15-2236

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

MYLAN PHARMACEUTICALS INC.,

Appellant,

—v.—

WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT US, LLC; MAYNE PHARMA GROUP LIMITED; MAYNE PHARMA INTERNATIONAL PTY. LTD.,

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BRIEF FOR AMICI CURIAE AARP, CONSUMERS UNION, AFSCME – DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN, CONSUMER ACTION, CONSUMER FEDERATION OF AMERICA, FAMILIES USA, SERGEANTS BENEVOLENT ASSOCIATION, NATIONAL HEALTH LAW PROGRAM, CENTER FOR MEDICARE ADVOCACY, AND UNITED STATES PUBLIC INTEREST RESEARCH GROUP IN SUPPORT OF PLAINTIFF-APPELLANT URGING REVERSAL

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CORPORATE DISCLOSURE STATEMENT OF AARP

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, Experience Corps, d/b/a. AARP Experience and AARP Financial.

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Consumers Union of United States, Inc., D/B/A Consumer Reports is a nonprofit membership organization. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

CORPORATE DISCLOSURE STATEMENT OF AFSCME -DC 37

AFSCME - District Council 37 Health & Security Plan ("the DC 37 Plan") 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.

CORPORATE DISCLOSURE STATEMENT OF CONSUMER ACTION

Consumer Action 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.

CORPORATE DISCLOSURE STATEMENT OF CONSUMER FEDERATION OF AMERICA

Consumer Federation of America ("CFA") is a non-profit association that operates as a tax-exempt organization under the provisions of § 501(c)(3) of the Internal Revenue Code. CFA has a membership of over 275 nonprofit consumer organizations. CFA has no parent corporation, nor has it issued shares or securities.

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Families USA 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.

CORPORATE DISCLOSURE STATEMENT OF SERGEANTS BENEVOLENT ASSOCIATION

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

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The National Health Law Program ("NHeLP") is a non-profit organization that offers no stock. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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September 30, 2015

Respectfully Submitted,

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INTERESTS OF AMICI CURIAE[1]

Product hopping—the practice of a brand name manufacturer altering an existing product without changing its underlying efficacy, combined with taking affirmative steps to restrict consumers' access to the previous version of the medication—has become a well-known tactic in the pharmaceutical industry that prevents generic medication from competing in the marketplace. Without generic competition, name brand manufacturers continue to reap higher profits and consumers pay higher prices. Amici are organizations that work to ensure that Americans have access to affordable medication. Among other efforts, Amici oppose market manipulation by pharmaceutical companies, including price hopping and "pay-for-delay" arrangements, which prevent competition from generic products that reduces the price of prescription medication. Amici write specifically to address anticompetitive practices, like those at issue in this case, which are designed specifically to delay entry of generics into the market.

AARP is a nonprofit, nonpartisan organization with a membership that helps people turn their goals and dreams into real possibilities, strengthens communities

[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 amici curiae and their counsel have contributed money intended to fund preparing or submitting the brief. All parties have consented to amici curiae filing this brief.

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

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.

The Consumer Federation of America (CFA) is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. CFA works at the local and national level to advocate for the consumer's right to safe products and fairly and competitively priced goods and services across many categories including encouraging strong competition in the marketplace.

Consumers Union is the public policy division 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. 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.

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.

For over forty-five years, the National Health Law Program (NHeLP) has engaged in legal and policy analysis on behalf of low income people, people with

disabilities, and older adults. NHeLP has provided legal representation, conducted research and policy analysis on issues affecting the health status and health access of these groups, including access to affordable prescription drugs. NHeLP works to help consumers and their advocates overcome barriers to health care, including a lack of affordable services.

Founded in 1986, the Center for Medicare Advocacy, Inc. is a non-profit public interest law organization that represents older and disabled people throughout the United States. The Center works to advance fair access to Medicare, Medicaid, and quality health care through individual representation, education, policy analysis, administrative advocacy, and litigation. A crucial component of this effort is to ensure that the elderly and disabled are able to obtain needed medications at reasonable prices.

U.S. PIRG, the federation of state Public Interest Research Groups ("U.S. PIRG"), 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.

