NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-3089

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION

MERCK & CO., INC.,
Appellant

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil Action No. 2-12-cv-03555)
District Judge: Honorable Chad F. Kenney

Argued July 9, 2024

Before: SHWARTZ, PHIPPS, and MONTGOMERY-REEVES, *Circuit Judges*.

(Opinion filed: October 7, 2024)

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OPINION*

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* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

MONTGOMERY-REEVES, *Circuit Judge*.

Antitrust law does not bar regulated parties from petitioning the government. And a petition is not a sham merely because it seeks and obtains a selfish result.

In the late 1990s, the Food & Drug Administration (the "FDA") approached Merck & Co, Inc. ("Merck") with concerns about the end-of-shelf-life potency of its mumps vaccine, the sole licensed mumps vaccine available in the United States. At the FDA's suggestion, Merck boosted the initial potency of its vaccine, presumably with the hope that increasing beginning-of-shelf-life potency would increase end-of-shelf-life potency too. This fix did not work. But Merck did not reveal that failing to the FDA because Merck was concerned that diminishing the relevant drug-label claims could hasten the arrival of competition by lowering the regulatory bar that a competitor would need to clear to show that its mumps vaccine was not inferior to Merck's, an apparent prerequisite for FDA approval. So rather than reveal that its vaccine might be misbranded, Merck allegedly (1) concealed its ongoing potency problems, (2) ran a flawed clinical trial, and (3) relied on that unreliable data to persuade the FDA to license a less potent vaccine.

Appellees are a collection of physicians and physicians' groups who filed a class-action lawsuit alleging that they bought Merck's mumps vaccines at inflated prices. Among other things, their complaint alleges that Merck unlawfully extended its apparent monopoly by making false drug-label claims with the goal of thwarting competition, in violation of § 2 of the Sherman Act, 15 U.S.C. § 2. After lengthy discovery, Merck moved for summary judgment on a few grounds, including that the *Noerr-Pennington*

doctrine purportedly shielded Merck from liability under the Sherman Act because the asserted harm to competition flowed from Merck's genuine and successful petitioning of the FDA. The District Court rejected Merck's motion for summary judgment on the antitrust claim and granted Merck's request to file an interlocutory appeal under 28 U.S.C. § 1292(b). This appeal followed.

The record contains troubling evidence that Merck sought to extend its apparent monopoly by misrepresenting facts about its mumps vaccines on the FDA-approved drug labeling. But those allegedly false claims were the result of Merck's genuine and successful petitioning of the FDA. And *Noerr-Pennington* immunity is not vitiated "simply because [the relevant petitioning] . . . ha[d] a commercial impact and involve[d] conduct that can be termed unethical." *E. R.R. Presidents Conf. v. Noerr Motor Freight*, 365 U.S. 127, 141 (1961). Thus, there is no genuine dispute of material fact that *Noerr-Pennington* immunity attaches to Merck's alleged anticompetitive scheme. And we will reverse-in-part the District Court's order denying summary judgment.

I. BACKGROUND[1]

Because Merck moved for summary judgment, the following recitation of the facts resolves all disputes and draws all reasonable inferences in Appellees' favor. *Physicians Healthsource, Inc. v. Cephalon, Inc.*, 954 F.3d 615, 618 (3d Cir. 2020).

A. Facts

From 1967 until 2022, Merck was the sole licensed manufacturer of mumps vaccines in the United States. Merck accompanied doses of its vaccine[2] with FDA-approved labeling that provided information about the drug, including its "shelf life, minimum potency requirements, basis for licensure, and effectiveness[.]" *See* App. 10,029. Merck had an ongoing duty to ensure that its drug label was accurate. *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009) ("[I]t [is] . . . a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.").

In the late 1990s, the FDA raised concerns that Merck's mumps vaccine might be sub-potent toward the end of its 24-month shelf life, meaning that doses might not contain the minimum amount of live virus stated on the drug label. Merck agreed—at the

[1] We write for the benefit of the parties and recite only essential facts. For a more detailed discussion of the factual background, see this Court's related decision in *United States ex rel. Krahling v. Merck & Co.*, No. 23-2553, 2024 WL 3664648, at *1–5 (3d Cir. Aug. 6, 2024).

[2] Merck sold two branded mumps vaccines during the years relevant to this appeal, MMR-II and ProQuad. For simplicity—and because the vaccines used the same mumps component—we refer to a singular "vaccine" when discussing Merck's mumps vaccines.

FDA's suggestion—to boost the initial potency of its vaccine, presumably with the hope that overfilled doses would have enough buffer to remain potent through the end of their shelf life.

