No. 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., a Colorado Corporation,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Massachusetts, Boston
No. 1:16-cv-10112-NMG

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION IN SUPPORT OF NEITHER PARTY AND IN FAVOR OF REVERSAL

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INTRODUCTION AND SUMMARY

Standards set by private business associations "have a serious potential for anticompetitive harm." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 (1988). Courts therefore must proceed cautiously before they shield conduct before a standard-setting organization (SSO) from antitrust liability under the *Noerr-Pennington* doctrine. While the Federal Trade Commission expresses no view on the merits of the underlying case, it urges this Court to reverse the district court's misapplication of the *Noerr* doctrine.

To begin with, *Noerr* does not apply where there is no petitioning of the government, yet the district court failed to identify the petitioning conduct it relied on. The district court effectively held that defendants petitioned the Food and Drug Administration (FDA), but they did not; the only petitioning at issue here took place before a private organization, not a governmental one.

Even if the defendants' conduct before the private SSO were properly deemed *indirect* petitioning of the government, the district court's ruling would still be erroneous. The Supreme Court established in *Allied Tube* that *Noerr* does not shield conduct before a private SSO

regardless of "whether the private standards are likely to be adopted into law." 486 U.S. at 506. At the very least, the district court should not have dismissed this case before it considered the defendants' alleged deception of the SSO.

Finally, *Noerr* does not shield the defendants' allegedly deceptive conduct because they later filed a patent infringement lawsuit. *Noerr* protection does not attach to the unlawful acquisition of market power merely because that market power is subsequently exploited through litigation.

INTEREST OF THE FEDERAL TRADE COMMISSION

The Federal Trade Commission is an independent federal agency that promotes competition and protects consumer welfare through enforcement of the federal antitrust laws. *See* 15 U.S.C. §§ 41 *et seq*. In that capacity, the FTC has issued staff reports concerning the appropriate scope and likely impact of antitrust exemptions such as the *Noerr-Pennington* doctrine.[1] The FTC also has challenged conduct of the

[1] *See, e.g.*, FTC Office of Policy Planning, *Enforcement Perspectives on the Noerr-Pennington Doctrine: An FTC Staff Report* (2006); FTC Office of Policy Planning, *Report of the State Action Task Force* (Sept. 2003).

very type alleged to be at issue here, involving deceptive conduct before SSOs.[2]

BACKGROUND

Plaintiffs Amphastar Pharmaceuticals, Inc. and its subsidiary, International Medication Systems, Ltd. (collectively, "Amphastar"), market the generic drug enoxaparin, an anticoagulant. *See* District Court's Memorandum & Order of July 27, 2016 (hereinafter, "Op."), at 2; Plaintiffs' Amended Complaint of September 17, 2015 (hereinafter, "Cmplt.") ¶¶1-2, 15. Defendant Sandoz sells its own generic enoxaparin in competition with Amphastar. Sandoz is the exclusive licensee of U.S. Patent No. 7,575,886 (the '886 patent), held by defendant Momenta Pharmaceuticals, Inc. (Momenta), which covers a testing method for assessing the strength, quality, and purity of enoxaparin known as the "207 Method." Op. 2; Cmplt. ¶¶3, 31. Through a "Collaboration Agreement," Momenta provides testing services for Sandoz's enoxaparin using the 207 Method. Op. 2; Cmplt. ¶¶4, 24, 31.

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[2] *See, e.g.*, *Rambus Inc. v. FTC*, 522 F.3d 456 (D.C. Cir. 2008); *Union Oil Co. of Cal. (Unocal)*, 138 F.T.C. 1 (2004); *Dell Comp. Corp.*, 121 F.T.C. 616, 618 (1996).

Amphastar alleges that the defendants deceptively induced the United States Pharmacopeial Convention (USP), a private standard-setting organization,[3] to adopt the 207 Method as the standard means for batch-testing enoxaparin. Defendants allegedly knew that their '886 patent applied to the USP 207 Method, and knew that the USP rules thus required them to disclose their rights to the '886 patent, but they nonetheless failed to disclose it. *See id.* ¶¶32-45. Amphastar further alleges that, when the FDA approved Amphastar's application to sell its enoxaparin product in September 2011, the FDA "instructed Amphastar" to use the 207 Method, adopted by the USP in 2009, to test its product. *Id.* ¶¶43, 49.

