

Drug Recall

COMMENTARY

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Drug Makers' Interactions with the FDA About Drug-Label Content Are Protected Under the *Noerr-Pennington* Doctrine

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Plaintiffs in pharmaceutical cases often criticize drug companies for engaging the Food and Drug Administration in dialogue, and sometimes debate, about what study data show and drug labels should say.

They claim that manufacturers use the regulatory process to "delay" the addition of new safety information to drug labels, even when the FDA ultimately agrees with the manufacturer's data interpretation and approves its labeling proposals. Such criticisms are misguided: Courts should not allow plaintiffs to transform protected and desirable regulatory interaction into tort liability.

Drug manufacturers have a constitutionally protected right to petition the FDA about appropriate content for drug labels. Under the *Noerr-Pennington* doctrine, which shields speech meant to influence public officials or government action, they should not be made liable for exercising that right. Nor would such liability make sense.

The FDA is the final arbiter of drug labeling, but it does not act in a vacuum. Data and scientific analysis from manufacturers are critical inputs to the FDA's decision-making. Imposing liability on manufacturers for engaging in this essential regulatory dialogue would stifle an important part of the scientific debate.

This is not to say the *Noerr-Pennington* doctrine can or should immunize drug manufacturers from all product liability claims. Most pharmaceutical cases are not predicated solely on protected activity, *i.e.*, the manufacturers' dialogue with the FDA. In such cases, the issue will be whether the doctrine limits plaintiffs' evidence or arguments at trial.

For example, defendant manufacturers may wish to seek orders precluding any evidence or argument that it was improper or inappropriate for the manufacturer to disagree with the FDA about the content of a label or to attempt to persuade the FDA to change its position. And if the evidence and argument are not precluded altogether, manufacturers may at minimum seek appropriate limiting instructions.

Although published decisions have not yet applied the *Noerr-Pennington* doctrine to drug labeling, the case law supports its application in this context. It is well established that the doctrine protects efforts to influence all departments of the government, including administrative agencies like the FDA, and that the doctrine precludes not only antitrust liability but also tort liability predicated on protected activity. Moreover, there is a presumption that favors drug manufacturers in these analyses: Admission of evidence of any such protected activity is presumptively prejudicial.

Drug Manufacturers' Efforts to Persuade the FDA About Drug-Label Content Constitute 'Petitioning Activity' Under *Noerr-Pennington*

The *Noerr-Pennington* doctrine is rooted in the First Amendment right to petition the government. Subject to the narrow exceptions noted below, parties who exercise their right to "influence public officials" or to influence "valid governmental action" are immune from liability premised on those efforts. See *E. R.R. Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127 (1961) ("*Noerr*"), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965) ("*Pennington*").

The right to petition “extends to all departments of the government,” including administrative agencies. *Cal. Motor Transp. v. Trucking Unlimited*, 404 U.S. 508 (1972). And *Noerr-Pennington* protection “applies to all facets of the exercise of the right of petition, from litigation to attempts to influence opinion.” *Ludwig v. Riverside County Super. Ct.*, 37 Cal. App. 4th 8 (Cal. Ct. App., 4th Dist. 1995).

Drug manufacturers’ efforts to present data to the FDA and persuade it about the proper interpretation and appropriate labeling treatment of such data fall squarely within the category of “petitioning activity” protected under *Noerr-Pennington*. Indeed, several courts have protected comparable conduct under the doctrine.¹ See *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 506 (D. Minn. 1984) (protecting efforts to influence the Occupational Safety and Health Administration’s decisions about exposure standards); *Diaz v. Sw. Wheel*, 736 S.W.2d 770, 773-74 (Tex. App. 1987) (protecting efforts to persuade the National Highway Traffic Safety Administration “not to recall or ban multi-piece rims”); *Anchorage Joint Venture v. Anchorage Condominium Ass’n*, 670 P.2d 1249, 1250-51 (Colo. Ct. App. 1983) (protecting condominium association’s right to petition local zoning board to overturn zoning variance); see also *Core-Vent Corp. v. Nobel Indus. Sweden*, No. 97-55294, 1998 WL 650269, at *3 n.3 (9th Cir. Sept. 9, 1998) (submissions to FDA about clinical studies requirement for dental implants subject to *Noerr-Pennington*).

