16-2113

IN THE

United States Court of Appeals

FOR THE FIRST CIRCUIT

AMPHASTAR PHARMACEUTICALS INC.;
INTERNATIONAL MEDICATION SYSTEMS LTD.,
Plaintiffs-Appellants,

—v.—

MOMENTA PHARMACEUTICALS, INC.; SANDOZ INC.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BRIEF FOR CONSUMER ACTION, NATIONAL HEALTH LAW PROGRAM, UNITED STATES PUBLIC INTEREST RESEARCH GROUP, IN SUPPORT OF PLAINTIFFS-APPELLANTS

David A. Balto
Bradley A. Wasser
Matthew C. Lane
LAW OFFICES OF DAVID A. BALTO
1325 G. Street, N.W.
Suite 500
Washington, D.C. 20005
(202) 577-5424
David.Balto@dcantitrustlaw.com

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 FOR THE NATIONAL HEALTH LAW PROGRAM

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.

CORPORATE DISCLOSURE STATEMENT OF UNITED STATES PUBLIC INTEREST RESEARCH GROUP

United States Public Interest Research Group ("U.S. PIRG") is a nonprofit, nonstock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

November 8, 2016

Respectfully Submitted,

/s/David A. Balto
David A. Balto

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authority

INTERESTS 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.

For nearly fifty 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 and conducted research and policy analysis on issues affecting the health status and health access of these groups, including access to affordable prescription drugs. We work to help consumers and their advocates overcome barriers to health care, including a lack of affordable services.

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

[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. Amici curiae seek leave to file this brief through attached motion.

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 importance of generic medication and the consumer harm that would result in expanding the Noerr-Pennington doctrine to cover private standard setting activity. Amici urge this Court to reverse the district court's ruling that the conduct at issue is immune under the Noerr-Pennington doctrine; otherwise, amici are concerned that the ruling will open the floodgates to increased market manipulation if not corrected.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Amici are concerned at the growing number of anti-generic strategies employed in the pharmaceutical industry that increase costs to consumers. Generic entry increases competition and greatly decreases the cost of medication. The amount that has been saved by consumers through generic competition is measured

in the trillions. These savings are vitally important to consumers who are facing ever-increasing costs of healthcare.

Antitrust law has long served to police anti-generic practices that harm competition and therefore consumers. For example, the Supreme Court established in *FTC v. Actavis* that reverse payment schemes, an anti-generic strategy where branded manufacturers can pay generic companies to not challenge weak drug patents, can be a violation of antitrust laws. The Second Circuit also upheld a preliminary injunction in *State of New York v. Actavis* that prevented product hopping, an anti-generic strategy where drugs are slightly modified before generic entry to prevent pharmacists from being able to substitute generic medications for their customers under state substitution laws once those generics become available. This case, involving a sole generic maintaining its position by excluding rival generics, is just as harmful to competition as the brand practices discussed above.

The Defendants-Appellees in this case employed an anti-generic strategy through manipulation of a standard setting process used to ensure the safety of medication. Defendants-Appellees were participants in the private standard setting body of United States Pharmacopeial Convention ("USP"). USP was tasked with adopting a quality standard for enoxaparin, an important blood thinner. USP required participants to disclose their intellectual property, but defendants purposefully concealed the fact that there was a pending patent application

concerning a quality standard being considered for use for enoxaparin. Defendants then encouraged USP to adopt the quality standard which would utilize defendant's patent, which USP did. When plaintiff Amphastar utilized the adopted USP standard in its application to the Food & Drug Administration ("FDA") to make a generic version of enoxaparin, and gained regulatory approval to enter the market, defendants sued Amphastar claiming infringement on their intellectual property. Defendant's scheme succeeded in blocking rival generics and excluding competition in the market. Amphastar in turn sued to counter the anticompetitive conduct of defendants.

Defendants, in furtherance of their anti-generic scheme, argued that their conduct is immunized from antitrust law since they lawfully acquired the rights to their patent and made non-frivolous infringement claims in their suit against Amphastar. Ignoring precedent that such argument does not withstand scrutiny, the district court granted defendants' motion on a Noerr-Pennington theory unsupported in law, and therefore inappropriately expands the application of the Noerr-Pennington doctrine. Despite defendants not even raising this theory, the district court nonetheless applied Noerr-Pennington to defendants' standard setting conduct because, it held, the FDA followed statutory requirements in instructing applicants to comply with USP standards and should therefore be immunized from antitrust scrutiny. However, defendants did not at any time make any petition with

the FDA, which is a fundamental action when invoking Noerr-Pennington protection. Its conduct was targeted at a private standard setting organization.

The Noerr-Pennington doctrine is a narrowly applied immunity that protects First Amendment covered conduct such as petitioning the government through litigation or lobbying, or speech such as publicity campaigns. This conduct is protected even if the intended consequence of the conduct is to decrease competition. For this reason, the Noerr-Pennington doctrine, like all antitrust immunities, should be narrowly construed and not expanded beyond its established scope.

