United States Court of Appeals
For the First Circuit

No. 16-2113

AMPHASTAR PHARMACEUTICALS INC.;
INTERNATIONAL MEDICATION SYSTEMS LTD.,

Plaintiffs, Appellants,

v.

MOMENTA PHARMACEUTICALS, INC.; SANDOZ INC.,

Defendants, Appellees.

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

[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Howard, Chief Judge,
Lynch and Lipez, Circuit Judges.

Chul Pak, with whom Jonathan M. Jacobson, Jeffrey C. Bank, Daniel P. Weick, Seth C. Silber, Elyse Dorsey, Wilson Sonsini Goodrich & Rosati, P.C., Alan D. Rose, Sr., Meredith W. Doty, Michael L. Chinitz, and Rose Chinitz & Rose were on brief, for appellants.

Robert S. Frank, Jr., with whom Robert M. Buchanan, Jr., Sophie F. Wang, Greta A. Fails, Choate Hall & Stewart LLP, Michael P. Kenny, Teresa T. Bonder, Matthew D. Kent, D. Andrew Hatchett, and Alston & Bird LLP were on brief, for appellees.

Deborah L. Feinstein, Director, Bureau of Competition,

Bradley S. Albert, Deputy Assistant Director, Bureau of Competition, Heather M. Johnson, Attorney, Bureau of Competition, Rajesh James, Attorney, Bureau of Competition, June Im, Attorney, Bureau of Competition, David C. Shonka, Acting General Counsel, Federal Trade Commission, Joel Marcus, Deputy General Counsel, Federal Trade Commission, and Imad D. Abyad, Attorney, Federal Trade Commission, on brief for amicus curiae Federal Trade Commission.

David A. Balto, Bradley A. Wasser, Matthew C. Lane, and Law Offices of David A. Balto on brief for amici curiae Consumer Action, National Health Law Program, and United States Public Interest Research Group.

March 6, 2017

HOWARD, **Chief Judge**. Plaintiff-Appellant Amphastar Pharmaceuticals Inc. and its wholly owned subsidiary International Medication Systems Ltd. (collectively, "Amphastar") appeal from the district court's dismissal of their complaint alleging antitrust violations by Defendant-Appellees Sandoz Inc. ("Sandoz") and Momenta Pharmaceuticals, Inc. ("Momenta"). Amphastar and Sandoz are competitors in the United States market for generic enoxaparin, an anticoagulant. Momenta serves as Sandoz's contract laboratory.

Amphastar's suit is predicated upon the defendants' alleged misrepresentations to the United States Pharmacopeial Convention ("USP"), a private standard-setting organization ("SSO") charged with ensuring the quality of drugs. According to the complaint, the defendants, in violation of a duty imposed by the USP, knowingly failed to disclose to the standard-setting body that a proposed method for testing generic enoxaparin might be covered by Momenta's pending patent application. The USP, in reliance on the defendants' misrepresentations, adopted the method, and the Food and Drug Administration ("FDA") required Amphastar to comply with it.

The defendants promptly brought an infringement suit against Amphastar, resulting in a temporary restraining order ("TRO") and subsequent preliminary injunction prohibiting Amphastar from selling enoxaparin. Although the preliminary

injunction was ultimately vacated, it did prevent Amphastar from selling its generic enoxaparin for a period of roughly three months.

Amphastar responded with the instant suit under the Sherman Act, see 15 U.S.C. §§ 1, 2, seeking damages for profits lost during the pendency of the TRO and injunction. The district court dismissed Amphastar's complaint under the so-called Noerr-Pennington doctrine, which immunizes good-faith petitioning of government entities from antitrust liability. Because its Noerr-Pennington ruling was dispositive, the court expressly declined to address the defendants' other arguments for dismissal. We hold that the district court erroneously applied Noerr-Pennington. Accordingly, we reverse the dismissal of Amphastar's complaint and remand for the district court to consider the defendants' other arguments in the first instance.

I.

In reviewing the district court's dismissal under Fed. R. Civ. P. 12(b)(6), we take as true the facts from the well-pled allegations in Amphastar's complaint. See, e.g., In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 549 (1st Cir. 2016).

In November 2003, Sandoz and Momenta entered into a collaboration agreement for the development and commercialization of enoxaparin. The agreement granted Sandoz an exclusive license to Momenta's (as yet unissued) United States Patent No. 7,575,886

("'886 patent"). It also created heavy incentives to ensure that Sandoz remained the sole provider of generic enoxaparin, including milestone and profit share payments to Momenta. Sandoz benefited because, as long as it was the only generic entrant in the market, it would be able to price enoxaparin at close to brand levels.