Immediately after Amphastar received FDA approval, defendants Momenta and Sandoz sued Amphastar for patent infringement, alleging that the '886 patent covered the 207 Method. Cmplt. ¶¶50-55. The district court in the patent case enjoined Amphastar from marketing its generic enoxaparin. *Id.* ¶¶58-59. On appeal, the Federal Circuit first

[3] The USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements worldwide. *See generally* U.S. Pharmacopeial Convention, About USP (last visited Nov. 5, 2016), http://www.usp.org/about-usp.

stayed and then vacated the injunction. *Id.* ¶60; *see Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).[4] Amphastar then sued for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and its California analog.

The district court dismissed the complaint. It held that Amphastar's "asserted injuries arise from the FDA's purported adoption of the 207 Method." Op. 13-14. Thus, according to the court, "*Noerr-Pennington* immunity bars Amphastar's federal antitrust claims because they allege injuries which flow from government action." Op. 13. The court acknowledged that the *Noerr-Pennington* doctrine "would not bar antitrust claims for anticompetitive effects resulting from" conduct before the USP. *Id.*

[4] The Federal Circuit subsequently held that the "safe harbor" provisions of 35 U.S.C. § 271(e) did not protect Amphastar's use of the 207 Method. *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 809 F.3d 610 (Fed. Cir. 2015), *cert. denied*, ___ S. Ct. ___, No. 15-1402, 2016 WL 2899129 (Oct. 3, 2016).

ARGUMENT

I. THE DISTRICT COURT MISAPPLIED THE *NOERR-PENNINGTON* DOCTRINE

The district court misapplied the *Noerr-Pennington* doctrine in this case. Petitioning the government for redress is generally exempt from antitrust liability. *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). The doctrine thus exempts genuine actions taken to persuade a governmental body, such as the FDA, to take a particular course of action. The district court identified no such actions by the defendants before the FDA, and the complaint alleged none. Even if defendants' alleged conduct before the USP could be viewed as a form of *indirect* petitioning of the FDA, the court's judgment could not be sustained because it failed to consider the defendants' deception before the USP.

A. The District Court Identified No Petitioning of the FDA By Defendants

Noerr applies only to "solicitation of governmental action." *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138 (1960). Absent government petitioning, *Noerr* does not apply.[5]

The district court held that *Noerr* protected the defendants' conduct on the ground that Amphastar's injuries stemmed from "the FDA's purported adoption of the 207 Method." Op. 13-14. But the court did not identify any petitioning of the FDA by the defendants. Indeed, the complaint does not allege any petitioning by the defendants of the FDA, and the defendants themselves did not claim *Noerr* protection on the basis of FDA petitioning. Without a basis to believe that defendants

[5] In limited circumstances, actions deemed "incidental" to genuine petitioning conduct—such as legitimate pre-litigation communications and non-sham cease-and-desist letters—have been held *Noerr*-exempt, "so as to preserve the breathing space required for the effective exercise of the rights [the Petition Clause] protects." *Sosa v. DIRECTV, Inc.*, 437 F.3d 923, 933 (9th Cir. 2006). *See, e.g.*, *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851 (1st Cir. 1985); *Coastal States Mktg., Inc. v. Hunt*, 694 F.2d 1358, 1366-67 (5th Cir. 1983). But the conduct at issue here—the defendants' allegedly deceptive inducement of the USP to adopt the 207 Method—is not so closely related or necessary to defendants' subsequent patent litigation that it can be deemed "incidental" to undertaking that litigation.

petitioned the FDA to adopt the 207 Method standard, the district court erred when it found *Noerr* protection attributable to FDA action.

B. Dismissal Would Be Inappropriate Under An Indirect Petitioning Theory Absent Consideration of the Alleged Deceptive Conduct

Although there is no evidence that the defendants petitioned the FDA about the 207 Method, the district court may have viewed defendants' conduct before the USP as indirect petitioning of the FDA. But even if that were a viable theory, granting *Noerr* protection here was erroneous without further consideration of defendants' allegedly deceptive conduct concerning the USP's adoption of the 207 Method.

The Supreme Court has made clear that *Noerr* does not automatically protect unethical or deceptive conduct before a standard-setting body even where the government subsequently adopts the private standard. In *Allied Tube*, the Court rejected the "absolutist position that the *Noerr* doctrine immunizes every concerted effort that is genuinely intended to influence governmental action." 486 U.S. at 503. Thus, where unethical or deceptive activity takes place "within the confines of a private standard-setting process" and not "in the open political arena," *Noerr* does not apply—regardless of "whether the

private standards are likely to be adopted into law." *Id.* at 506. The antitrust laws do not "necessarily immunize what are in essence commercial activities simply because they have a political impact." *Id.* at 507.

