a product hopping strategy to avoid the impending "patent cliff" so it could continue reaping monopoly profits on Namenda.

The purpose of product hopping is to prevent "meaningful generic competition." Brief for Federal Trade Commission as *Amicus Curiae*, *Mylan Pharms., Inc.*, *supra* at 8. Product hopping is a two-step process that involves both

a change in the product and taking affirmative steps to restrict consumers' access to the initial product. In order for a generic to receive approval through the ANDA process, the generic manufacturer must demonstrate that the generic is bioequivalent, defined as identical "in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." *Generic Drugs: Questions and Answers*, FDA.Gov, http://www.fda.gov/Drugs/Resources ForYou/Consumers/Questions/Answers/ucm100100.htm (last visited Feb. 18, 2015). The first step of product hopping occurs when a brand name drug manufacturer makes a minor change in a drug, such as a change in dosage amount, and creates a "new" version of the brand name drug so that a generic substitute of the old drug is no longer therapeutically equivalent to the new drug. As a result, pharmacists can no longer offer patients who are prescribed the "new" version of the drug a generic substitute unless the patient's doctor changes the prescription to the old version. For this reason, generic manufacturers cannot meaningfully enter a market where product hopping has occurred. *E.g.*, Op. at 116-17. The second step involves the brand manufacturer impeding consumer access to the initial product, forcing patients to purchase the "new" drug.

In July of 2013, Forest introduced a new drug, Namenda XR, to the market. Although it will have new market exclusivity under the patent laws until its patent expiration in 2029, Namenda XR is a brand name drug with no pharmacological

differences from Namenda IR. *Id.* at 37. The only difference between the two drugs is that Namenda IR requires twice-daily usage while Namenda XR is taken once a day. *Id.* at 38. Forest took numerous steps to discontinue the usage of Namenda IR and thereby force physicians to prescribe and patients to use Namenda XR.[8] This hop to a new product is taking place *before* generics have the opportunity to enter the market. The overwhelming evidence presented by the State of New York in this case, and embraced by the District Court in granting preliminary injunction, clearly demonstrates that the product hop from Namenda IR to XR serves only one purpose, to inappropriately prolong Forest's monopoly profits.

Even if the availability of Namenda XR is shown to have benefits for some patients as an alternative to Namenda IR,[9] the State of New York also presented overwhelming evidence that there is no procompetitive justification for removing Namenda IR from the market.[10] If some patients actually come to prefer Namenda XR over Namenda IR, its sales would naturally overtake those of Namenda IR if

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[8] Along with a February 2014 press release and statement to the FDA announcing Forest's discontinuation of Namenda IR, Forest wrote to the Centers for Medicare & Medicaid Services seeking IR's removal from the "Formulary Reference File." Op. at 50, 52.

[9] In fact, the District Court noted that the benefits of switching from IR to XR are "often marginal." Op. at 53.

[10] This brief focuses on the challenged activity of the removal of Namenda IR from the market. However, this should not be construed to suggest that other methods of product hopping are beyond challenge.

the two were allowed to compete on their merits. Such market-driven substitution would reward Forest for innovation that would have been shown to be desirable to doctors and patients. By contrast, once a patient is forcibly switched from Namenda IR to XR solely because the former is no longer available, the patient will be unable to obtain substitution of generic memantine without physician supervision, because there is no generic equivalent to Namenda XR and will not be until its patent expires in 2029. The removal of Namenda IR from the market only serves the purpose of disrupting the intended cycle of drugs from patented exclusivity to competition that decreases costs to consumers.

Amici curiae submit this brief to illustrate several points. First, product hopping is an anticompetitive practice that threatens to deter the availability of more affordable generic pharmaceuticals. Second, Forest's anticompetitive conduct will harm the consumers of Namenda, who will be denied the more affordable generic alternatives. Third, the application of antitrust laws to product hopping under the test put forth by the State of New York does not harm innovation as suggested by *amici* for Defendants. Finally, maintaining the preliminary injunction is necessary to prevent irreparable harm to consumers and avoid a dangerous precedent that would allow anticompetitive product hopping to continue and spread.