Amici have a strong interest in protecting their members and the public from market manipulation that increases the cost of prescription medication. Amici's participation in this case will assist this Court to understand the use of product hopping in the pharmaceutical industry and its significant role in both increasing the cost of medication and interfering with health care decisions. Amici urge this Court to reverse the district court's ruling that the conduct at issue is not anticompetitive; otherwise, we are concerned that the ruling will open the floodgates to increased market manipulation if not corrected.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The prices of prescription medications are a driving force behind ever-increasing healthcare expenditures. Improved access to generic medications, pharmaceutical substitutes with the same therapeutic benefits as the brand-name product, helps to combat the high price of prescription medications. In 2013 alone, generic medications saved consumers $239 billion. *Generic Drug Savings in the U.S.* 1, Generic Pharmaceutical Ass'n (6th ed. 2014), *available at* http://goo.gl/cmHLrj. Given their affordability, over 80 percent of all dispensed prescriptions are for a generic substitute. IMS Inst. for Healthcare Informatics,

Medicine Use and Shifting Costs of Healthcare, 30 (2014), *available at* http://goo.gl/i7UOSk.

For decades, Congress and the states sought to encourage access to and use of generic medication. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified as amended at* 21 U.S.C. § 355 (1994), encourages quick and effective entry of generic pharmaceuticals into the marketplace once patents on brand-name drugs expire or are found to be invalid. "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

A manufacturer may seek approval from the Food and Drug Administration ("FDA") to offer a generic version of a name brand drug using the Abbreviated New Drug Application ("ANDA"). 21 C.F.R. § 320.21 (2015). This abbreviated process allows the generic manufacturer to rely on the safety data for the name brand drug, so long as it can show the generic version is bioequivalent, meaning "the rate and extent of absorption" of the active ingredient is the same as that of the brand name drug. 21 U.S.C. § 355(j)(8)(B)(i) (2015). The ANDA significantly "speeds the introduction of low-cost generic drugs to market, thereby furthering

drug competition." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (internal quotation marks, alteration, and citation omitted). Once approved as bioequivalent, the generic may also be "AB-rated" as being also pharmaceutically equivalent to the brand drug, meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug. *See* U.S. Food and Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, at vii-x (35th ed. 2015), *available at* http://goo.gl/s4wBl. The AB-rating requirement is "designed to provide guidance regarding which drugs are therapeutically equivalent, but, as has been observed, it also provides an opportunity for brand manufacturers to 'game' the system." *New York v. Actavis*, 787 F.3d at 645.

Additionally, states have enacted generic substitution laws to ensure consumers have access to FDA-approved generic substitutes. *See State Regulations on Generic Substitution*, Pharmacists' Letter (April 2009), *available at* http://goo.gl/sjX0gi. Such laws permit pharmacists to substitute the lower-priced AB-rated generic medication for a name brand, unless a physician or patient specifically directs otherwise, thereby benefiting both insurers and consumers by significantly reducing costs of prescription medication. *See* William H. Shrank, et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 Health Aff's 7, 1383-1390 (July 2010) (finding that certain types of generic

substitution laws could lead to $100 million in savings for Medicaid on just three brand name drugs). Under many state laws, only AB-rated generics can be substituted. *See* Jesse C. Vivian, Generic-Substitution Laws, tbl.2, *U.S. Pharmacist* (June 19, 2008), *available at* http://goo.gl/QmT7jY.

The entry into the market of a lower-cost generic medication directly reduces the brand-name's profitability. After only a single year of generic competition, brand-name manufacturers can lose 84 percent of sales on the brand-name drug. Henry Grabowski, et al., *Recent Trends in Brand-Name and Generic Competition*, 17 J. of Med. Econ. 3, 207 (2014). Brand-name manufacturers have responded to such threats to their profits by engaging in various schemes to delay entry of generic competition into the market. Such schemes are antithetical to Congress's express intent to quickly "get generic drugs into the hands of patients at reasonable prices" under the Hatch-Waxman Act. *See FTC v. Actavis*, 133 S. Ct. at 2236-37 ("pay-for-delay" settlements can violate the Sherman Act if the purpose of the conduct is to hinder competition); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir 1991).

In the current matter, Appellant Mylan alleges that Appellees Warner Chilcott ("Warner") and Mayne Pharma ("Mayne") engaged in a series of product hops for the sole purpose of preventing meaningful generic competition. Mem. Op. at 4-6, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824,

ECF No. 680 (Apr. 16, 2015) [hereinafter Opinion]. Product hopping is a two-step process that involves both a change in the brand-name drug and affirmative steps to restrict consumers' access to the previous version of the drug.