In *Senart*, for example, the plaintiffs asserted that manufacturers of toluene diisocyanate, a substance used in foam insulation, wrongfully influenced OSHA to reject a more stringent TDI exposure standard. 597 F. Supp. at 504. The plaintiffs alleged that the defendants relied on “inadequate scientific data” and conspired to “‘obfuscate and confuse’ scientific findings which supported a more stringent standard.” *Id.*

The defendants “readily admit[ted] that they disagreed with and criticized the ... proposal for a more stringent exposure standard [and] worked ... to persuade OSHA to reject [it].” *Id.* at 506. Ultimately the court ruled that “plaintiffs assail defendants for taking a particular view in a scientific debate and for trying to retain a regulatory standard which defendants preferred. Not only do these actions not constitute torts, they are protected by the first amendment.” *Id.*

By contrast, communications with administrative agencies about ministerial actions are not protected. In those situations there is no opportunity to “influence” the government or otherwise exercise one’s First Amendment right to petition. As explained in *In re Bupirone Patent*

Litigation, “it is critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or nondiscretionary capacity in direct reliance on the representations made by private parties.” 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002).

There, the defendant’s listing of its patent in the FDA’s “orange book” did not qualify as protected “petitioning activity” because the FDA lacked discretion on whether to publish the patent in the book. *Id.* at 371. The agency did not independently assess the validity of the patent but had to assume the truth of the information because it was not an expert on patent validity. *Id.* at 370-73.

The FDA’s regulation of drug-label content is the opposite of “ministerial.” Though drug manufacturers often submit new medical data and may even request specific modifications of their labels, the agency independently determines whether it agrees with their interpretations of the data and any proposed labeling changes.

The FDA has independent medical expertise and need not assume the truth of representations about the significance of scientific or medical data. Indeed, in many cases the agency consults advisory committees, composed largely of outside experts, to review the clinical data and make recommendations as well.

The Protections of the Noerr-Pennington Doctrine Extend Beyond Antitrust Cases To Tort Liability

The Supreme Court initially articulated the *Noerr-Pennington* doctrine in the antitrust arena. *Noerr*, 365 U.S. at 138-39 (publicity campaign aimed at influencing government action to harm competitors constitutes “solicitation of government action” protected by the Bill of Rights); *Pennington*, 381 U.S. at 670 (lobbying Secretary of Labor to increase minimum wage in coal industry to drive smaller competitors out of business is not illegal, regardless of underlying purpose). But as many lower courts have since recognized, “the principle of constitutional law that bars litigation arising from injuries received as a consequence of First Amendment petitioning activity should be applied, regardless of the underlying cause of action asserted by the plaintiffs.” *Ludwig*, 37 Cal. App. 4th at 21 n.17 (citations, quotation marks and alterations omitted).

Multiple courts have recognized that the doctrine applies to tort liability generally. See, e.g., *Sosa v. DirecTV*, 437 F.3d 923, 931 (9th Cir. 2006) (*Noerr-Pennington* “applies equally in all contexts.”); *Mann v. Quality Old Time Serv.*, 120 Cal. App. 4th 90, 108 (4th Dist. 2004) (“The *Noerr-*

Pennington doctrine protects private parties from tort liability when they engage in the constitutional right to petition the government.”); *Ludwig*, 37 Cal. App. 4th at 21 n.17 (*Noerr-Pennington* applies to “virtually any tort”); *Video Int’l. Prod. v. Warner-Amex Cable Commc’ns*, 858 F.2d 1075, 1084 (5th Cir. 1988) (“There is simply no reason that a common-law tort doctrine can any more permissibly abridge or chill the constitutional right of petition than can a statutory claim such as antitrust.”); *Cheminor Drugs v. Ethyl Corp.*, 168 F.3d 119, 128 (3d Cir. 1999) (“We are persuaded that the same First Amendment principles on which *Noerr-Pennington* immunity is based apply to the New Jersey tort claims.”); “To hold otherwise would effectively chill the defendants’ First Amendment rights,” *Ludwig*, 37 Cal. App. 4th at 21 n.17.