ARGUMENT

I. Forest's Usage of Product Hopping to Forcibly Switch Consumers From Namenda IR to XR Is Anticompetitive.

Product hopping is an anticompetitive strategy to improperly extend the time a drug earns monopoly profits past its patent's expiration date by forcing patients to switch to a supposedly "new" version of the drug before generics have an opportunity to enter the market. *See* Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FL. L. REV. 1009 (2010). Ordinarily, a manufacturer's creation of a new product is considered procompetitive. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F. 2d 263, 281 (2d Cir. 1979) ("Because as we have already indicated, a monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success it may achieve through 'the process of invention and innovation' is clearly tolerated by the antitrust laws") (citation omitted). However, in the case of product hopping, there is frequently no actual consumer or innovation benefit that justifies the switch. HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3 at 15-75 (2d. ed. 2010) ("The patentee is making a product change with no technological benefit solely in order to delay competition."). Product hopping involves making minor changes to the existing drug, as in the delivery method, or from instant release to extended release, solely in order to create a "new" drug for the purposes of restarting the patent clock and thereby prolonging the reaping of monopoly

profits. *See generally* David Balto, *Removing the Obstacles to Generic Drug Competition: A critical priority for health care reform*, CTR. FOR AM. PROGRESS at 14.[11] Given the nature of drug product reformation, the anticompetitive practice of product hopping is limited only by the number of changes a drug manufacturer can devise to perform on a drug. *See Abbott Laboratories v. Teva Pharmaceuticals USA Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006). [12]

The facts outlined by both the State of New York and the District Court establish that Forest utilized a coercive product hopping strategy to switch patients from Namenda IR to XR. Namenda IR and XR have no therapeutic differences; the only change between IR and XR was moving from twice-a-day to once-a-day usage. Op. at 38. Moreover, instead of allowing Namenda IR to remain on the market, absent the injunction, Forest will implement a "forced switch" by discontinuing Namenda IR. The only way patients may gain access to Namenda IR is through a Medical Necessity Order form.[13] Prior to the lower court's

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[11] *Available at* http://cdn.americanprogress.org/wp-content/uploads/issues/2009/06/pdf/generic_drugs.pdf.

[12] In *Abbott Laboratories*, Tricor customers were forcibly switched twice, from capsules to tablets and from tablets to "new tablets," before the activity was finally challenged and ended.

[13] Despite suggestions that this is evidence that no harmful removal of Namenda IR has occurred, Defendants own survey data indicated that only 2.4 percent of all patients will be able to obtain Namenda IR under the medical necessity standard. *Id.* at 69. Furthermore, Forest's decision to require a Medical Necessity Form was used to further limit access to generic memantine substitutes, not for medical reasons. *See Id.* at 67.

injunction and "in anticipation of a lack of availability of Namenda IR," a significant number of Alzheimer's patients have switched from Namenda IR to XR. Complaint at 22, *State of New York v. Actavis et al*, (S.D.N.Y. Dec. 7, 2014).

By circumventing the Hatch-Waxman Act and state substitution laws, Forest's conduct will forestall competition and increase costs. According to an FDA study using average retail drug prices, between 1999 and 2004, generic competition is important in bringing down healthcare costs. Entry of multiple generic competitors can reduce prices to as little as 20 percent of the previous branded price . U.S. Food & Drug Admin., *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last visited Feb. 18, 2015). Over the past ten years, generic products saved the U.S. health system nearly $1.5 trillion. *Generic Drug Savings in the U.S.*, *supra*. Product hopping impacts a significant portion of the drug market. In reviewing all product hopping cases since 2009, a law review article found that "reformulations have impaired competition against brand products with $28.1 billion in annual sales." Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 3 (2009).