The first step of product hopping occurs when a brand name drug manufacturer makes a change to a drug, such as changing the delivery system from capsules to tablets, to create a "new" version of the brand name drug that affects the patient essentially the same way that the initial version did. Under state laws, pharmacists may not substitute a generic for the new version of the name brand medication until it is FDA-approved and AB-rated. *See* Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1009 (2010). Thus, in order to compete effectively with the brand name medication—pursuant to the statutory scheme established by the interplay of federal and state laws—a generic manufacturer is forced to redesign their own product to match any changes made by the name brand manufacturer and apply for and obtain new approval through the FDA ANDA process.

The second step of anticompetitive product hopping involves conduct by the brand name manufacturer to impede consumer access to the previous version of the drug, forcing patients to switch to the "new" brand-name drug and greatly reducing or eliminating prescriptions for the drug in which a bioequivalent generic is, or will

be, available. Commonly used tactics to accomplish this include removing the old drug from the market, buying back supplies of the old drug, and removing the drug from drug formularies. *See, e.g.*, *Abbott Laboratories v. Teva Pharmaceuticals USA Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

In this matter, the district court "was compelled to find that Defendants made the Doryx 'hops'—even the six-year developmental 'hop' from capsules to tablets—primarily to defeat generic competition." Opinion at 9. Four separate product hops, which Mylan claims were anticompetitive, included switching from capsules to tablets, changing the dosage of tablets, and adding scoring lines that allowed consumers to use the dosage they were using with the initial product. *See id.* at 8. Warner and Mayne also allegedly utilized various anticompetitive methods to limit consumer access to an old version of Doryx, including not selling older versions of the drug, thus cutting off generic substitution pursuant to state laws. *Id.* at 5. Mylan asserted that Warner and Mayne's actions improperly extended the life of the name brand Doryx product line, ensuring their monopoly profits and limiting consumer access to lower cost alternatives. Mylan argued that generic manufacturers cannot meaningfully enter a market where product hopping has occurred because the generic does not match the version of the brand name product that is actually available.

The district court entered summary judgment against Mylan, finding that Appellants could not show that the product hopping was anticompetitive. The district court found that it merely denied Mylan the opportunity to benefit from the federal and state substitution generic competition framework, which it characterized it as a "regulatory bonus." *Id.* at 25. The court also erroneously found, based on unsubstantiated assumptions about generic competition, that the challenged conduct did not prohibit Mylan from competing in other ways, such as by marketing their own product.

Amici write to argue that generic entry into the market and the competition that is encouraged by the interplay of the Hatch-Waxman Act and state substitution laws is not merely a regulatory bonus; it is the applicable statutory scheme in which this case arises. Absent the alleged anticompetitive conduct, Mylan and other generic firms claim they would have entered the market in 2005, increasing competition and lowering costs to consumers. The district court erred in misconstruing competition in the generics marketplace. *See Verizon v. Trinko,* 540 U.S. 398, 411 (2004) (noting that an analysis of anticompetitive conduct "must always be attuned to the particular structure and circumstances of the industry at issue.").

Second, determining whether product-hopping schemes are anticompetitive requires an evaluation of whether the alleged conduct harmed consumers by

limiting choice and raising costs. Thus, the district court erred in resolving on summary judgment the fact intensive question of whether the alleged conduct was anticompetitive. Finally, the district court erred in finding that the product hopping conduct could not be anticompetitive because it erroneously assumed that applying antitrust law to product hopping would harm innovation.

ARGUMENT

I. THE PRODUCT HOPPING CONDUCT ALLEGED IN THIS CASE IS ANTICOMPETITIVE AND SUBJECT TO THE ANTITRUST LAWS.

The district court incorrectly held that the conduct alleged could not be anticompetitive. Opinion at 31 ("Mylan's reading of the Sherman Act would not only require federal courts to serve as FDA adjuncts, it would strongly discourage pharmaceutical innovation and development"). "Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition." *New York v. Actavis*, 787 F.3d at 652. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010) ("changes in product design are not immune from antitrust scrutiny."). A manufacturer's creation of a new product may be considered procompetitive, but not all new products are outside the reach of the antitrust laws. Courts evaluating antitrust allegations balance the anticompetitive effects of a product change or reformulation, including whether consumers have a choice to adopt the new product, against any potential procompetitive benefits. *Id*.