Overfilling doses did not fix the end-of-shelf-life potency problem with Merck's mumps vaccine. But Merck did not share that information with the FDA because Merck was concerned that the FDA might—at a minimum—order Merck to reduce the drug-label claims about the shelf life and seroconversion of its mumps vaccine.[3] Weakening label claims was not a palatable option to Merck because a rival pharmaceutical manufacturer, GlaxoSmithKline ("GSK"), sold a comparable mumps vaccine in Europe and wanted to bring that vaccine to the United States. Merck feared that GSK's domestic launch was "imminent." App. 4840. And Merck was wary of hastening GSK's arrival by lowering the bar to entry, as GSK needed to show that its mumps vaccine was not inferior to Merck's mumps vaccine to gain FDA approval. So rather than open the door to competition by disclosing that its mumps vaccine might be misbranded, Merck sought to extend its apparent monopoly by (1) misrepresenting or concealing information about the end-of-shelf-life potency of its vaccine and (2) filing a Supplemental Biologics

[3] Seroconversion "refers to a person going from being 'seronegative' prior to vaccination, which generally means lacking pathogen specific antibodies, to being 'seropositive' after vaccination, which means possessing such antibodies." *In re Merck Mumps Vaccine Antitrust Litig.*, 685 F. Supp. 3d 280, 293 (E.D. Pa. 2023).

License Application ("sBLA") seeking the FDA's approval to maintain the existing drug-label claims about shelf life and seroconversion with a less potent vaccine.

To support its sBLA, Merck ran a new trial—called Protocol 007—to demonstrate that Merck could reduce the potency of its vaccine without impairing the existing drug-label claims about seroconversion. According to Appellees, Protocol 007 was a flawed study that did not reliably capture immunogenicity.[4] Nonetheless, Merck leveraged the results of Protocol 007 to persuade the FDA to approve Merck's sBLA. As a result of the FDA's approval, Merck continued to make unsupported or misleading claims about the shelf life and seroconversion of its mumps vaccine on the drug label.

GSK could not replicate Merck's drug-label claims about seroconversion. And that led GSK to conclude that the FDA would view GSK's mumps vaccine as inferior to Merck's. Eventually, GSK accessed the methodology underlying Protocol 007 and relied on the same or similar assays[5] as Merck to establish non-inferiority. The FDA—which knew about Merck's end-of-shelf-life potency problems and the alleged flaws with Protocol 007, *see United States ex rel. Krahling v. Merck & Co.*, No. 23-2553, 2024 WL

[4] Immunogenicity "provides information about how a subject's immune system responds to different stimuli, including vaccination." *In re Merck Mumps Vaccine Antitrust Litig.*, 685 F. Supp. 3d at 293.

[5] Assays refer to types of tests. *See*, *e.g.*, *Assay*, Oxford English Dictionary, https://www.oed.com/dictionary/assay_n?tab=meaning_and_use#37098486 (last visited Sept. 29, 2024) ("The trying (of a person or things); trial imposed upon or endured by any object, in order to test its virtue, fitness, etc.").

3664648, at *8 (3d Cir. Aug. 6, 2024)—accepted GSK's clinical evidence and, in 2022, approved GSK's application to sell a competing mumps vaccine in the United States.

To date, the FDA has not asked Merck to change the relevant drug-label claims, issued a recall, ordered revaccinations, or taken any other action against Merck for the purported issues with its mumps vaccine. The Centers for Disease Control and Prevention (the "CDC") continues to buy mumps vaccines from Merck and GSK. *Id.* at *5. And the CDC's Advisory Committee on Immunization Practices continues to recommend Merck's mumps vaccine and deems it "fully interchangeable" with GSK's vaccine. *Id.*

B. Procedural History

Appellees are a collection of physicians and physicians' groups who claim that they bought Merck's mumps vaccine at an inflated price. Their operative complaint alleges several claims against Merck, including monopolization in violation of § 2 of the Sherman Act, 15 U.S.C. § 2. After lengthy discovery, Merck moved for summary judgment on a few bases, including that (1) *Noerr-Pennington* immunity purportedly attached to all of Merck's allegedly anticompetitive conduct, and (2) Appellees purportedly failed to adduce evidence of antitrust injury.

The District Court granted-in-part and denied-in-part Merck's motion for summary judgment,[6] rejecting Merck's contentions that it was entitled to summary

[6] The District Court granted Merck's motion for summary judgment with respect to Appellees' state-law claims. Appellees do not challenge that decision on appeal, so we do not address it.

judgment on *Noerr-Pennington* immunity and antitrust injury. Merck sought and obtained the District Court's permission to file an interlocutory appeal under 28 U.S.C. § 1292(b). This Court accepted the appeal.

II. DISCUSSION[7]

"[T]his case is and always has been about Merck's label for its [mumps vaccines] and its use of those labels to keep GSK out of the market." App. 264. So our analysis begins—and ends—with the FDA-approved drug label.

A. Law

"Section 2 of the Sherman Act 'makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce.'" *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 433 (3d Cir. 2016) (quoting *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007)). Appellees assert that Merck violated § 2 by "implement[ing] a scheme to unlawfully protect its monopoly" through "false and misleading claims on its mumps-vaccine labels that GSK needed to match to enter the U.S. market." Response Br. 1. According to Appellees,

[7] The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1367. We have jurisdiction under 28 U.S.C. § 1292(b).