The availability of generic drugs after a successful product hop does little to reverse consumer harm. This is due to the unique nature of the drug market.

Generic companies have no incentive to market their drugs because, as one of several generic competitors, there is no guarantee that the benefit of a changed prescription will accrue to them. Op. at 78. Furthermore, generic manufacturers primarily compete on price – both with the branded manufacturer and among other generic manufacturers – and spending money on marketing would require them to increase prices, and thus would undercut their ability to compete. *Id.* at 78-79. This is further complicated by the opaque nature of healthcare costs. *See* Martha Hostetter and Sarah Klein, *Health Care Price Transparency: Can It Promote High-Value Care?*, QUALITY MATTERS (May 2012) (noting the unique nature of healthcare markets in that "patients rarely know what they'll pay for [healthcare] services").[14] Actual consumers of medications may not know the true cost of prescriptions covered by insurance and therefore may not be motivated to comparison shop. This is shown when payors attempted to use utilization plans to shift subscribers from branded Lipitor to generic simvastatin, which only resulted in 30 percent of patients switching. Op. at 80.

In the case of Namenda, the monopoly prices that consumers will pay due to impaired competition if the product hopping is allowed to stand will be significant. For the 2014 fiscal year, Forest's revenues on Namenda were $1.6 billion. *Id.* at

[14] Available at http://www.commonwealthfund.org/publications/newsletters/quality-matters/2012/april-may/in-focus.

11. Given that generics typically cost 80 percent less than a brand name counterpart, if Forest did not preclude meaningful generic entry then competition could decrease total spending on memantine by $1.3 billion. But with only five to thirty percent anticipated to switch back to generic memantine sometime after it becomes available, most of these savings will not be realized. *Id.* at 82.

In addition to increasing costs to consumers and their payors and eliminating meaningful generic entry, product hopping schemes also discourage pharmaceutical innovation. By diverting resources into creating and patenting marginal changes in drugs to extend their effective patent life, product hopping produces only marginal benefits to the consumer. These changes would not be worth investing in absent the perverse features of the drug and patent laws that make product hopping profitable. This harm to innovation is borne out in industry data. The number of original application submissions and approvals for new drugs has been in a decline, while spending on drug redesign and incremental improvements has significantly increased. Janice M. Reichert, *Trends in Development and Approval Times for New Therapeutics in the United States*, 2 NATURE REVIEWS 695, 701 (2003); Iain M. Cockburn, *Is the Pharmaceutical Industry in a Productivity Crisis?*, 7 INNOVATION POL'Y AND THE ECONOMY at 1 (2006); Jayashree Dubey & Rajesh Dubey, *Pharmaceutical Innovation and Generic Challenge: Recent Trends and Causal Factors*, 4 INT'L J. OF PHARM. &

HEALTHCARE MARKETING 175 (2010). It is apparent that efforts to maintain market power for popular drugs are at least partially responsible for this trend. Dubey & Dubey, *supra* at 189 (noting that the threat of generic competition has caused pharmaceutical companies to "explor[e] the route of incremental innovation to increase market life of their existing blockbuster products").[15]

II. Vulnerable Alzheimer's Patients Will Be Harmed by Forest's Anticompetitive Conduct.

Forest's anticompetitive conduct will have a negative effect on Alzheimer's patients who take Namenda. Forest's product hopping directly increases prices on Alzheimer's patients who take Namenda. Alzheimer's patients who use Namenda spend roughly $3,600 per year on the drug. Andrew Pollack, *New York Files an Antitrust Suit Against the Maker of an Alzheimer's Drug*, N.Y. TIMES, Sept. 15, 2014, http://www.nytimes.com/2014/09/16/business/new-york-files-antitrust-suit-against-maker-of-alzheimers-drug.html (finding the average cost of Namenda at $300 per month). A generic memantine drug would likely cost patients only $720 per year, a significant savings for patients who are mostly elderly, retired, and

[15] For more information, *see* Brief of Intellectual Property and Antitrust Law Professors as Amici Curiae, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott PLC* (E.D. Pa. 2014) (No. 12-9824), *available at* https://www.law.stanford.edu/sites /default/files/child-page/619657/doc/slspublic /2014-05-07%20Final%20Brief%20w_Pacer%20Stamp.pdf.

receiving limited income. Under Forest's product hopping scheme, patients will have trouble gaining access to these generic options.

