No. 17-1714

United States Court of Appeals

for the First Circuit

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND, on behalf of themselves and others similarly situated; LABORERS HEALTH AND WELFARE TRUST FUND FOR NORTHERN CALIFORNIA, on behalf of themselves and others similarly situated; AFSCME HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; MINNESOTA LABORERS HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of themselves and others similarly situated; LOUISIANA HEALTH SERVICE AND INDEMNITY COMPANY, d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA, on behalf of themselves and others similarly situated,

Plaintiffs, Appellants,

v.

Novartis Pharmaceuticals Corporation; Novartis Corporation; Novartis AG,

Defendants-Appellees.

RXDN, INC., on behalf of themselves and others similarly situated,

Plaintiff, Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS CORPORATION; NOVARTIS AG,

Defendants, Appellees.

Plaintiffs-Appellants' Petition for Panel Rehearing

BRIEF OF OPEN MARKETS INSTITUTE AS AMICUS CURIAE IN SUPPORT OF THE PLAINTIFFS-APPELLANTS' PETITION FOR PANEL REHEARING

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INTRODUCTION AND INTEREST OF THE AMICUS CURIAE

The Open Markets Institute is a non-profit organization dedicated to promoting fair and competitive markets. It does not accept any funding or donations from for-profit corporations. Its mission is to safeguard our political economy from concentrations of private power that undermine competition and threaten liberty, democracy, and prosperity. The Open Markets Institute regularly provides expertise on antitrust law and competition policy to Congress, journalists, and other members of the public. The vigorous enforcement of the antitrust laws against mergers and monopolies is essential to protecting the U.S. economy and democracy from concentrated private power.

The *Noerr-Pennington* doctrine protects the right of citizens to petition the government. The doctrine immunizes from antitrust liability petitioning that results in legislation, regulation, or other governmental action with anticompetitive effects in a market. *E. R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). The Court's decision, however, threatens to immunize a broad range of misrepresentations and other false submissions to government agencies and courts and allow corporations to abuse governmental processes to monopolize markets. While the focus of the Court's decision is on the materiality of the misrepresentations, it is built on a foundation that assumes only two exceptions to

Noerr-Pennington immunity: false statements in patent filings and "sham" litigation. Even though these are two examples in which the Supreme Court has found express or implied exceptions in actual disputes, they are illustrative and not doctrinally exhaustive. In panel rehearing, this Court must not be limited to this narrow framework and should follow the approach of other courts of appeals and the Federal Trade Commission, which limit immunity for misrepresentations to an administrative body or court. The Open Markets Institute files this brief to explain the legal authorities and policy considerations that support denying *Noerr-Pennington* protection to a misrepresentation or omission (hereafter collectively "misrepresentations") to an administrative agency or court that is "deliberate, subject to factual verification, and central to the legitimacy of the affected governmental proceeding[.]" *In re Union Oil Co. of Cal.*, 138 F.T.C. 1, 57 (2004).

Given the adverse public consequences of an unbounded *Noerr-Pennington* immunity, the courts have established important limitations on the doctrine. *See generally* Fed. Trade Comm'n, Enforcement Perspectives on the *Noerr-Pennington* Doctrine (2006). The Supreme Court in a series of decisions has suggested that misrepresentations to administrative bodies and courts may not be entitled to *Noerr-Pennington* immunity. Informed by the Supreme Court's statements, the courts of appeals generally have recognized that misrepresentations to administrative agencies and courts do not enjoy *Noerr-Pennington* protection.

Excluding misrepresentations from *Noerr-Pennington* protection helps maintain the integrity of administrative and judicial proceedings. Decision-making by administrative agencies and courts is typically premised on truthful submissions from participants. *Union Oil*, 138 F.T.C. at 51-55 (2004). In adjudicatory matters, agencies and courts are especially dependent on the parties for factual information and typically cannot undertake their own investigations. Enforcement Perspectives on the *Noerr-Pennington* Doctrine, *supra*, at 27. Permitting parties to submit false information and claim *Noerr-Pennington* immunity would subvert administrative and judicial decision-making. Furthermore, the exclusion for misrepresentations and omissions bars firms from abusing administrative and judicial processes to acquire or maintain a monopoly. If misrepresentations were entitled to *Noerr-Pennington* protection, "building a monopoly through blatant lying would be protected." *Union Oil*, 138 F.T.C. at 45-46.