We exercise plenary review over the District Court's order denying summary judgment. *Huber v. Simon's Agency, Inc.*, 84 F.4th 132, 144 (3d Cir. 2023) ("Our review of an order granting [or denying] summary judgment is plenary, meaning we review anew the District Court's summary judgment decision, applying the same standard it must apply." (cleaned up) (quoting *Ellis v. Westinghouse Elec. Co.*, 11 F.4th 221, 229 (3d Cir. 2021))). Summary judgment is appropriate only if there is no genuine dispute of material fact and the movant is entitled to judgment as a matter of law. *Id.* (citing Fed. R. Civ. P. 56(a)).

"Merck knew [that] neither its vaccine, nor GSK's, could meet those claims." *Id.* But Merck did not reveal that reality to the FDA or the public. As a result, "Merck's strategy succeeded: it delayed GSK's entry into the U.S. market by over a decade." *Id.*

The record contains evidence that Merck sought to extend its apparent monopoly by artificially raising the bar that GSK had to clear to obtain FDA approval for its competing mumps vaccine. That alleged anticompetitive conduct might not have violated the Sherman Act, however, because "[a] party who petitions the government for redress generally is immune from antitrust liability" even if their petitioning "causes an anti-competitive effect." *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999) (collecting cases).

This petitioning immunity—named the *Noerr-Pennington* doctrine after a pair of seminal Supreme Court decisions, *see E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)—is rooted in a few considerations, including constitutional-avoidance concerns related to the First Amendment's Petition Clause, *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc. ("P.R.E.")*, 508 U.S. 49, 56 (1993), and the notion that Congress did not intend to proscribe harm to competition that "is the result of valid government action, as opposed to private action," *Noerr*, 365 U.S. at 136.[8] The immunity extends to

[8] *See also City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 383 (1991) ("As we have described, *Parker* and *Noerr* are complementary expressions of the principle that the antitrust laws regulate business, not politics; the former decision protects the States' acts of governing, and the latter the citizens' participation in government."); *Edinboro Coll. Park Apartments v. Edinboro Univ. Found.*, 850 F.3d 567,

petitioning of all three branches of government, including administrative agencies like the FDA. *Cheminor*, 168 F.3d at 122 ("This immunity extends to persons who petition all types of government entities—legislatures, administrative agencies, and courts." (citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972))).

While *Noerr-Pennington* immunity is broad, its scope "is not absolute." *In re Wellbutrin XL Antitrust Litig. Indirect Purchasers Class*, 868 F.3d 132, 148 (3d Cir. 2017). And controlling precedent recognizes one exception implicated here: petitions that are "not genuinely aimed at procuring favorable government action" are deemed a sham and receive no immunity. *P.R.E.*, 508 U.S. at 58 (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 n.4 (1988)). "[E]vidence of anticompetitive intent or purpose alone cannot transform otherwise legitimate activity into a sham." *Id.* at 59 (collecting cases). Rather, the sham exception hinges on whether the petitioner sought to use the invocation of governmental process—as opposed to the result of that process—to harm competition. If the former, the petition is a sham, and no immunity attaches. If the latter, the petition is not a sham, and the sham exception does not apply.

For a petition to be a sham, two things must be true. First, the petition "must be objectively baseless in the sense that no reasonable [petitioner] could realistically expect success on the merits." *P.R.E.*, 508 U.S. at 60. Second, the petitioner must subjectively

572 (3d Cir. 2017) ("In *Parker v. Brown*, 317 U.S. 341 (1943), the Supreme Court held that the Sherman Act does not prohibit anticompetitive state action.").

intend to "use . . . governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon" "to interfere *directly* with the business relationships of a competitor." *Armstrong Surgical Ctr., Inc. v. Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 158 n.2 (3d Cir. 1999) (cleaned up) (quoting *P.R.E.*, 508 U.S. at 60–61). Courts consider the petitioner's "subjective motivation" "[o]nly if [the] challenged [petition] is objectively meritless." *P.R.E.*, 508 U.S. at 60. Thus, evidence of a petitioner's subjective intent cannot create a genuine dispute of material fact about whether *Noerr-Pennington* immunity applies if a petition has objective merit. *See id.*

When a petition contains misrepresentations, this Court "determine[s] whether [the] petition [is] objectively baseless under the [first step of the] Supreme Court's test in *PRE*, without regard to those [false] facts[.]" *Cheminor*, 168 F.3d at 123 (emphasis omitted). Even if a petition would be objectively meritless with the truth, the petition is not a sham unless the plaintiff "pass[es] the second[] 'subjective test'" by showing that the petitioner's subjective "purpose was [*not*] to secure the *outcome* of the [governmental] process" that they invoked. *Armstrong*, 185 F.3d at 158 n.2. *See also Omni*, 499 U.S. at 380 ("A 'sham' situation involves a defendant whose activities are 'not genuinely aimed at procuring favorable government action' at all, not one 'who genuinely seeks to achieve his governmental result, but does so *through improper means*.'" (quoting *Allied Tube*, 486 U.S. at 500 n.4, 508 n.10)).