Indeed, even deceptive conduct *directly* before a governmental body can vitiate *Noerr* protection. In *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 424 F.2d 25 (1st Cir. 1970), for example, this Court held that *Noerr* does not protect the efforts of an industry leader "to impose his product specifications by guile, falsity, and threats." *Id.* at 32. *See also Whelan v. Abell*, 48 F.3d 1247, 1255 (D.C. Cir. 1995) (*Noerr* "cannot be stretched to cover petitions based on known falsehoods"); *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1261 (9th Cir. 1982) (no *Noerr* protection "for furnishing with predatory intent false information to an administrative or adjudicatory body").[6]

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[6] *See also Juster Assocs. v. City of Rutland*, 901 F.2d 266 (2d Cir. 1990); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119 (3d Cir. 1999); *Woods Expl. & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286 (5th Cir. 1971); *Potters Med. Ctr. v. City Hosp. Ass'n*, 800 F.2d 568 (6th Cir. 1986); *Metro Cable Co. v. CATV of Rockford, Inc.*, 516 F.2d 220 (7th Cir. 1975); *Porous Media Corp. v. Pall Corp*, 186 F.3d 1077 (8th Cir. 1999); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056 (9th Cir. 1998)*; St.*

The FTC has reached the same conclusion. In *Unocal*, supra note 2, the company Unocal purportedly induced the California Air Resources Board to adopt an industry standard covered by patents that Unocal failed to disclose. 138 F.T.C. at 2. The FTC held that misrepresentations or omissions to a governmental entity outside of the political context can warrant denial of *Noerr* protection where they are deliberate, factually verifiable, and central to the legitimacy of the governmental proceeding. *Id.* at 57.

Here, the complaint alleged misrepresentations and omissions by the defendants during USP's process of deliberation and adoption of the 207 Method. Cmplt. ¶¶32-45. Even if defendants' conduct before the USP could be deemed indirect petitioning before the FDA, the district court erred in dismissing the case without analyzing whether the alleged misrepresentations and omissions vitiate *Noerr* protection.

II. A SUBSEQUENT PATENT SUIT DOES NOT CONFER *NOERR* PROTECTION ON ALLEGEDLY ANTICOMPETITIVE CONDUCT BEFORE A PRIVATE SSO

Defendants argued below that *Noerr* foreclosed Amphastar's antitrust action, not because the FDA purportedly adopted the 207

Joseph's Hosp. v. Hosp. Corp. of Am., 795 F.2d 948 (11th Cir. 1986); *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294 (Fed. Cir. 1999).

Method, as the district court later held, but because Amphastar's injuries flowed directly from the defendants' patent suit, which *Noerr* protects. The district court did not address this argument, but it is also incorrect.

Amphastar has alleged that the defendants' deception led the USP to adopt a standard that effectively forced Amphastar to violate defendants' patent. Under Amphastar's theory, the defendants unlawfully acquired market power not from the patent lawsuit, but from the deceptive acts that preceded it.

Noerr does not retroactively protect unlawful agreements or schemes to acquire, maintain, or jointly exercise market power that defendants subsequently exploit through litigation. In *PrimeTime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92 (2d Cir. 2000), for example, a satellite television provider sued broadcast networks, local stations, and trade associations for acting in concert to deny access to programming. *Id*. at 95-97. The district court dismissed those claims, reasoning that because defendants' subsequent enforcement of their copyrights through litigation against the plaintiff was *Noerr*-protected,

their concerted refusal to license, like "the rejection of [a] settlement offer," was also protected. *Id.* at 97, 102.

The Second Circuit reversed. It noted that defendants' refusal to license could not amount to a rejection of a settlement offer, because the plaintiff's "initial offer predated the copyright infringement lawsuits," and that, at any rate, "copyright holders may not agree to [refuse to license] before, during, or after the lawsuit." *Id.* at 103. "Such an agreement would, absent litigation, violate the Sherman Act, * * * and cannot be immunized by the existence of a common lawsuit." *Id.*