Limiting *Noerr-Pennington* protection in this fashion—and ensuring that antitrust enforcement can protect the public against firms "building a monopoly through blatant lying," *id.* at 45—is critical in pharmaceutical markets. Through the submission of false information to federal agencies, including the U.S. Patent and Trademark Office, branded drug manufacturers can block generic drug competition and deprive the public of valuable price competition. Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs*

Associated with Numbers of Manufacturers, 377 New Eng. J. Med. 2597, 2598 (2017); U.S. Food & Drug Admin., *Generic Competition and Drug Prices*, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm. By thwarting generic competition through exclusionary practices and thereby preserving monopolistic pricing, branded drug companies can inflict major harms on patients' economic and physical well-being. Mustaqeem Siddiqui & S. Vincent Rajkumar, *The High Cost of Cancer Drugs and What We Can Do About It*, 87 Mayo Clinic Proc. 935 (2012).

ARGUMENT

I. Legal Authority and Policy Considerations Support Denying *Noerr-Pennington* Immunity to Misrepresentations and Omissions to an Administrative Agency or Court

While the *Noerr-Pennington* doctrine generally confers immunity against antitrust liability[1] for the petitioning of government that results in anticompetitive legislation, regulation, or other governmental action, *E. R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965), this immunity has important

[1] "Although the *Noerr-Pennington* doctrine is frequently referred to as an antitrust immunity, it provides only a defense to liability, not an immunity from suit." *Acoustic Sys., Inc. v. Wenger Corp.*, 207 F.3d 287, 295 (5th Cir. 2000) (internal citations omitted); *accord Segni v. Commercial Office of Spain*, 816 F.2d 344, 345-46 (7th Cir.1987). Therefore, it must be raised as an affirmative defense. *Bayou Fleet, Inc. v. Alexander*, 234 F.3d 852, 860 (5th Cir. 2000).

limitations. *See generally* Enforcement Perspectives on the *Noerr-Pennington* Doctrine, *supra*. A significant body of case law has recognized that misrepresentations and omissions (hereafter collectively "misrepresentations") to administrative agencies and courts are not entitled to *Noerr-Pennington* protection. In contrast to sham petitioning that seeks to abuse governmental *process* to impair rivals and is indifferent to the *outcome*,[2] "the purpose of misrepresentations is to obtain government action." *In re Union Oil Co. of Cal.*, 138 F.T.C. 1, 43 (2004). Excluding misrepresentations from *Noerr-Pennington* immunity is necessary for protecting administrative and judicial decision-making and ensuring that firms cannot abuse legal and regulatory proceedings to obtain and maintain monopoly power. In pharmaceutical markets, which are governed by extensive federal regulation, protecting against the misuse of administrative and judicial processes is essential.

[2] For purposes of the *Noerr-Pennington* doctrine, the Supreme Court has defined unprotected sham petitioning as both "objectively baseless in that no reasonable litigant could realistically expect success on the merits" and "conceal[ing] an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, Inc., 508 U.S. 49, 60-61 (1993).

A. Legal Precedent Generally Denies *Noerr-Pennington* Immunity for Misrepresentations to Administrative Agencies and Courts

Although the Supreme Court has not decided expressly whether misrepresentations fall outside the boundaries of *Noerr-Pennington*,[3] it has indicated in a series of decisions that they may not be protected. The Court has held that the procurement of a patent through the intentional submission of false information and omission of material information to the U.S. Patent and Trademark Office can be actionable under the antitrust laws. *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 174 (1965). The Court did not examine the relevance of *Noerr-Pennington* in *Walker Process*. It, however, established the principle that material misrepresentations to one administrative agency can give rise to antitrust liability, implicitly limiting the breadth of *Noerr-Pennington* protection.[4] Marina Lao, *Reforming the* Noerr-Pennington *Antitrust Immunity Doctrine*, 55 Rutgers L. Rev. 965, 1021 (2003).

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[3] *See Prof'l Real Estate Investors*, 508 U.S. at 61 n.6 (citation omitted) ("In surveying the forms of illegal and reprehensible practice which may corrupt the administrative or judicial processes and which may result in antitrust violations, we have noted that unethical conduct in the setting of the adjudicatory process often results in sanctions and that misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process. We need not decide here whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations.").

[4] The Supreme Court also has held that "petitions to the President that contain intentional and reckless falsehoods do not enjoy constitutional protection[.]" *McDonald v. Smith*, 472 U.S. 479, 484 (1985) (internal citations omitted).

The Supreme Court has stated that misrepresentations may bar application of the *Noerr-Pennington* doctrine. When addressing the boundaries of the immunity, the Court has written that "[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972). Observing that "[t]he scope of [*Noerr-Pennington*] protection depends, . . ., on the source, context, and nature of the anticompetitive restraint at issue," *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988), the Court stated that "unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations." *Id.* at 500.