B. Party Arguments

Merck argues that its purported anticompetitive scheme boils down to successfully petitioning the FDA to maintain the existing claims about seroconversion, shelf life, and

potency that Merck included on the drug label for its mumps vaccine. *Noerr-Pennington* immunity shields legitimate petitions that seek to harness government action for selfish purposes. *See, e.g.*, *P.R.E.*, 508 U.S. at 58 ("In short, '*Noerr*[*-Pennington* immunity] shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose.'" (quoting *Pennington*, 381 U.S. at 670)). Merck claims that its alleged anticompetitive scheme fits that bill, so it is immune from liability under the Sherman Act.

Appellees respond that there is a genuine dispute of material fact about whether *Noerr-Pennington* immunity bars their antitrust claim for three main reasons. First, Appellees argue that "Merck's responses to [the] FDA [were] not petitioning actions but rather required answers in a regulatory proceeding" and thus were a "mere *incident* of regulation" not cloaked by immunity. Response Br. 58–59 (quoting *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 807 (2d Cir. 1983)). Second, Appellees argue that Merck's petitions were a sham because "Merck knowingly misrepresented the specifications of its vaccines," and those "misrepresentations caused [the] FDA to have 'no negative feedback.'" *Id.* at 61–62 (quoting App. 5575, 9784). Third, Appellees appear to argue that even if *Noerr-Pennington* immunity shields Merck's communications with the FDA, summary judgment is improper because "Merck's misleading *public label claims*" were themselves—or were the result of—private conduct, not government action. *Id.* at 54, 54–58. And Appellees claim that they can rely on "facts indisputably outside of *Noerr* protection" to prove that Merck violated the

Sherman Act, like "public statements," "internal documents" from Merck and GSK, "and unrebutted expert testimony." *Id.* at 31.

The following analysis begins by addressing whether Merck petitioned the FDA and then turns to the sham exception and Merck's non-petitioning conduct.

C. Analysis

There is no genuine dispute of material fact that *Noerr-Pennington* immunity shields Merck from liability for its alleged anticompetitive conduct. For starters, we have no trouble concluding that Merck's communications with the FDA involved petitioning. Required or not, those communications sought to persuade the FDA to approve or refrain from changing the claims about seroconversion, shelf life, and potency that Merck included on the drug label for its mumps vaccine. Asking the FDA to raise the bar for competition by confirming that Merck—and, by extension, GSK—must meet inflated claims about immunogenicity to sell a mumps vaccine in the United States fell within the heartland of petitioning activity. *See, e.g.*, *Noerr*, 365 U.S. at 136 (describing petitioning as "an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly."). And nothing was

incidental or passive about the FDA's continued approval of Merck's drug-label claims in response to petitioning designed to elicit that exercise of governmental discretion.[9]

Likewise, it is apparent that Merck's petitioning was not a sham.[10] "A winning [petition] is by definition a reasonable effort at petitioning for redress and therefore not a sham." *P.R.E.*, 508 U.S. at 60 n.5. There is no dispute that Merck succeeded in persuading the FDA to approve the relevant claims about seroconversion, shelf life, and potency that Merck included on the drug label for its mumps vaccine. So it appears at first blush that Merck's petitioning necessarily had objective merit because it persuaded the FDA.

Appellees push back on this analysis by pointing to evidence that Merck allegedly withheld or misrepresented information when corresponding with the FDA. Even if we assume that Merck's petitions would lack objective merit without those alleged

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[9] *See also Wyeth*, 555 U.S. at 568 ("Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application."); *cf. Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 707 (1962) (no petitioning involved because the defendants "were engaged in private commercial activity, no element of which involved seeking to procure the passage or enforcement of laws"); *Litton*, 700 F.2d at 806–07 ("filing of . . . tariffs" with the Federal Communications Commission was "a mere *incident* of regulation" not entitled to immunity because "[t]he decision to impose and maintain the . . . tariff was made in [the defendant-company's] boardroom, not at the [Commission]"); *In re ZF-TRW Airbag Control Units Prods. Liab. Litig.*, 601 F. Supp. 3d 625, 751 (C.D. Cal. 2022) (mandatory responses to government agency did not involve petitioning because the responses did not "urge [the agency] to exercise its administrative discretion by taking or refraining from an action" (cleaned up)).