Similarly, in *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n*, 814 F.2d 358 (7th Cir. 1987), the defendants entered into a collective bargaining deal that was tantamount to a price-fixing agreement and sought to enforce that agreement against the plaintiff contractor through breach-of-contract lawsuits. The Seventh Circuit held that although the defendants had sought to enforce their agreement through litigation, the *Noerr* doctrine did not protect the defendants from the contractor's antitrust claims. "The first amendment does not protect efforts to enforce private cartels," the court reasoned, "in court or out." *Id.* at 376. Likewise, in *Clipper Exxpress*,

supra, the Ninth Circuit held that antitrust violations "[do] not become immune simply because" the violators subsequently "used legal means * * * to enforce the violations." 690 F.2d at 1264.[7]

These decisions also have support in Supreme Court cases that have long held, post-*Noerr*, that antitrust claims are not foreclosed by patent infringement lawsuits brought to exploit market power acquired, maintained, or jointly exercised through the challenged antitrust misconduct. *See United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). In *Singer*, a domestic manufacturer of sewing machines conspired with two of its foreign rivals to exclude competition by assigning patents to one another and subsequently enforcing those patents through litigation against Japanese competitors. 374 U.S. at 176-192. The Court overturned the dismissal of the Government's antitrust conspiracy claim, finding it "well settled that the possession of a valid patent or patents does not give the patentee any exemption from

[7] *See also, e.g.*, *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 429 (D. Del. 2006) ("an unlawful agreement * * * or an overall unlawful scheme * * * do not become lawful because they may be enforced by immunized litigation") (internal citations omitted).

the provisions of the Sherman Act beyond the limits of the patent monopoly." *Id*. at 196-97 (citing, *inter alia*, *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942)).

In *Walker Process*, the Court held that the limited antitrust exception provided by the Patent Act does not preclude "attack[ing] the *misuse* of patent rights." 382 U.S. at 176 (emphasis added). Thus, proof that the antitrust defendant "knowingly and willfully misrepresent[ed] facts to the Patent Office * * * would be sufficient to strip [the defendant] of its exemption from the antitrust laws." *Id*. at 177.

While no claims for a *Noerr*-based exemption had been raised in either case, the Court's denial of a comparable exemption on the basis of patent rights—themselves grounded, like *Noerr*, in the federal constitution, *see* U.S. Const. art. I, § 8, cl. 8—and its reasoning about the interplay between those rights and the antitrust laws equally apply to defendants' *Noerr* argument. *See Premiere Elec.*, 814 F.2d at 374 (denial of *Noerr* immunity to litigation to enforce price-fixing agreement has support in *Singer* and *Walker Process*). Like the patent holders in those cases, the defendants here seek to retroactively shield their

alleged antitrust misconduct behind their right to bring a patent infringement action against the antitrust plaintiffs. But while the infringement lawsuit might *itself* be protected by *Noerr*—in the sense that it cannot *alone* give rise to antitrust liability—when the lawsuit exploits market power acquired through an unlawful scheme or agreement, the lawsuit cannot alone shield the overall scheme or agreement from antitrust liability.

"It is well settled that exemptions from the antitrust laws are to be narrowly construed," *Grp. Life & Health Ins. Co. v. Royal Drug Co.*, 440 U.S. 205, 231 (1979), and there is no good reason to stretch the boundaries of *Noerr* in this case. As the district court recognized, *Noerr* does not protect defendants' allegedly deceptive conduct before the USP. Op. 13-14. And for good reason: There is no constitutional right to petition a private body, as there is to petition the government. But allowing the defendants to shield conduct from antitrust scrutiny simply by instituting subsequent proceedings to exploit the market power they allegedly acquired through such conduct would effectively extend *Noerr* to petitioning before *private* bodies. *See* I Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶210, at 347 (4th ed. 2013) ("an

important premise of *Noerr* is that petitions to the government yield no antitrust liability because the government itself, rather than the private actor, takes the action challenged as anticompetitive.").

Equally troubling, shielding deception of private bodies could give deceptive parties, in certain circumstances, the power to exclude competition without any governmental decision to grant them such power. In those circumstances, as alleged here, creating market power through deception does not arise "from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Their market power would instead be the fruit of their deceptive acts. A rule that effectively endorsed such behavior likely would reduce competition without serving any of the constitutional values that give sense to *Noerr* and its progeny.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's ruling and remand for further proceedings.

Respectfully submitted,

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November 7, 2016

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), because it contains 3,017 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). I further certify that the brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) & (6), because it has been prepared in a proportionally spaced 14-point Century Schoolbook typeface, using Microsoft Word 2010.

Dated: November 7, 2016

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 7, 2016, I filed the foregoing amicus brief using the Court's appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and, thus, service on them will be accomplished by the CM/ECF system.

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