A. The district court erred in ruling that Appellees' conduct could not violate the antitrust laws.

In this matter, Appellant's evidence to show that Appellee's product hops served the anticompetitive purposes of denying generic competition was sufficient to survive a motion for summary judgment. Prior to generic Doryx entry, Warner and Mayne reformulated Doryx by moving from capsules to tablets. Opinion at 5. Additionally, evidence established that Warner and Mayne's conduct went beyond simple reformulation because they actively "took steps to switch the market" to each newer product. *Id.* In addition to preventing consumer access to the older Doryx capsules, alleged conduct included refusing to sell the capsules to wholesalers, removing capsules from the website, using auto-referencing to ensure physicians prescribed Doryx tablets, and "inform[ing]" prescribers and purchasers that Doryx capsules have been "replaced" by tablets. *Id.* The district court was compelled to find that these steps were taken to prevent generic substitution. Opinion at 9-21. The three other product hops also involved only superficial changes to the Doryx product and were accompanied by further efforts to force further delay, with generic competitors having to similarly reformulate their products in order to satisfy generic substitution requirements. *Id.* at 4-6. As a result, there was limited-to-no competition between Doryx and generic drugs until 2012. *See* Mylan Br. in Opp. to Sum. Jgmt. at 7-8, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, ECF No. 587 (May 2, 2014)

The district court improperly found that the evidence failed to establish a claim of anticompetitive conduct. First, the court reasoned that the brand-name manufacturer has "no duty" to assist a generic manufacturer "by keeping older versions of [the] branded [drug] on the market." Opinion at 25 (citation omitted). This reasoning ignores the reality that unless the older version of the drug is available in the market, there can be no effective product substitution by generic equivalents as contemplated by the Hatch-Waxman Act and state substitution laws.

The district court found further support in the length of time that Doryx has been off patent to find that the conduct could not be anticompetitive. It noted that Doryx has been off-patent since 1985, stating that Mylan "waited until the sales of branded Doryx were so great that huge generic sales—buoyed by regulatory compulsion—were assured." Opinion at 31. But the number of years a drug is off-patent is irrelevant to the analysis of competitive harm in a product hopping matter. Antitrust analysis of product hopping cases should focus on when generics *attempt to enter* the market to compete with the brand-name drug. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 2 (2009) (product hopping occurs in "anticipat[ion of] entry by generics"). Mylan and Sandoz did not attempt to enter the generic market for Doryx capsules until around 2005. Opinion at 6-8. In response, Warner and Mayne first thwarted generic competition by introducing and forcibly switching

patients (by removing the older versions of Doryx from the market) to the superficially altered "new" tablet version of Doryx.

B. The district court failed to consider the alleged conduct in the specific context of competition in the pharmaceutical market.

Despite the district court's finding that the Defendants made the Doryx product hops "primarily to defeat generic competition," it nevertheless found that Mylan "has failed to produce initial evidence of anticompetitive conduct." Opinion at 21. It is clear the district court failed to consider the conduct in the context of the pharmaceutical market.

As an initial matter, the district court discounted the antitrust claims based on an unsupported presumption that the generic firm's "refusal to incur promotion costs," such as advertising entry of a generic drug, makes a generic manufacturer a "'victim' of its own business strategy." *Id.* at 23. The court disregarded substantial evidence that generic competition is incentivized and accomplished through operation of state substitution laws that can be thwarted easily by product hopping.

Moreover, the court's erroneous and unsupported presumption that advertising will improve competition with the brand-name drug has already been rejected by the Second Circuit, which found that "[a]dditional expenditures by generics on marketing would be *impractical and ineffective* because a generic manufacturer promoting a product would have no way to ensure that a pharmacist

would substitute its product, rather than one made by one of its generic competitors." *New York v. Actavis*, 787 F.3d at 656 (emphasis added). It is improper for the district court to require that a generic manufacturer spend money on advertising, sacrificing some of the savings it can offer consumers for very little benefit, in order to avail itself of antitrust protection.