[10] Because it is apparent that Merck's petitioning was not a sham, we need not—and do not—decide whether the sham exception is limited to the adjudicative sphere, or whether Merck's communications with the FDA should be characterized as adjudicative or legislative.

falsehoods,[11] Appellees concede that they "do not allege injury from the process at all, never mind an abuse of that process," Response Br. 63. Thus, Appellees' theory of the case seems to be that Merck intended to use the *result* of petitioning the FDA to thwart competition by "ma[king] misrepresentations that caused [the] FDA to give 'no negative feedback'" about Merck's end-of-shelf-life potency problems and the sBLA. *Id.* (quoting App. 5575, 9784). By definition, Merck cannot have intended to commit a sham if it sought to use the result of petitioning the government (*i.e.*, FDA-approved drug label claims)—as opposed to the petitioning itself—to harm competition. *See P.R.E.*, 508 U.S. at 60–61. And Appellees do not explain how there can be a genuine dispute of material fact about whether Merck subjectively intended to commit a sham if there is no evidence that Merck's invocation of process itself harmed competition. Thus, Appellees have failed as a matter of law to satisfy the subjective prong of the *P.R.E.* test because there is no genuine dispute of material fact that Merck did not intend to commit a sham. And there is no need to send this case to trial on objective merit if a reasonable jury could not find that the subjective prong of the *P.R.E.* test is met. *Cf. Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("[S]ummary judgment will not lie if the dispute about a

[11] At least with respect to immunogenicity, that is a dubious premise considering that the FDA has not ordered Merck to change the relevant drug-label claims or taken any action against Merck after learning of the alleged end-of-shelf-life potency problems and Protocol 007. *See Krahling*, 2024 WL 3664648, at *7–8.

material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.").[12]

Finally, Appellees' attempt to rely on evidence of Merck's non-petitioning conduct to establish an antitrust violation has a minor flaw and a major flaw. The minor

[12] Several of our sister circuits appear to recognize a standalone exception to *Noerr-Pennington* immunity for petitions—made in an adjudicative setting—containing fraudulent misrepresentations. *See, e.g.*, *Amphastar Pharms. Inc. v. Momenta Pharms., Inc.*, 850 F.3d 52, 56 (1st Cir. 2017) ("*Noerr-Pennington* immunity . . . has a well-established exception for knowing misrepresentations, at least in the administrative and adjudicatory contexts." (cleaned up)); *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 842 (7th Cir. 2011) ("[T]here is little doubt that fraudulent misrepresentations may render purported petitioning activity a sham not protected from antitrust liability." (cleaned up)); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1060 (9th Cir. 1998) ("[I]n the context of a judicial proceeding, if the alleged anticompetitive behavior consists of making intentional misrepresentations to the court, litigation can be deemed a sham if a party's knowing fraud upon, or its intentional misrepresentations to, the court deprive the litigation of its legitimacy." (cleaned up)). *See generally* Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 203a–b, d–f (last updated May 2024).

Appellees expressly disclaim reliance on a separate exception for fraudulent misrepresentation. Response Br. 65 (arguing that the Seventh Circuit's opinion in *Mercatus* is distinguishable because it "addressed a separate exception for fraudulent misrepresentation—an exception the Third Circuit rejects" (first citing 641 F.3d at 845–46; and then citing *Cheminor*, 168 F.3d at 124)). Thus, Appellees have waived any argument based on that purported exception. *Barna v. Bd. of Sch. Dirs. of the Panther Valley Sch. Dist.*, 877 F.3d 136, 147 (3d Cir. 2017) ("Waiver . . . is the intentional relinquishment or abandonment of a known right." (cleaned up)); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 336 (3d Cir. 2009) ("[E]xplicitly disclaim[ing]" an argument "clearly demonstrates . . . that the issue is waived"). And we may not address it on appeal. *TD Bank N.A. v. Hill*, 928 F.3d 259, 276 n.9 (3d Cir. 2019) ("[W]e may affirm on any ground supported by the record as long as the appellee did not *waive*—as opposed to *forfeit*—the issue." (collecting cases)).

Moreover, even if we were to construe Appellees' brief as forfeiting—as opposed to waiving—an argument based on the fraudulent-misrepresentation exception, *but see Barna*, 877 F.3d at 147 ("Forfeiture is the failure to make the timely assertion of a right,

an example of which is an inadvertent failure to raise an argument." (cleaned up) (quoting *United States v. Olano*, 507 U.S. 725, 733 (1993))), *Cheminor* expressly declined to adopt a standalone exception for fraudulent misrepresentations in the adjudicative sphere. 168 F.3d at 123 (The plaintiff "argues either that *Noerr-Pennington* immunity does not apply at all to petitions containing misrepresentations or that [the petitioner's] alleged misrepresentations led to the conclusion that the relevant petition "was objectively baseless. We decline to carve out a new exception to the broad immunity that *Noerr-Pennington* provides. Rather, we will determine whether [the] petition was objectively baseless under the Supreme Court's test in *PRE*, without regard to those facts that [the plaintiff] alleges [the petitioner] misrepresented." (emphasis removed)). *See also id.* at 131–32 (Sloviter, J., dissenting) ("The majority's decision to disregard the facts that [the plaintiff] alleges [the petitioner] misrepresented is contrary to the position of the two other courts of appeals that have considered this issue. Both of these courts read *PRE* to preserve a fraud exception to antitrust immunity, although they vary in their interpretation of that exception." (citations omitted); "Unlike the majority, I conclude that the District Court erred in recognizing only a single exception to *Noerr-Pennington* immunity based on 'objective baselessness[.]'").