Unsurprisingly, therefore, courts have not hesitated to apply the doctrine in product liability cases. See, e.g., *Tuosto v. Phillip Morris USA*, No. 05 Civ. 9384 (PKL), 2007 WL 2398507, at *5-6 (S.D.N.Y. Aug. 21, 2007) (dismissing fraud claim in product liability action against cigarette manufacturer in part because the claim was based on protected conduct); *Senart*, 597 F. Supp. at 506 (dismissing claim in product liability action that was premised solely on defendant chemical manufacturers’ efforts to persuade OSHA to reject proposal for more stringent exposure standards); *Hamilton v. Accu-tek*, 935 F. Supp. 1307, 1316-1317 (E.D.N.Y. 1996) (concluding that lobbying federal officials to prevent handgun regulations cannot form basis of a tort claim in action against handgun manufacturers); *Cipollone v. Liggett Group*, 668 F. Supp. 408, 410 (D.N.J. 1987) (“furnishing false and misleading information to Congress” about product “entitled to protection as political speech” under *Noerr-Pennington*, but decision about admissibility put off until trial); *Diaz*, 736 S.W.2d at 773-74 (manufacturer’s efforts to persuade the NHSTA not to recall or ban multi-piece wheel rims constitute protected activity and cannot satisfy overt act requirement of conspiracy claim in product liability action).

In *Tuosto v. Phillip Morris*, for example, the court ruled that manufacturer’s statements to Congress about smoking and health could not support plaintiff’s product liability case for design defect, failure to warn and fraud — even if those statements were false and misleading, 2007 WL 2398507, at *5. And in dismissing the plaintiff’s fraud claim — which was predicated on statements to the public as well as to Congress — the court granted leave to amend only “as to those claims of fraud not precluded by *Noerr-Pennington*.” *Id.* at *9.

Similarly, in *Hamilton v. Accu-tek*, a product liability action against handgun manufacturers for design defect, fraud

and negligence, the court found that *Noerr-Pennington* protected defendants’ lobbying activities, 935 F. Supp. at 1321. Rebuffing the plaintiffs’ claim that defendants “defrauded federal officials to prevent more stringent regulation of handguns” (*id.* at 1315), the court explained that “[l]obbying before either federal or state authorities was not tortious.” *Id.* at 1321.

Admission of ‘Petitioning Activity’ Is Presumptively Prejudicial

Though courts routinely prohibit claims predicated solely on protected petitioning activity, they are not obligated to exclude all evidence of petitioning activity protected by the doctrine.

Instead, such evidence is admissible if it “tends reasonably to show the purpose and character” of a defendant’s conduct, as long as it is “deemed ... probative and not unduly prejudicial.” See *Pennington*, 381 U.S. at 670 n.3; see also *Feminist Women’s Health Ctr. v. Mohammad*, 586 F.2d 530, 543 n.7 (5th Cir. 1978) (though evidence of medical society’s meeting and resolution prior to litigation had “some evidentiary bearing” on the plaintiff’s conspiracy claim, it was “far outweighed by the defendants’ first amendment interests”); *In re Brand Name Prescription Drugs Antitrust Litigation*, No. 94 C 897, MDL 997, 1995 WL 509666, at *2 (N.D. Ill. Aug. 18, 1995) (noting that plaintiffs must “address significant evidentiary concerns,” including risk of undue prejudice, if they intend to introduce evidence of lobbying activities).

When assessing the admissibility of protected petitioning activity, however, courts ordinarily must begin the analysis with a presumption of prejudice. As one court explained, “evidence which by its very nature chills the exercise of First Amendment rights is properly viewed as presumptively prejudicial.” *U.S. Football League v. National Football League*, 634 F. Supp. 1155, 1181, 1171 (S.D.N.Y. 1986) (striking allegations that the NFL participated in sports-related antitrust legislation, citing the “strong interest in preserving [defendants’] First Amendment rights to petition Congress” but deferring ruling on allegations that the NFL pressured local government authorities to deny stadium access to plaintiffs until trial), *aff’d*, 842 F.2d 1335, 1373-75 (2d Cir. 1988); *cf. Cipollone*, 668 F. Supp. at 411 (presumption of prejudice does not apply where the “lobbying activity, though protected, is alleged to be ethically questionable”).

In pharmaceutical cases the probative value of the petitioning activity may vary significantly depending on the facts. In a “post-label-change” case, for example, where the drug is prescribed *after* communications with the FDA have ended and *after* the new label is in place, evidence of

the drug manufacturer's prior efforts to petition the FDA about the content of the label likely will have minimal, if any, probative value. In such cases the presumption against admissibility should preclude efforts to introduce evidence or argument about a drug manufacturer's prior label discussions with the FDA.