Due to the nature of the healthcare system, which is designed to spread often opaque costs among patients, their health insurers, and the federal government programs like Medicare and Medicaid, this lack of access to generic drug options due to product hopping will increase costs for all Americans. This increased burden on the healthcare system is not insignificant. Large prescription drug payments were to blame for an eight percent Medicare spending jump from October 2014 through January 2015, costing taxpayers an additional $14 billion for that quarter. Alicia Caramenico, *Expensive Prescription Drugs, the Big Driver Behind Medicare Spending*, AHIP (Feb. 9, 2015), http://www.ahipcoverage.com/2015/02/09/expensive-prescription-drugs-the-big-driver-behind-medicare-spending/.

Moreover, Forest's conduct unjustly restricts a patient's or family's choice of drug. If Forest were introducing Namenda XR straightforwardly and on the merits, Alzheimer's patients and their families could choose between remaining on Namenda IR and gaining the benefits of available generic substitutes in July 2015, or switching to Namenda XR. Instead, a patient's choice is greatly reduced by Forest's conduct, eliminating the possibility that patients switched to Namenda XR will receive generic memantine when it becomes available. *Cf.* Neil Averitt and Robert Lande, *Using Consumer Choice Approach to Antitrust Law*, 74 ANTITRUST

L.J. 175, 183 (2007) ("Antitrust should protect any type of choice that is of practical importance to consumers.").

In addition, Alzheimer's patients will face an increased chance of adverse events as a direct result of Forest's conduct. The memantine drug is used by patients with moderate-to-severe Alzheimer's. In their advanced condition, patients require a high degree of stability. In fact, "[e]ven a small change in a patient's condition can require him or her to be moved to a care facility." Op. at 91 (quoting Lah Decl. (PX85)). Drug adherence can be disrupted by the forced switch from a twice a day treatment to a once a day treatment. Given that Alzheimer's patients suffer from memory issues, extra care must be taken so that patients and their caretakers are properly educated on how the new medication is taken. *Id.* This creates some risk of overdose or improper drug adherence due to miscommunication, under-communication, or simple forgetfulness.

While some patients might potentially see some advantage from a once-a-day drug regimen, this should be a decision left to the physician on a case-by-case basis.[16] *See Id.* at 92 (physician testimony that drug regimen changes should be a "choice to be decided between myself and my patients") (citation omitted)). A

[16] It is important to note that, under the injunction granted by the District Court, patients that wish to, will still be able to receive Namenda XR.

physician might not want to risk an adverse event caused by improper drug adherence due to this change in medications for a patient.

III. Applying Established Antitrust Jurisprudence to Product Hopping Does Not Harm Innovation and Allows Consumers and Doctors to Decide When an Innovation Justifies the Costs of Switching Medications.

Several *amici* supporting Forest present a false choice between allowing Forest's product hopping strategy and supporting innovation or blocking product hopping and harming innovation.[17] These *amici* argue that pharmaceutical companies will stop innovating or will lose their incentive to innovate without the ability to product hop. The arguments that enforcing antitrust laws against product hopping will somehow harm drug innovation are completely wrong.