A few months later, this Court's decision in *Armstrong* clarified that a plaintiff still must show that the petitioner sought to use government process itself—as opposed to the result of that process—as an anticompetitive weapon to invoke the sham exception to *Noerr-Pennington* immunity, confining the narrow exception that *Cheminor* recognized to the first prong of the *P.R.E.* test, objective merit. *See* 185 F.3d at 158 n.2. In so doing, *Armstrong* explained that "[w]hile *Cheminor* focuse[d] on the sham exception to *Noerr* immunity, it also reject[ed the plaintiff's] more general argument that '*Noerr-Pennington* immunity does not apply at all to petitions containing misrepresentations.'" *Id.* (quoting *Cheminor*, 168 F.3d at 123). *Armstrong* then seems to have—like *Cheminor*—rejected a general fraud exception to *Noerr-Pennington* immunity, explaining that "[l]iability for injuries caused by . . . state action is precluded even where it is alleged that a private party urging the action did so by bribery, deceit or other wrongful conduct that may have affected the decision making process." *Id.* at 162. *See also id.* at 164 (Schwartz, D.J., dissenting) ("With its decision today, the majority holds private parties who make misrepresentations that pervasively influence the decision making process of public entities are entitled to immunity under both the state action immunity doctrine and the *Noerr–Pennington* immunity doctrine.").

While reasonable minds can and do differ, *see* Dissenting Op. at 4–6, we read *Cheminor* and *Armstrong* to reject a standalone exception to *Noerr-Pennington* immunity for petitions containing fraudulent misrepresentations in this context. And we are bound by those decisions even if we disagree with the result that they produce in this appeal. *United States v. Harris*, 68 F.4th 140, 146 (3d Cir. 2023) ("[I]t is a well-established

flaw is that Appellees sometimes appear to treat *Noerr-Pennington* immunity like an evidentiary privilege that bars the *use* of genuine petitions to prove an antitrust violation. But *Noerr-Pennington* immunity is not a rule of evidence that prevents plaintiffs from using the contents of a genuine petition to prove an antitrust violation. Rather, *Noerr-Pennington* immunity is a substantive principle of antitrust law—derived from the statutory text and purpose of the Sherman Act—that shields defendants from liability based on the notion that "[t]he federal antitrust laws . . . do not regulate the conduct of private individuals in seeking anticompetitive action from the government." *Omni*, 499 U.S. at 379–80.[13] So the question is not whether Appellees adduced non-petition evidence showing that Merck schemed to unlawfully extend its apparent monopoly. Rather, the question is whether the evidence that Appellees adduced supports a reasonable inference that it was Merck's private conduct—not the FDA's exercise of

'tradition of this court' that an opinion with precedential authority 'is binding on subsequent panels.'" (quoting 3d Cir. I.O.P. 9.1)).

[13] *See also Pennington*, 381 U.S. at 670 n.3 ("It would of course still be within the province of the trial judge to admit . . . evidence" of an alleged conspiracy between private parties and a government actor "under the established judicial rule of evidence that testimony of prior or subsequent transactions, which for some reason are barred from forming the basis for a suit, may nevertheless be introduced if it tends reasonably to show the purpose and character of the particular transactions under scrutiny." (cleaned up) (collecting cases)); *Nat.-Immunogenics Corp. v. Newport Trial Grp.*, No. SACV 15-02034 JVS(JCGx), 2018 WL 6137597, at *3 (C.D. Cal. May 16, 2018) ("*Noerr-Pennington* insulates parties from liability for their petitioning conduct, it is not an independent evidentiary privilege.").

regulatory discretion, which Merck's petitioning sought to induce—that delayed the launch of GSK's competing vaccine.

The major flaw is that the evidence Appellees adduced cannot link Merck's private conduct to GSK's delay without passing through the drug-label claims about seroconversion, shelf life, and potency that Merck persuaded the FDA to approve. That regulatory approval was an act of governmental discretion, not Merck's private conduct in the marketplace, and thus is shielded by *Noerr-Pennington* immunity.

The crux of Appellees' theory of antitrust injury is that Merck "delayed the launch of [GSK's] competing vaccine by over a decade" by making or preserving "deceptive statements on its mumps-vaccine labels." Response Br. 29. Those deceptive statements caused delay, Appellees assert, because GSK's plan for its mumps vaccine aimed to match the publicly available information within Merck's label. That was necessary, in Appellee's view, because GSK needed to configure its vaccine to reach the relative effectiveness of Merck's vaccine. Thus, "Merck's false, inflated labeling claims [allegedly] delayed GSK's entry by over a decade" by improperly exaggerating the claims about "potency, shelf-life, and seroconversion" that GSK had to meet to show that its vaccine "was 'non-inferior' to Merck's vaccine," a prerequisite "[t]o gain U.S. approval." *Id.* at 5–6 (cleaned up).