In a scenario where the drug is prescribed while the drug manufacturer is engaged in dialogue with the FDA and *before* the new label is issued, the manufacturer may want to introduce evidence of its interactions with the FDA for various reasons. If the manufacturer introduces such evidence, the court may find that the manufacturer has "opened the door" for the plaintiff to introduce additional evidence on the same topic. See *City of Cleveland v. Cleveland Elec. Illuminating Co.*, 538 F. Supp. 1257, 1279 (D.C. Ohio 1980) ("Although plaintiff may not ... initiate inquiry designed solely to trigger admission of *Noerr-Pennington* conduct, the court recognizes ... the defendant's evidence may 'open the door.'").

But even in this scenario the manufacturer may be able to obtain an order restricting the plaintiff's argument and a limiting instruction informing the jury that it may not predicate liability on conduct protected by the First Amendment. See, e.g., *U.S. Football League*, 634 F. Supp. at 1181 (noting that to introduce evidence of petitioning activity, a trial court would be "required to instruct the jury that petitioning conduct is entirely lawful"); *Confederated Tribes of Siletz Indians v. Weyerhaeuser Co.*, No. CV 00-1693-PA, 2003 WL 24901381, at *7 (D. Or. July 5, 2003) ("Had defendant timely asserted the *Noerr-Pennington* doctrine, ... plaintiff could have limited its claims and evidence, if necessary, and the court could have given the jury any required limiting instructions.").

Exceptions to *Noerr-Pennington* Doctrine

There are two exceptions to the *Noerr-Pennington* doctrine that plaintiffs in pharmaceutical cases likely will raise, but neither should apply in most label-change suits.

First, the "sham" exception "encompasses situations in which a person uses the governmental process — as opposed to the *outcome* of that process — as an anti-competitive weapon" or a means of harassment. *City of Columbia v. Omni Outdoor Adver.*, 499 U.S. 365, 380; see also *Noerr*, 365 U.S. at 144 ("There may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor, and the application of the Sherman Act would be

justified."); *Hi-Top Steel Corp. v. Lehrer*, 24 Cal. App. 4th 570, 579 (2d Dist. 1994).

This exception does not apply where the petitioner's actions were "genuinely aimed at procuring [a] favorable government action." *Omni Outdoor Adver.*, 499 U.S. at 380 (explaining that a "sham" involves a defendant "whose activities are not genuinely aimed at procuring favorable government action at all," as opposed to a defendant "who genuinely seeks to achieve his governmental result, but does so through improper means"); see also *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492, 500 n.4 (1988).

Where a drug manufacturer is genuinely interested in the outcome of its efforts to petition the FDA about label content, the "sham" exception should not apply — even if the agency ultimately rejects the manufacturer's position. And of course, "a successful 'effort to influence governmental action ... certainly cannot be characterized as a sham.'" *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 58 (1993) ("*PREI*") (quoting *Allied Tube & Conduit Corp.*, 486 U.S. at 502).

Second, though not yet addressed by the Supreme Court, some courts have found that misrepresentations or fraud by drug manufacturers may not be protected under the doctrine. See *PREI*, 508 U.S. at 61 n.6 ("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."); *Whelan v. Abell*, 48 F.3d 1247, 1254 (D.C. Cir. 1995) ("We see no reason to believe that the right to petition includes a right to file deliberately false complaints."); *Clipper Express v. Rocky Mountain Motor Tariff Bureau*, 690 F.2d 1240, 1261 (9th Cir. 1982) ("There is no First Amendment protection for furnishing with predatory intent false information to an administrative or adjudicatory body."). See also *Cheminor Drugs*, 168 F.3d at 124 (determining that only "material misrepresentations" are precluded from *Noerr-Pennington* protection because "not every misrepresentation is material to the question of whether a petition such as [the defendant's] had an objective basis").

But fraud on the FDA, though alleged with increasing frequency, is rarely supported in fact. And such allegations would raise independent questions of federal preemption under cases holding that policing of alleged fraud on the FDA regulatory process is wholly the province of the FDA and not private tort plaintiffs. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004).

Conclusion

Depending on the facts of their cases, defense counsel in pharmaceutical products liability cases should carefully consider the potential for preclusion of prejudicial evidence or argument under the *Noerr-Pennington* doctrine.

Notes

¹ The doctrine not only protects petitioning activity, but internal e-mails, communications and memoranda that outline the details of a company's petitioning efforts constitute evidence of 'conduct incidental to a petition' and are therefore similarly protected. See *Freeman v. Lasky, Haas & Cohler*, 410 F.3d 1180, 1184 (9th Cir. 2005).

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