The district court also overlooks the legislative framework established by the state and federal governments that provides a clear path that incentives generic competition in order to lower medication costs. This path first incentivizes innovation by protecting a branded manufacturer's period of monopoly status through patent protection and other special extensions provided through the Hatch-Waxman Act. *See*, 35 U.S.C. § 156 (2015). Once a patent expires, generic competition is incentivized through faster and less expensive approval through the ANDA process. The district court improperly mischaracterized the entire legislative scheme and the careful balance Congress established between innovation and generic competition as being merely a "more profitable means of distributing" generic medications or a "regulatory bonus." Opinion at 24-25. The district court's apparent disagreement with the statutory scheme does not excuse refusing to apply antitrust law in the context of that framework. *See Verizon Comm's v. Trinko*, 540 U.S. 398 (2004).

Moreover, the district court incorrectly found that Mylan's allegations could not establish anticompetitive conduct based on the incorrect assumption that "Mylan remains able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development." Opinion at 25. This statement is both legally and factually incorrect. First, the court misconstrued antitrust law applicable in the generic medication marketplace. "For there to be an antitrust violation, generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones.'" *New York v. Actavis*, 787 F.3d at 656 (quoting *U.S. v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001)); *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."). Second, as discussed above, advertising and promotion by generic manufacturers is considered impractical and ineffective. *See New York v. Actavis*, 787 F.3d at 656. Generic competition pursuant to state substitution laws only occurs if a pharmacist is permitted to substitute a generic medication for a name brand one. Indeed, that inability to qualify for generic substitution pursuant to state law is the point of this litigation. Similarly, superior product development is irrelevant to a generic manufacturer who must make a product that is pharmaceutically equivalent and to the branded drug in order to be sold.

The district court also relies upon other facts that are not relevant to an antitrust analysis to support its erroneous conclusion that the alleged conduct cannot be anticompetitive. For example, the district court cites the fact that Mylan is a larger company overall in order to support its conclusion that competition was not harmed. Opinion at 24. Antitrust law, however, focuses on size in the relevant market, not size overall. The district court also finds that Mylan's charging of prices as the exclusive seller of generic 75 and 100 mg tablets that were even higher than the named branded Doryx prices undercuts its claims that Warner and Mayne's conduct was anticompetitive. *Id.* at 31. Its finding that Mylan would likely raise its prices higher than Doryx if allowed to compete under state substitution laws, *id.* at 23, is both wrong and, again, disregards the impact of generic competition on prices. States only substitute generics for name brands if they are lower in price. Mylan's price increases for the 75 and 100 mg tablets occurred only after Warner and Mayne removed its name branded product from the market to avoid competition. Thus, rather than undercutting Mylan's claims, as the district court found, Mylan's price increase shows that absent competition, prices increase rather than decrease. In any event, pricing strategies do not affect whether harm to the competitive process has occurred.

The district court's disregard for the statutory framework established to encourage generic competition as merely a "regulatory windfall" and "preferred

place" misconstrues antitrust law applicable to generic competition. Opinion at 31. The district court's decision should be reversed. Allowing such the district court's opinion to stand would greatly undermine both antitrust law and healthcare policy in general.

II. APPELLEES' PRODUCT HOPPING SCHEME IS ANTICOMPETITIVE BECAUSE IT INTERFERES WITH BOTH AN INDIVIDUAL'S RIGHT TO DIRECT THEIR OWN HEALTH CARE AND THE RELATIONSHIP WITH THEIR PHYSICIAN.

A. Consumer choice is a critical and fact-intensive factor in determining the existence of anticompetitive conduct.

The district court improperly failed to determine whether the alleged conduct interfered with consumer choice in order to evaluate whether the conduct was anticompetitive. Reformulation alone is usually not anticompetitive, but frequently, pharmaceutical reformulations offer no actual consumer benefit that would prompt a consumer to switch to the reformulated version. 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 triggers application of the antitrust laws when a brand name manufacturer also takes action to ensure consumers are denied access to the original product. Consumers are forced to switch if the original version is no longer available, and pharmacists are not able to dispense a generic substitute for the original version as a result. *Id*. In order to compete effectively—

pursuant to the interplay of federal and state law—a generic manufacturer must reformulate its generic version, and apply for and obtain FDA approval and AB rating.