Amici write to express two concerns important to consumers. First, generic entry into the market and the competition that is encouraged through the Hatch-Waxman Act serve to decrease costs to the United Stated health care system and help consumers through lower costs and better health outcomes. Defendants' anti-generic strategy prevents generic competition by restricting generic manufacturers' ability to perform the tests necessary to meet FDA guidelines and receive FDA approval. Without generic entry, consumers lose out on vital competition and are forced to continue to pay high prices for enoxaparin.

Second, the district court's ruling effectively expands the application of Noerr-Pennington doctrine at the expense of consumer welfare. Expanding immunity to allow for anticompetitive conduct in the private standard setting arena

based on deception in a standard setting process, not a petition to the government, is problematic and will increase costs to consumers based on its exclusionary effect of competition in the market. Thus, the district court erred in its expansion of applicability of the Noerr-Pennington doctrine.

ARGUMENT

I. LOW COST GENERIC MEDICATION IS VITALLY IMPORTANT TO CONSUMER WELFARE AND ANTI-GENERIC STRATEGIES INFLICT SIGNIFICANT HARM.

The prices of prescription medications are a driving force behind ever increasing healthcare expenditures. In 2014, Americans spent $374 billion on prescription medications, a 13 percent increase from the previous year. Bill Berkot, *U.S. Prescription Drug Spending Rose 13 Percent in 2014: IMS Report*, REUTERS (Apr. 14, 2015 12:01 AM), http://goo.gl/0kzYli. Although pharmaceutical cost increases may be due to a number of factors, the added expense of brand-name medications contributes significantly to the high cost of prescription drugs. See Jordan Rau, *Brand-Name Medicines Dominate Medicare's $103 Billion Drug Bill*, NPR.COM (May 1, 2015, 9:30 AM), http://goo.gl/biS04u (finding that brand-name drugs are "among the most expensive" for the federal government's Medicare prescription benefit "costing more than $1 billion each in 2013"). The high cost of brand-name drugs can create significant financial burdens for consumers. *See* Bill Walsh, *The Tier 4 Phenomenon: Shifting the High Cost of*

Drugs to Consumers, AARP at 3 (2009), available at http://goo.gl/9w3Q0T (finding that high drug costs can cause consumer to "forgo basic living expenses").

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

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 2014 alone, generic medications saved consumers $254 billion. *Generic Drug Savings in the U.S.* 1, Generic Pharmaceutical Ass'n (7th ed. 2015), *available at* goo.gl/rIaDea. In recent years, prices for brand-name drugs have continued to climb while prices for their generic counterparts decrease. *See* Stephen Schondelmeyer and Leigh Purvis, *Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2013* (2015), *available at*: http://goo.gl/Cyoc8n (finding that "retail prices

for 280 generic prescription drugs widely used by Medicare beneficiaries fell by an average of 4.0 percent in 2013, [while] the retail prices for 227 brand name prescription drugs most widely used by Medicare beneficiaries increased by an average of 12.9 percent"). 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).

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 $1.7 trillion. *Generic Drug Savings in the U.S.* 1, Generic Pharmaceutical Ass'n (7th ed. 2015), *available at* goo.gl/rIaDea. This price competition can be disastrous for the sales of expensive brand-name medications. After only a single year of unfettered generic entry, 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, sometimes using agreements or incentives to work with generic manufacturers, have responded to such threats to their profits that comes from generic entry by engaging in various anti-generic strategies 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. 2223, 2236-37 (2013); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir 1991). For example, the anti-generic strategy called product hopping "impaired competition against brand products with $28.1 billion in annual sales" in the period from 1995 to 2009. Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 3 (2009). Indeed, in a case before the Second Circuit the court found that a single instance of product hopping would

cost consumers and third-party insurers over $1 billion. *State of New York v. Actavis*, 787 F.3d 638, 661 (2d Cir. 2015) (enjoining the challenged behavior).

Anti-generic strategies have traditionally been rejected and found to be potentially anticompetitive by courts due to their harm to consumers, and this case should be no different. *E.g.*, *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013) (finding reverse payment schemes can violate the antitrust laws); *State of New York*, 787 F.3d 638 (granting preliminary injunction preventing a product hopping scheme). In this case the defendants deceived USP, a private standard setting body, so that the only test to determine the quality of enoxaparin was controlled through a patent held by Momenta that covers the test. Because the FDA adopts these quality tests set by USP, any generic manufacturer that seeks FDA approval for generic enoxaparin would be guilty of patent infringement. This anti-generic strategy prevents generic competition by restricting generic manufacturers' ability to perform the tests necessary to meet FDA guidelines and receive FDA approval. Without generic entry, consumers lose out on vital competition and are forced to continue to pay high prices for enoxaparin. This strategy is yet another anti-generic strategy that the antitrust laws are meant to protect against.

II. THE NOERR-PENNINGTON DOCTRINE, LIKE ANY IMMUNITY, SHOULD BE NARROWLY CONSTRUED BECAUSE ANY EXPANSION WOULD COME AT THE EXPENSE OF CONSUMER WELFARE.