For starters, while pharmaceutical product hopping has only been a practice for a decade or so, the pharmaceutical industry has existed and continuously innovated for hundreds of years.[18] The pharmaceutical industry continued to

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[17] *E.g.* Brief of Antitrust Economists in Support of Defendants-Appellants, *State of New York v. Actavis et al*, at 17 (No. 14-7473) (2d Cir. Jan 15, 2015); Brief of Dolin, Holte, Lande, Mossoff, and Osenga in Support of Defendants-Appellants and Urging Reversal, *State of New York v. Actavis et al*, at 7 (No. 14-7473) (2d Cir. Jan 15, 2015); Brief of Business and Policy Professors as *Amici Curiae* in Support of Defendants-Appellants, *State of New York v. Actavis et al*, at 12 (No. 14-7473) (2d Cir. Jan 15, 2015).

[18] The first product hopping case was decided in 2006. *Abbott Labs.*, 432 F. Supp. 2d at 408 (denying defendant's motion to dismiss). The pharmaceutical industry arose in the mid-1800s. *See*, *e.g.*, *Our History*, GLAXOSMITHKLINE, http://www.gsk.com/en-gb/about-us/our-history/ (last visited Feb. 18, 2015); *History*, MERCK,

innovate after the birth of the generic pharmaceutical industry in the early 1960s and its boom following the passage of the Hatch-Waxman Act in 1984. The original Namenda patent itself was filed in 1990, six years after the passage of the Hatch-Waxman Act. U.S. Patent No. 5,061,703 (issued Oct. 29, 1991). The inventors of Namenda did not rely on the ability to product hop in order to have the incentive to innovate. Rather, they should have anticipated having a limited period of exclusivity, after which generics would enter and bring prices down under the Hatch-Waxman Act and state generic substitution laws.

Furthermore, the argument that the discontinuation of products is a necessary part of innovation discounts the role of consumer choice and competition in picking winners and losers among innovations.[19] Often, it is up to consumers to decide whether a new product will supplant an existing product. If consumers choose an older product rather than a new one containing an innovation, then it shows that the innovation is not one that is valuable to consumers. This normal operation of the market means that innovations must not only be new, they must also have value to consumers. *See* Giada Di Stefanoa, Alfonso Gambardellab, & Gianmario Verona, *Technology push and demand pull perspectives in innovation*

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http://www.emdgroup.com/emd/company/history/history.html (last visited Feb. 18, 2015).

[19] This argument was put forward by Brief of Business and Policy Professors as *Amici Curiae* in Support of Defendants-Appellants, State of New York v. Actavis *et al*, at 5 (No. 14-7473) (2d Cir. Jan 15, 2015).

studies: Current findings and future research directions, 41 RES. POL'Y, 1283, 1283 (2012). Allowing the market to operate does not harm innovation, but rather directs innovation in such a way that it will produce the most value.

Amici supporting Appellants-Defendants cite Apple's iPhone product cycle as an example for their argument.[20] This example fails because the rule proposed by the State of New York would not prohibit a product withdrawal that makes business sense, only product withdrawals that have no legitimate business justification other than to harm competitors. Apple would not be barred from discontinuing iPhones under such a rule. In addition, the pharmaceutical market has a different regulatory environment than the technology industry.

Moreover, a different example from the technology industry illustrates the counterpoint that consumer choice can be an important part of innovation. On October 26, 2012, Microsoft released Windows 8 intending to replace its Windows 7 operating system. Mary Jo Foley, *Windows 8's Delivery Date: October 26*, ZDNET, http://www.zdnet.com/article /windows-8s-delivery-date-october-26/ (last visited Feb. 18, 2015). Despite these intentions, Windows 8 sales were greatly surpassed by those of Windows 7, which was allowed to remain on the market. Chris Merriman, *Windows 8 sales are down millions on Windows 7*, THE INQUIRER,

[20] Brief of Business and Policy Professors as *Amici Curiae* in Support of Defendants-Appellants, State of New York v. Actavis *et al*, *supra* at 5.

http://www.theinquirer.net/inquirer/news /2329063/windows-8-sales-are-down-millions-on-windows-7 (last visited Feb. 18, 2015). Market share analytics showed that Windows 7 continued to grow, despite Windows 8's launch, and that those leaving older operating systems were migrating to Windows 7 rather than Windows 8. Nicole Kobie, *Windows 7 picks up XP leavers, not Windows 8.1*, PC PRO, http://www.pcpro.co.uk/news/390079 /windows-7-picks-up-xp-leavers-not-windows-8-1 (last visited Feb. 18, 2015).