Existing case law on product hopping is clear that the absence of consumer choice is a critical factor in determining that a series of planned switches to newer versions of a brand-name drug violates antitrust laws. In *Abbott Labs. v. Teva Pharms.*, Teva alleged that Abbott Labs, manufacturer of name-brand TriCor, engaged in anticompetitive behavior by switching the market between different formulations of TriCor—first, from capsule form to tablet form, and second, from the initial tablet form to a second tablet form. *Abbott Labs. v. Teva Pharms.*, 432 F. Supp. 2d 408, 415-18. Upon each reformulation, Teva alleged that the Abbott Labs eliminated or limited the availability of the preceding formulation. *Id*. In denying Abbott Labs' motion to dismiss, the court noted that "when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate." *Id*. at 421.

Conversely, the presence of consumer choice in the marketplace is significant in a court's analysis as to a finding that such conduct is not "anticompetitive." In *Walgreen Co. v. AstraZeneca Pharms.*, 534 F. Supp. 2d 146 (D.D.C. 2008), the plaintiff alleged that AstraZeneca engaged in exclusionary conduct by introducing name-brand Nexium to compete with its own "virtually

identical" drug Prilosec. *Id.* at 149. In granting AstraZeneca's motion to dismiss, the court noted that "plaintiffs have alleged no coercion, bundling, or elimination of consumer choice." *Id*. at 152.

Availability of consumer choice is a highly fact-intensive inquiry that is generally inappropriate for resolution in summary judgment. As many commenters have observed, when comparing the court's analysis in the *Abbott Labs* and *Walgreen* cases, "one might infer that the viability of product hopping antitrust claims turns largely on the strength of the facts." Sean Royall, et al., *Antitrust Scrutiny of Pharmaceutical "Product-Hopping,"* 28 Antitrust ABA 71, 73-74 (Fall 2013). These facts include whether the Defendant "[withdrew] the prior formulation from the marketplace and thereby arguably limit[ed] consumer choice." *Id.*

This was the conclusion reached by the Second Circuit in evaluating whether to uphold a district court's injunction forbidding Actavis from withdrawing name-brand versions of its Alzheimer's drug Namenda IR from the market in favor of a newer, but bioequivalent, version known as Namenda XR. The New York Attorney General had alleged that Actavis planned this withdrawal to thwart entry of lower-priced generic versions of Namenda IR. The Second Circuit's opinion focuses largely on whether consumers have a choice between different versions of Namenda. In the Court's view, "[b]y removing Namenda IR from the market prior

to generic IR entry, Defendants sought to deprive consumers of that choice." *New York v. Actavis* 787 F.3d at 655.

In this case, the parties do not dispute that Warner and Mayne limited or eliminated access to certain versions of Doryx. As to the remaining choices left to consumers, the district court's opinion does not view the scope of the market from the consumer's perspective; rather, it presumes a market that includes all drugs in the same general class, even those that realistically are not available to or appropriate for a particular consumer. For example, in granting Warner and Mayne's motion for summary judgment, the district court virtually ignores expert testimony that "effective acne treatment must be 'tailored to the patient'" and that Doryx is "not functionally interchangeable with other tetracyclines." Opinion at 15 (internal citations omitted). As Mylan noted in its own Motion for Summary Judgment, while "[a]ll doxycyclines have the potential to cause nausea or gastrointestinal irritation," Doryx has "a delayed-release coating that prevents the active ingredient from releasing until it reaches the small intestine, thereby reducing the side effects." Mylan Br. in Supp. of Mot. for Sum. Jgmt. at 18, ECF No. 553 (Mar. 17, 2014). For many consumers, older adults included, this difference could be the sole reason for choosing a version of Doryx over other tetracyclines in the same class.

Existing case law is clear that product hopping schemes could violate the antitrust laws when these schemes limit consumer choice. The district court's opinion injects uncertainty where there is none and "raises more fundamental questions about the merits of 'novel' product hopping allegations." *See* Sean Royall, et al., *Antitrust Scrutiny of Pharmaceutical "Product-Hopping"*, 28 Antitrust ABA 71, 73 (Fall 2013). Instead of following the clear factors laid out by earlier cases, the district court's opinion instead denies even the possibility that "a new product formulation should ever constitute an antitrust violation." *Id*.