Guided by the Supreme Court's statements, most courts of appeals have ruled that misrepresentations to administrative agencies and courts are not entitled to *Noerr-Pennington* protection. Some courts have held or implied that misrepresentations fall outside the scope of petitioning under *Noerr-Pennington* or trigger an independent exception to *Noerr-Pennington*. *Amphastar Pharmaceuticals Inc. v. Momenta Pharmaceuticals Inc.*, 850 F.3d 52, 56 (1st Cir. 2017); *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1298 (5th Cir. 1971); *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1259-63 (9th Cir. 1982); *St. Joseph's Hosp. v. Hospital Corp. of America*, 795 F.2d 948, 955 (11th Cir. 1986); *Whelan v. Abell*,

48 F.3d 1247, 1255 (D.C. Cir. 1995); *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1307 (Fed. Cir. 1999). *See also Tal v. Hogan*, 453 F.3d 1244, 1260 (10th Cir. 2006) ("[The *Noerr-Pennington*] immunity does not encompass fraudulent or illegal actions."). Other courts have characterized misrepresentations as one species of unprotected sham petitioning. *Litton Sys., Inc. v. American Tel. & Tel. Co.*, 700 F.2d 785, 810-11 (2d Cir. 1983); *Potters Medical Ctr. v. City Hosp. Assn.*, 800 F.2d 568, 578 (6th Cir. 1986); *Mercatus Group LLC v. Lake Forest Hosp.*, 641 F.3d 834, 843 (7th Cir. 2011); *Razorback Ready Mix Concrete Co. v. Weaver*, 761 F.2d 484, 487 (8th Cir. 1985); *Kearney v. Foley & Lardner, LLP*, 590 F.3d 638, 646-47 (9th Cir. 2017).

This Court has stated that misrepresentations to administrative bodies or courts could trigger an exception to *Noerr-Pennington*. In *Amphastar* this Court had to decide whether false submissions to a private standard setting body are entitled to *Noerr-Pennington* immunity. 850 F.3d at 56. Because they were made to a private (as opposed to governmental) entity, these submissions were deemed to fall outside the scope of protected petitioning activity. *Id.* Nonetheless, in dictum, this Court stated that misrepresentations to administrative and judicial bodies would *not* receive *Noerr-Pennington* immunity. *See id.* ("[E]ven assuming the questionable proposition that *Noerr-Pennington* immunity would otherwise apply,

it has a well-established exception for knowing misrepresentations, at least in the administrative and adjudicatory contexts.").

Notwithstanding the different doctrinal labels applied, most courts of appeals hold that misrepresentations to administrative agencies and courts do not receive *Noerr-Pennington* protection.[5] Synthesizing the relevant court decisions, the FTC has held that "a misrepresentation or omission" that is "deliberate, subject to factual verification, and central to the legitimacy of the affected governmental proceeding" is not entitled to *Noerr-Pennington* protection. *Union Oil*, 138 F.T.C. at 57.

B. Denying *Noerr-Pennington* Immunity for Misrepresentations Safeguards Administrative and Judicial Proceedings and Protects the Public Against Monopolization by Deception

Excluding misrepresentations from *Noerr-Pennington* protection helps maintain the integrity of administrative and judicial proceedings. Decision-making by administrative agencies and courts is typically premised on truthful submissions from participants. *Union Oil*, 138 F.T.C. at 51-55. In adjudicatory matters,

[5] The Third Circuit has held that "a material misrepresentation that affects the very core of a litigant's . . . case will preclude *Noerr–Pennington* immunity," *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 124 (3d Cir. 1999), but declined to apply the misrepresentation exception in circumstances in which the governmental decision-maker engaged in its own fact-finding. *Armstrong Surgical Center, Inc. v. Armstrong Country Memorial Hosp.*, 185 F.3d 154, 164 n.8 (3d Cir. 1999). The Fourth Circuit has stated that "[i]f a fraud exception to *Noerr*[-]*Pennington* does exist, it extends only to the type of fraud that deprives litigation of its legitimacy." *Baltimore Scrap Corp. v. David J. Joseph Co.*, 237 F.3d 394, 401-02 (4th Cir. 2001).

agencies and courts are especially dependent on the parties for factual information and generally cannot undertake their own investigations. Enforcement Perspectives on the *Noerr-Pennington* Doctrine, *supra*, at 27. Permitting parties to submit falsehoods and claim *Noerr-Pennington* immunity would subvert administrative and judicial decision-making.