The trouble for Appellees is that the heart of their case—allegedly false or misleading claims about seroconversion, shelf life, and potency that Merck included on the FDA-approved label for its mumps vaccine—was both the object and the result of Merck's successful petitioning of the FDA. When the FDA approached Merck with

concerns about the end-of-shelf-life potency of its mumps vaccine, Merck had two main options: (1) reveal that its mumps vaccine might be misbranded and then consider remedial actions, like reducing the 24-month shelf life that Merck listed on the drug label; or (2) persuade the FDA that overfilling doses fixed that problem with end-of-shelf-life potency even though Merck knew that was not true and then file an sBLA requesting the FDA's permission to maintain the existing drug-label claims about seroconversion with a less potent, and hence longer-lasting, mumps vaccine. Merck chose the second option. That gambit worked. And the FDA did not order Merck to change its drug label or take any action against Merck after learning the truth about the purported problems with its vaccine. So even if Merck publicly admitted to misrepresenting claims on its mumps vaccine, Appellees cannot show how their harm flowed from Merck's *private* conduct when the FDA—*government* process—approved the label. That is because GSK's vaccine *still* would have lacked approval and licensure on account of the FDA who—with knowledge of the purported problems—allowed Merck to retain its existing drug-label claims. Thus, there is no genuine dispute of material fact that GSK's delay was caused by *the FDA's* exercise of regulatory discretion in response to Merck's successful petitioning. And *Noerr-Pennington* immunity bars Appellees' § 2 claim against Merck as a matter of law because the antitrust injury that

Appellees assert is the result of government action, not private conduct. *See, e.g.*, *Omni*, 499 U.S. at 379–80.[14]

Appellees' brief contains some scattered arguments to the contrary. None changes our analysis. For example, Appellees seem to argue that Merck engaged in private conduct every time that it printed or distributed its allegedly deceptive drug label because it was Merck—not the FDA—that arranged those publications. "Prospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 304 (2019) (citations omitted). The end result of that work is a drug label that the manufacturer provides or makes available to physicians, pharmacies, patients, and other interested parties. *See id.* at 303–04 ("Although we commonly understand a drug's 'label' to refer to the sticker affixed to a prescription bottle, in [some] context[s] the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy." (citing 21 U.S.C. § 321(m))). Thus, Appellees appear to suggest an overbroad rule that would vitiate *Noerr-Pennington* immunity whenever a pharmaceutical manufacturer successfully petitions the FDA to sell a new drug, as a plaintiff could evade immunity by focusing on the contents of the FDA-

[14] Of course, had Appellees raised a genuine dispute of material fact about whether an exception to *Noerr-Pennington* immunity applies, like the sham exception, Merck could be liable under the Sherman Act even if the alleged antitrust injury flowed from Merck's petitioning of the FDA.

approved label instead of the FDA's discretionary decision to approve the drug. We are reluctant to remove *Noerr-Pennington* immunity root-and-stem from the drug-approval process. And Appellees offer no controlling authority to support that sweeping proposition.

Moreover, Appellees fail to explain how it was Merck's decision to publish the label—instead of the FDA's decision to approve the underlying drug-label claims—that delayed GSK's entry. As discussed above, Appellees' core theory of antitrust injury is that Merck sought to thwart competition by raising the bar that GSK had to clear to obtain FDA approval. Merck's allegedly false or misleading label claims may have helped cause that impediment. But that is because *the FDA* approved those statements and thus could be expected to hold other pharmaceutical manufacturers to the same standard when examining non-inferiority.[15] Accordingly, based on the evidence and arguments presented here, there is no genuine dispute of material fact that it was the FDA's approval of the relevant claims that Merck included on its drug label that

[15] Things might be different, for example, if a pharmaceutical manufacturer included information on a drug label that the FDA did not approve. And a rival manufacturer inferred that its vaccine was inferior based on the false impression that the FDA had approved those unapproved claims. We are not presented with that sort of fringe circumstance here, however, as Appellees base their claim on information that the FDA allowed Merck to include on the drug label for its mumps vaccine.

allegedly delayed GSK's entry to the U.S. market. And Appellees' attempt to cast the content of Merck's FDA-approved drug label as private conduct fails.[16]

Next, Appellees cite internal documents allegedly showing that Merck intentionally sought to thwart competition so that Merck could keep collecting monopoly rents. These documents support a reasonable inference that Merck acted with anticompetitive intent. But anticompetitive intent does not defeat *Noerr-Pennington* immunity. *Noerr*, 365 U.S. at 140 (The "legality" of a petition "[is] not at all affected by any anticompetitive purpose it may have had."). And Appellees cannot explain how Merck's *internal* machinations delayed GSK's arrival without passing through the FDA-approved drug-label, which was the object and result of Merck's genuine petitioning—and thus involved government action, not private conduct—for the reasons offered above.