The Supreme Court struck a careful balance in the *Noerr* and *Pennington* cases between protecting legitimate government petitioning and protecting competition. The Noerr-Pennington doctrine created does not immunize anticompetitive conduct itself (when it is the *means* of getting to anticompetitive result), but instead immunizes petitioning activities designed to lead to a government action that has anticompetitive effects (when it is the intended *consequence* of the actions). This balance makes sense because in legitimate petitioning activity a government official or governing body, who is accountable to the public, has the ultimate decision of whether to adopt or reject the result being petitioned for. *See Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 US 492, 502 (1988) ("But where, as here, the restraint is imposed by persons unaccountable to the public and without official authority, many of whom have personal financial interests in restraining competition, we have no difficulty concluding that the restraint has resulted from private action."). This important balance is seen in the *Noerr* and *Pennington* cases themselves. While the conduct immunized by the Supreme Court in the *Noerr* and *Pennington* cases is far from exemplary, it was ultimately up to public figures to adopt the laws and rules being petitioned for. In *Eastern R. Conf. v. Noerr Motors*, 24 railroad companies worked together to launch a publicity campaign "designed to foster the adoption and retention of laws and law enforcement practices destructive of the trucking business, to create an

atmosphere of distaste for the truckers among the general public, and to impair the relationships existing between the truckers and their customers." 365 US 127, 129 (1961). In *Mine Workers v. Pennington*, large mining companies and the miner union worked together to petition the government to raise the minimum wage higher than what smaller mining companies would be able to pay and remain competitive. In both instances, those being petitioned could simply not adopt the rules and laws being petitioned for due to their harm to the public interest. 381 US 657 (1965).

Courts have therefore long applied the Noerr-Pennington doctrine narrowly so that only legitimate (non-sham) petitioning activity is immunized. *E.g.*, *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 424 F. 2d 25, 33 (1st Cir. 1970) (decision not to extend immunity does not "encroach on the freedom of speech and right to petition protected by the First Amendment"); *FTC v. Superior Court Trial Lawyers Assn.*, 493 US 411, 424-25 (1990) (Noerr-Pennington doctrine immunizes "mere attempts to influence the passage or enforcement of laws") (citation omitted); *Allied Tube*, 486 U.S. at 504 ("That rounding up supporters is an acceptable and constitutionally protected method of influencing elections does not mean that rounding up economically interested persons to set private standards must also be protected."); *Sandy River Nursing Care v. Aetna Cas.*, 985 F. 2d 1138, 1143 (1st Cir. 1993) ("[A] conspiracy to press for legislation

permitting defendants to charge higher rates was permissible unless it was implemented through an actual restraint on trade.").

Amici believe that the district court's ruling represents an ill-advised expansion of the Noerr-Pennington doctrine. The anticompetitive conduct at issue in this case is the deception of a private standard setting organization, not a petition of the government or speech directed at influencing government action. Any holding that immunizes this conduct based on later government adoption of the standards or the use of litigation to enforce the monopoly granted by such deception would therefore be an expansion of the Noerr-Pennington doctrine. It does not find support in any of the case law cited in this brief, nor is it the kind of conduct associated with First Amendment rights. Indeed, the district court's ruling appears to be in direct contradiction to the Supreme Court's analysis in *Allied Tube, Inc.*, 486 U.S. at 501-504 (declining to extend *Noerr* immunity "simply because the ultimate aim of the effort to influence the private standard-setting process was (principally) legislative action. The ultimate aim is not dispositive.").

This expansion of the Noerr-Pennington doctrine is especially harmful because it could immunize a wide range of standard setting activities. Standard setting is important in many different industries, including phones, the internet, education, construction, hotels, supply chains, automobiles and electricity, among many others. As the Supreme Court explains generally in *Allied Tube*, while

standard setting can be extremely beneficial to industries, there is also a clear risk of anticompetitive behavior that would confer monopoly power to raise prices and decrease competition. "Indeed, because private standard-setting by associations comprising firms with horizontal and vertical business relations is permitted at all under the antitrust laws only on the understanding that it will be conducted in a nonpartisan manner offering procompetitive benefits, [] the standards of conduct in this context are, at least in some respects, more rigorous than the standards of conduct prevailing in" political or litigation contexts. *Allied Tube*, 486 U.S. at 506-07 (explaining why Noerr-Pennington immunity does not apply to defendant's conduct in a private standard setting context).

Courts should uphold the well-reasoned balance the Supreme Court has struck through the Noerr-Pennington line of cases and not needlessly expand the Noerr-Pennington doctrine. Like any immunity, any expansion in the Noerr-Pennington doctrine would come at the expense of consumers. It is consumers who ultimately pay the bill when competition is reduced. We urge the First Circuit to continue the long-standing tradition of construing the Noerr-Pennington doctrine narrowly to only protect legitimate petitioning activity.

CONCLUSION

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

Date: November 8, 2016

/s/David A. Balto
LAW OFFICES OF DAVID A. BALTO
1325 G Street, N.W.
Suite 500
Washington, D.C. 20005
(202) 577-5424
David.Balto@dcantitrustlaw.com
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 3,165 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2013 in 14-point Times New Roman font.

Dated: November 8, 2016

By: /s/David A. Balto
David A. Balto
Attorney for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on November 8, 2016.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

By: /s/David A. Balto
David A. Balto
Attorney for Amici Curiae