B. Product hopping schemes interfere with an individual's right to make choices about their own health care.

Cases involving a "switch" between older and newer versions of the same name-brand drug raise a fundamental question of consumer autonomy regarding their own health care. To be clear, an individual can and should have the option of switching to other versions of a particular medication if and when it is available, if appropriate for the individual. Indeed, Warner and Mayne claim that each newer version of Doryx was a marked improvement over the preceding version. *See, e.g.*, Mylan Br. in Opp. to Mot. for Sum. Jgmt. at 34.

By withdrawing older versions of their product from the market, however, Warner and Mayne refuse to let the market decide the relative benefits of different products, undercutting any argument that the sequentially newer versions actually provided any of the purported "benefits." As the Federal Trade Commission has

noted, "[i]f…the firm withdraws its existing product when it introduces a new one, a presumption of consumer benefit may not be warranted." John B. Kirkwood, *The Essence of Antitrust: Protecting Consumers and Small Suppliers from Anticompetitive Conduct*, 81 Fordham L. Rev. 2425, 2458 n.137 (2013). In the FTC's view, in this situation "it may be equally inappropriate to characterize the new product introduction as superior performance." *Id*.

People have the right to make choices about their own medical treatment, a concept firmly rooted in Western concepts of medical ethics. Gail Van Norman, *Informed Consent: Respecting Patient Autonomy*, 61 Cal. Soc'y Anesthesiologists Bull. 36, 36 (2012). Providers encourage their patients to take a more active role in their health care decision-making. *See, e.g.*, Nancy Calabretta, *Consumer-Driven, Patient-Centered Health Care in the Age of Electronic Information*, J. Med. Libr. Ass'n 32, 33 (2002). Now more than ever, providers and public health officials expect patients to "keep track of their medical data, seek preventative care, and stay on top of chronic conditions." *See* Laura Landro, *The Health-Care Industry Is Pushing Patients to Help Themselves*, Wall St. J., June 8, 2014, 4:54 PM, http://goo.gl/bSCU18. This evolving doctor-patient relationship demands and presumes a higher respect for patient autonomy and patient choice that is inconsistent with the anticompetitive practice of removing older formulations from the market to impede introduction of generic alternatives.

The right to autonomy in health care decision-making is also recognized in a wide variety of state and federal laws and policies empowering people to control the direction of their own health care; these policies include statutes allowing for surrogate decision-makers, advance medical directives to refuse treatment, and informed consent to treatment. *See* Michael Ash & Stephen Arons, *Economic Parameters of End-of-Life Care: Some Policy Implications in an Era of Health Care Reform*, 31 W. New Eng. L. Rev. 305, 314 (2009) ("Although the reach and limitations of advance directives vary from state to state, they all express the principle of patient autonomy … to refuse unwanted medical treatment or have it withdrawn").

C. Anticompetitive product hopping leads to higher prescription medication costs.

While brand-name manufacturers reap monopoly profits from anticompetitive extensions of product line monopolies through product hops, the conduct increases medication costs for individuals and public and private insurers. The most effective way to lower prices is to increase competition. U.S. Food & Drug Admin., *Generic Competition and Drug Prices*, *available at* http://goo.gl/7njkcZ (last visited Sept. 22, 2015). Entry of generic competitors can reduce drug prices by 80 percent. *Id.* Over the last decade, competition between brand-name and generic drugs have saved the U.S. health system nearly $1.5

trillion. *Generic Drug Savings in the U.S.*, 1 Generic Pharmaceutical Ass'n (6th ed. 2014), *available at* http://goo.gl/cmHLrj.

Product hopping, conversely, ensures that consumers continue to pay high prices by improperly preventing generic competition, thereby increasing the duration of the monopoly on sales of brand-name drugs past that intended under U.S. law and policy. Indeed, "reformulations have impaired competition against brand products with $28.1 billion in annual sales" since 2009. Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 3 (2009). In the *New York v. Actavis*, the Second Circuit found that the product hop from Namenda IR to XR would cost consumers and third-party insurers over $1 billion. *Id.*, 787 F.3d at 661. While there has been little public information provided in this case on costs, according to Mylan, the numerous switches instituted by Warner and Mayne delayed generic entry and costs consumers "many millions of dollars." Mylan Br. in Opp. to Mot. for Sum. Jgmt., *supra* at 1. Importantly, the district court did not dispute that the reformulations to Doryx prevented consumer savings. It merely found that the conduct was not anticompetitive because it found Mylan was not precluded from other means of marketing the generic versions of a product that were not AB-rated. Product hopping schemes not only harm generic manufacturers, but lead to a considerable consumer welfare loss that constitutes antitrust injury.