In early 2007, the USP began the process of establishing standards for enoxaparin, including a testing method to determine whether the relevant criteria have been met. Ultimately, in late 2009, the USP would adopt Method <207> ("Method 207") as the testing standard. Federal law requires that pharmaceutical products comply with applicable USP standards. See 21 U.S.C. § 351(b).

USP policy requires all members and participants in the standard-setting process to disclose any potential conflicts of interest, including intellectual property rights. The USP staff typically reviews these conflict of interest policies at the beginning of panel meetings. Dr. Zachary Shriver, a Momenta employee who would later be named as an inventor on the '886 patent, represented Momenta on the USP panels involved in developing the enoxaparin standard. Sandoz also participated in the panel discussions.

During the standard-setting process, the USP was unaware of the pending '886 patent application. After the patent issued in August 2009, the defendants would take the position that it

covered Method 207. Notwithstanding this potential conflict, the defendants failed to disclose the pending application to the USP.

The defendants' failure to disclose their own potential conflict stands in sharp contrast to their vigilance in raising a similar issue relating to Sanofi-Aventis ("Aventis"). In 1995, Aventis had obtained approval for the original branded version of enoxaparin. During the standard-setting process, the defendants complained to the USP that Aventis had a pending patent application that, if issued, would potentially cover Method 207. The USP accordingly persuaded Aventis to allow its application to lapse. Subsequently, the USP staff reported that it was "not aware of any patent issue that may cover the test."

In December 2009, the USP approved and adopted Method 207. The method thus became "the official test method that the FDA required of Amphastar to test . . . its enoxaparin in order to obtain and maintain its generic enoxaparin approval." Sandoz became the first entity to receive FDA approval to sell generic enoxaparin in July 2010. Amphastar received approval in September 2011.

Just two days after Amphastar's approval, the defendants filed the suit, mentioned earlier, claiming infringement of the '886 patent. The district court issued a TRO on October 7, 2011, and a preliminary injunction on October 28. The TRO and subsequent injunction prohibited Amphastar from selling enoxaparin. The

injunction was stayed (and later vacated) on appeal by the Federal Circuit on January 25, 2012. See Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1352, 1361 (Fed. Cir. 2012).

In September 2015, Amphastar filed the instant antitrust action, seeking damages for profits lost during the pendency of the TRO and preliminary injunction entered in the infringement suit. Amphastar initially filed in the Central District of California, but the case was later transferred to the District of Massachusetts. After the transfer, the district court granted the defendants' motion to dismiss.

In dismissing the complaint, the court relied exclusively upon the Noerr-Pennington doctrine, which immunizes from antitrust liability "valid efforts to elicit favorable government action . . . even if the ultimate purpose or incidental consequence of the efforts is an anti-competitive restraint on trade." The court noted that Amphastar's claimed injuries resulted from the injunction issued in the patent infringement case. It then went on to find "that the asserted injuries arise from the FDA's purported adoption of the 207 Method" and, for that reason, Noerr-Pennington barred the antitrust claims. The court rejected Amphastar's argument that the defendants' misrepresentations to the USP deprived them of immunity. Finally, the district judge expressly "decline[d] to address [the defendants'] other arguments

for dismissal" because its Noerr-Pennington ruling was "dispositive."

II.

We review the dismissal of Amphastar's complaint de novo. See, e.g., Loestrin, 814 F.3d at 549. Applying this standard, we hold that the district court erred in dismissing the complaint under Noerr-Pennington.

The Noerr-Pennington doctrine provides that a Sherman Act violation cannot be "predicated upon mere attempts to influence the passage or enforcement of laws." E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 135 (1961); see also United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). While Noerr and Pennington dealt with petitioning of the legislative and executive branches, the Court later held that "[t]he same philosophy governs the approach of citizens . . . to administrative agencies . . . and to courts." Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). Here, the defendants argue that Noerr-Pennington protects their petitioning of the federal court in the infringement suit.

At oral argument, the defendants expressly declined to take the position that Noerr-Pennington separately immunizes their conduct before the USP. Indeed, the Supreme Court has held that

petitioning of a private SSO, like the USP, generally does not trigger Noerr-Pennington protection. See Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 500 (1988). And we need not decide whether "the context and nature of the activity" at issue here is sufficiently distinct from that addressed in Allied Tube to warrant a different result. Id. at 507 n.10. This is because, even assuming the questionable proposition that Noerr-Pennington immunity would otherwise apply, it has a well-established exception for knowing "[m]isrepresentations," at least in the administrative and adjudicatory contexts. Cal. Motor, 404 U.S. at 513; see also, e.g., Allied Tube, 486 U.S. at 500. Amphastar's allegations, if proven, are sufficient to establish such an intentional misrepresentation.