By protecting the integrity of administrative and judicial proceedings, the exclusion for misrepresentations bars firms from abusing these processes to acquire or maintain a monopoly. In the absence of this exclusion, firms seeking to monopolize markets would have a *legal path* for doing so. If misrepresentations were entitled to *Noerr-Pennington* protection, "building a monopoly through blatant lying would be protected." *Union Oil*, 138 F.T.C. at 45-46. Denying *Noerr-Pennington* immunity for misrepresentations allows antitrust law to police this type of monopolization strategy.

Ensuring that antitrust law can protect the public against firms "building a monopoly through blatant lying," *Union Oil*, 138 F.T.C. at 45, is critical in pharmaceutical markets. Pharmaceutical markets are structured by, in addition to common law rules, extensive federal regulation, including by the Food and Drug Administration and U.S. Patent and Trademark Office. In carrying out their missions relevant to the pharmaceutical sector, both agencies are dependent on parties submitting truthful information to them. Enforcement Perspectives on the

Noerr-Pennington Doctrine, *supra*, at 4; *Beckman Instruments, Inc. v. Chemtronics, Inc.*, 439 F.2d 1369, 1379 (5th Cir. 1970).

Through the submission of false information to these federal agencies, branded drug manufacturers can block generic drug competition and deprive the public of valuable price competition. *See* Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 New Eng. J. Med. 2597, 2598 (2017) (finding that the entry of three generic drug manufacturers into a branded prescription drug market led to significant price reductions); U.S. Food & Drug Admin., *Generic Competition and Drug Prices*, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (observing significant reductions in generic prices (relative to branded drug prices) as more generic drug manufacturers entered the market). By abusing the patent system and preserving their monopolistic pricing, branded drug companies can extract unjustified tolls from patients and payors and impair drug access and thereby imperil patient health. Mustaqeem Siddiqui & S. Vincent Rajkumar, *The High Cost of Cancer Drugs and What We Can Do About It*, 87 Mayo Clinic Proc. 935 (2012).

CONCLUSION

Significant legal authority holds that misrepresentations to an administrative body or court are *not* entitled to *Noerr-Pennington* immunity. This limitation on *Noerr-Pennington* protects the integrity of administrative and judicial proceedings and ensures that firms cannot obtain monopoly power by lying to administrative agencies and courts. Curbing *Noerr-Pennington* protection in this fashion is especially critical in pharmaceutical markets. Through the submission of false information to federal agencies or courts, branded drug manufacturers can block generic drug competition and deprive the public of valuable price competition.

In affirming the district court's dismissal of the plaintiffs-appellants' complaint, this Court only considered the *Walker Process* and sham exceptions to the *Noerr-Pennington* immunity. The Court failed to apply a separate misrepresentation exception under which "a misrepresentation or omission" that is "deliberate, subject to factual verification, and central to the legitimacy of the affected governmental proceeding" is denied *Noerr-Pennington* protection. *Union Oil*, 138 F.T.C. at 57. Accordingly, this Court should grant the plaintiffs-appellants' petition for panel rehearing.

CORPORATE DISCLOSURE STATEMENT

As required by Federal Rule of Appellate Procedure 26.1, I certify that amicus curiae Open Markets Institute is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it.

September 21, 2018

/s/ Andrew Schmidt
Andrew Schmidt

CERTIFICATE OF COMPLIANCE

According to the word-processing system used to prepare the foregoing brief (Microsoft Word for Mac 2011), the brief complies with Federal Rule of Appellate Procedure 29(b)(4) because it contains fewer than 2588 words. No party or counsel to any party to this matter authored this brief or contributed money to preparing this brief.

September 21, 2018

/s/ Andrew Schmidt
Andrew Schmidt

CERTIFICATE OF SERVICE

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September 21, 2018

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Andrew Schmidt

United States Court of Appeals
For the First Circuit

NOTICE OF APPEARANCE

No. 17-1714 **Short Title:** RXDN, Inc. v. Novartis Phar

The Clerk will enter my appearance as counsel on behalf of ***(please list names of all parties represented, using additional sheet(s) if necessary)***:

_____ as the

[ ] appellant(s) [ ] appellee(s) [✔] amicus curiae

[ ] petitioner(s) [ ] respondent(s) [ ] intervenor(s)

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Has this case or any related case previously been on appeal?

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Attorneys for both appellant and appellee must file a notice of appearance within 14 days of case opening. New or additional counsel may enter an appearance outside the 14 day period; however, a notice of appearance may not be filed after the appellee/respondent brief has been filed without leave of court. 1st Cir. R. 12.0(a).

Counsel must complete and file this notice of appearance in order to file pleadings in this court. Counsel not yet admitted to practice before this court must promptly submit a bar application. 1st Cir. R. 46.0(a)(2).