The failure of Windows 8 will undoubtedly cause Microsoft to incorporate the desirable aspects of Windows 7 and address the undesirable aspects of Windows 8 in its next Windows iteration. Meanwhile, Microsoft's choice to leave Windows 7 on the market has benefitted consumers in the short term by not forcing an undesirable product on them, and has benefitted innovation in the long term by incentivizing Microsoft to innovate in a manner desired by consumers. This lesson is equally applicable in drug markets, where patient and physician preference will cause desired innovations to be adopted, while undesired modifications to drugs will prove unsuccessful.

The test advocated by the State of New York to determine whether product hopping is unlawful, which was accepted by the lower court, supports the market and innovation by not putting courts in the position of determining what an innovation is. New York's Memorandum of Law in Support of its Motion for

Preliminary Injunction at 26, *State of New York v. Actavis et al*, (S.D.N.Y. Dec. 7, 2014) (No. 7473) ("[conduct] is "exclusionary" and not lawful "competition on the merits" if the conduct (1) harms competition, and (2) has no legitimate business justification (or the proffered justification is outweighed by the harm to competition)"). What an innovation is and whether it is valued is for consumers to judge in a properly functioning market. If a drug is innovative in a way that doctors and consumers prefer, then the market will naturally shift to the new drug, and the pharmaceutical company will continue to earn monopoly profits because it is giving doctors and consumers what they want. But if the drug is not innovative in a way preferred, then consumers will continue to use the existing drug, at a significant discount because of generic availability. This test also takes account of legitimate business justifications for discontinuing an old drug – like the inability to support both drugs with the pharmaceutical company's existing resources. The test is well-supported by case law, *see Id.*, and does not harm innovation, but in fact promotes it.

IV. A Preliminary Injunction in a Product Hopping Case Is Essential to Prevent Irreparable Harm to Consumers.

"The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). Irreparable harm exists "where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of

the action the parties cannot be returned to the positions they previously occupied." *Brenntag Int'l Chems., Inc. v. Bank of India*, 175 F.3d 245, 249–50 (2d Cir. 1999).

Product hopping, by its very nature, creates a harm that cannot be undone and for which money alone cannot atone. *See Morton v. Beyer*, 822 F.2d 364, 372 (3d Cir. 1987) (citation omitted). Where the prospect of generic competition for an older version of a drug is on the horizon, consumers are in a position to save significantly on prescription medications, and the execution of a product hopping scheme directly undercuts that. In this case specifically, the District Court noted that consumers and payors bear the burden of paying "almost $300 million more for a memantine drug" if Forest continues its product hopping sales pattern in the absence of a preliminary injunction. Op. at 131. As the District Court noted, there are significant, potentially insurmountable, costs, practical difficulties, and risks in switching back to a former version of a drug once an initial switch to a new version is made. *See Id.* at 91-92, 131. After product hopping is successfully executed, consumers are, for the most part, effectively locked in to the new patented drug at the monopoly price.

Product hopping harms not only impact consumers of the particular medication involved, but consumers of healthcare in general, because our healthcare system spreads the costs of healthcare through health insurance and absorption of unpaid medical bills by providers. If product hopping schemes are

allowed to proceed, the eventual costs to the healthcare system will be far greater than even the potential $1.3 billion in savings directly at issue in this case.

CONCLUSION

For the reasons set forth above, the District Court's order granting a preliminary injunction should be affirmed.

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CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of February, 2015, I filed the foregoing Brief for *Amici Curiae* in Support of Plaintiff-Appellee with the Clerk of the United States Court of Appeals for the Second Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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