The defendants similarly do not rely on the FDA's alleged adoption of Method 207 in support of their immunity argument. While the district court appeared to base its dismissal order, at least in part, on the FDA's involvement, neither party has identified any direct petitioning activity before that agency. Indeed, the defendants did not even raise this theory for dismissal in district court. Accordingly, the district court erred in applying Noerr-Pennington on this ground.[1]

[1] It is true that, under another line of cases, antitrust liability cannot be predicated upon government action. See, e.g., Tri-State Rubbish, Inc. v. Waste Mgmt., Inc., 998 F.2d 1073, 1076 (1st Cir. 1993) (citing Parker v. Brown, 317 U.S. 341 (1943)).

Before reaching the merits, we are confronted with a choice-of-law question. The defendants assert that we must apply the law of the Federal Circuit. See, e.g., Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1067 (Fed. Cir. 1998) (holding that "[w]hether conduct in the prosecution of a patent is sufficient to strip a patentee of its immunity from the antitrust laws" implicates the Federal Circuit's "exclusive jurisdiction" and, accordingly, should be decided under the law of that circuit). As an initial matter, Nobelpharma is not binding on us. And, in any event, the present dispute involves conduct before a private SSO, not patent prosecution or any other issue within the Federal Circuit's exclusive jurisdiction. See generally 28 U.S.C. § 1295(a). Accordingly, we apply our own precedent.[2]

Turning to substance, the defendants primarily contend that, regardless of whether Noerr-Pennington applies to their conduct during the standard-setting process, the doctrine precludes Amphastar from recovering damages resulting from the TRO and injunction issued in the infringement suit. This argument conflates the alleged antitrust violation with the damages caused

---

The defendants, however, do not develop any argument on this point, and we, therefore, decline to address the applicability of this distinct basis for immunity.

[2] We also note that the parties have failed to demonstrate any meaningful difference between our own law and that of the Federal Circuit on the issues relevant to this appeal.

by that violation. Courts have recognized that "[t]here is an important difference, for purposes of the Noerr-Pennington doctrine, between using litigation . . . as a basis of antitrust liability and awarding damages for efforts to use the courts to carry out private cartel agreements." Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc., 814 F.2d 358, 374 (7th Cir. 1987) (Easterbrook, J.); see also McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1561 (11th Cir. 1992) (citing Premier for the proposition that "the institution of state court litigation against the Sherman Act plaintiff . . . could furnish the source of the antitrust injury . . . even if it could not provide a basis for a Sherman Act violation under the Noerr-Pennington doctrine"). The mere existence of a lawsuit does not retroactively immunize prior anti-competitive conduct. See, e.g., Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965); United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963); Primetime 24 Joint Venture v. Nat'l Broad. Co., Inc., 219 F.3d 92, 102-03 (2d Cir. 2000).[3]

Applying these principles to the present context, the defendants' infringement suit "cannot itself be the antitrust

[3] The Federal Trade Commission, in its amicus brief, similarly takes the position that "Noerr does not retroactively protect unlawful agreements or schemes to acquire, maintain, or jointly exercise market power that defendants subsequently exploit through litigation."

violation without invoking Noerr." 2 Hovenkamp et al., IP & Antitrust § 35.05[B] (3d ed. 2017). But where "the antitrust violation is intentional deception of the standard-setting organization," the mere fact that the alleged damages are based, in part, on a lawsuit seeking an injunction does not "defeat the antitrust claim based on conduct before the standard-setting organization."[4] Id. (quoting Microsoft Mobile Inc. v. Interdigital, Inc., No. 15-723-RGA, 2016 WL 1464545, at *3 (D. Del. Apr. 13, 2016)). In essence, the mere fact that the defendants brought protected patent litigation against Amphastar does not immunize them from liability for the full amount of damages caused by their alleged antitrust violation. Significantly, the antitrust violation need not be the "sole cause" of Amphastar's injury, so long as it was a "material cause." Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994) (citation omitted).

Aside from the question of immunity, the defendants argue on appeal that Amphastar's complaint is insufficient with respect to certain elements of an antitrust claim, including

[4] As explained below, we hold only that the defendants are not protected by Noerr-Pennington immunity and otherwise express no opinion on whether Amphastar's allegations are sufficient to state a claim. We do, however, note that intentional deception of an SSO may, at least in some circumstances, constitute an antitrust violation. See, e.g., Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 314 (3d Cir. 2007); 2 Hovenkamp et al., IP & Antitrust § 35.05[B] (3d ed. 2017).

causation. They also contend that the alleged Sherman Act violations were compulsory counterclaims, which had to be raised, if at all, in the infringement suit. Because it found that the defendants were protected by Noerr-Pennington, the district court expressly declined to rule on these issues. Accordingly, we leave the defendants' additional arguments for the district court to address in the first instance on remand.

III.

For the foregoing reasons, we **REVERSE** the dismissal of Amphastar's complaint and remand to the district court for further proceedings consistent with this opinion. No costs are awarded.