III. APPLYING ANTITRUST LAW TO PRODUCT HOPPING DOES NOT HARM INNOVATION.

The district court concluded that applying antitrust law to product hopping "could well have adverse, unintended consequences." Opinion at 27. Specifically, the district court postulated that Mylan's "theory also risks slowing or even stopping pharmaceutical innovation." *Id.* at 28. The district court's assessment ignores both the robust nature of innovation incentives in the pharmaceutical industry and the harmful effects of incentivizing marginal innovation for anticompetitive rewards.

In *New York v. Actavis*, the Second Circuit rejected the argument that applying antitrust law to product hopping will harm innovation. *Id.*, 787 F.3d at 659. In that case, defendants and several of their supporting *amici* presented a false choice between allowing a product hopping strategy and supporting innovation or blocking product hopping and harming innovation. The court found that "[d]efendants have presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation." *Id.*

The Second Circuit's conclusion is well-founded. 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. Notably, the industry continued to 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.

Furthermore, in a properly functioning competitive market, it is for consumers, not the industry, to decide what qualifies as an "innovation" and what its relative value is. If a reformulated medication is innovative in a way that doctors and consumers take notice of and prefer, then the market will naturally shift to the new drug, and the pharmaceutical company will continue to earn monopoly profits. But if the reformulation is not innovative in a noticeable and preferable way, then consumers will continue to use the older version, and at a significant discount due to generic availability. Normal operation of a competitive market requires that innovations, to succeed, must not only be new, they must also have value to consumers. *See* Giada Di Stefanoa, et al., *Technology Push and Demand Pull Perspectives in Innovation Studies: Current Findings and Future Research Directions*, 41 Res. Pol'y, 1283, 1283 (2012). Allowing the market to operate through competition on the merits of the product, as opposed to the mere availability of a particular formulation, does not harm innovation, but rather ensures that innovation will produce the most value to consumers.

Market forces are especially important in directing pharmaceutical resources towards developing new and improved drugs that are truly needed by health care consumers, as opposed to remaking newer versions of existing products. As

recognized by the Second Circuit in *New York v. Actavis*, "immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." *Id*. at 659.

The truth of the Second Circuit's observation is demonstrated in this case, where the changes to Doryx were not likely to be worth investing in absent the features of the statutory framework that can be gamed to make product hopping profitable by impeding generic competition. For example, Warner and Mayne offered a capsule product that offered the advantage of being available to sprinkle on applesauce for people who could not swallow it. In its first product hop, it then eliminated the capsule form from the market. Defendants then scored their 75 mg and 100 mg tablets for greater dosing flexibility, only to later eliminate those tablets in favor of a single scored and then double scored 150 mg tablet. Inexplicably, patients no longer have access to 37.5 mg and 75 mg dosing options because of these changes.

Moreover, as discussed by the Second Circuit, product-hopping can actually harm innovation, as evidenced by industry data concerning developments of new drugs compared to drug redesigns. The number of original application submissions and approvals for new drugs has declined, while spending on drug

redesign and incremental improvements has significantly increased. *See, e.g.*, Jayashree Dubey & Rajesh Dubey, *Pharmaceutical Innovation and Generic Challenge: Recent Trends and Causal Factors*, 4 Int'l J. of Pharm. & Healthcare Marketing 175 (2010); Iain M. Cockburn, *Is the Pharmaceutical Industry in a Productivity Crisis?*, 7 Innovation Pol'y and the Economy at 1 (2006); Janice M. Reichert, *Trends in Development and Approval Times for New Therapeutics in the United States*, 2 Nature Reviews 695, 701 (2003). It is apparent that efforts to maintain market share for popular drugs are a significant factor behind 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").[2]

[2] For more information, *see* Brief of Intellectual Property and Antitrust Law Professors as Amici Curiae, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, ECF No. 596-3 (May 7, 2014).

CONCLUSION

For the foregoing reasons, amici curiae respectfully urge this Court to reverse the district court and remand for further consideration.

Date: September 30, 2015

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