Last, Appellees imply that Merck's decision *not* to inform the FDA about problems with Merck's mumps vaccine—as opposed to actively misrepresenting facts while corresponding with the FDA—did not constitute petitioning and thus fell under the umbrella of private conduct. Merck's alleged decision to omit facts from the petitions that it filed with the FDA about the relevant drug-label claims was "incidental" to

[16] The handful of cases that Appellees cite do not support their assertion that Merck's drug-label claims involved private conduct because none of those cases relied on government-approved information heightening a government-imposed licensing requirement to show antitrust injury. *Cf. Ticor Title Ins. Co. v. FTC*, 998 F.2d 1129, 1138 (3d Cir. 1993) (collective rate setting approved by insurance regulators); *Barton's Disposal Serv., Inc. v. Tiger Corp.*, 886 F.2d 1430, 1436–37 (5th Cir. 1989) (suggesting that "predatory pricing" may be private conduct); *In re: Lipitor Antitrust Litig.*, 868 F.3d 231, 264 (3d Cir. 2017) (private settlement agreement submitted to government); *Litton*, 700 F.2d at 807 (unilateral tariff).

Merck's "valid effort to influence governmental action," *Allied Tube*, 486 U.S. at 499 (quoting *Noerr*, 365 U.S. at 143), as Merck naturally had to decide what information to include—and what information to omit—when petitioning the FDA. Indeed, categorizing omissions as private conduct would seem to carve out a vast exception to *Noerr-Pennington* immunity, as plaintiffs could evade the doctrine altogether—include its exceptions, like the sham-petition exception—by focusing on omissions from petitions instead of the petitions themselves. *See, e.g.*, *Allied Tube*, 486 U.S. at 507 (explaining that *Noerr-Pennington* immunity does not apply to "commercial activities simply because they have a political impact" (citing *Noerr*, 365 U.S. at 141)).

Given that concern, we are satisfied that the existing limitations on immunity, like the sham-petition exception, suffice to preserve antitrust liability consistent with the spirit and purpose of the *Noerr-Pennington* doctrine.[17] We therefore reject Appellees' argument that Merck's decision to omit information when corresponding with the FDA constituted private conduct in the marketplace, categorically unprotected by *Noerr-Pennington* immunity.

* * * * *

In sum, we hold that (1) Merck engaged in petitioning activity when it sought and obtained the FDA's approval to make the relevant drug-label claims; (2) Merck's

[17] As mentioned above, *see infra* note 12, other circuit courts appear to recognize a standalone exception to *Noerr-Pennington* immunity for fraudulent misrepresentation. Appellees expressly disclaim reliance on that exception, and we read controlling precedent to have expressly declined to adopt that exception, so we do not address it.

petitioning conduct was not a sham because it genuinely sought and obtained that governmental action; and (3) Appellees' alleged antitrust injury flows from the FDA's discretionary decision to approve Merck's drug-label claims, not Merck's private conduct. Accordingly, Merck is entitled to summary judgment on the antitrust claim because *Noerr-Pennington* immunity shields Merck from liability for its alleged scheme to unlawfully raise the regulatory bar for competition by preserving false or misleading claims on the FDA-approved drug label for Merck's mumps vaccine.[18]

III. CONCLUSION

For the reasons discussed above, we will reverse-in-part the District Court's order and remand this case with instructions to enter summary judgment for Merck.

[18] Because we hold that Merck is shielded by *Noerr-Pennington* immunity, we need not address whether there is a genuine dispute of material fact about antitrust injury. *See Ethypharm S.A. Fr. v. Abbott Lab'ys*, 707 F.3d 223, 232 n.17 (3d Cir. 2013) (antitrust standing does not implicate Article III jurisdiction).

SHWARTZ, Circuit Judge, dissenting.

This case presents an important question: should a party who makes misrepresentations and material omissions when petitioning the government be granted antitrust immunity? I think not. As a result, I depart from my colleagues and would affirm the District Court's order denying Merck summary judgment because a jury should resolve factual disputes over whether Merck made misrepresentations that preclude it from obtaining Noerr-Pennington immunity for its petitioning activity. I would also affirm because, even without considering Merck's petitioning activity, a reasonable jury could still conclude that Merck engaged in anticompetitive conduct by maintaining misrepresentations on its vaccine's label to protect its monopoly in the mumps vaccine market.[1]

I

A

Under the Noerr-Pennington doctrine, "[a] party who petitions the government for redress generally is immune from antitrust liability." Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir. 1999). The doctrine is rooted in the First Amendment's right to free speech and to petition the government for redress. See New W., L.P. v. City of Joliet, 491 F.3d 717, 722 (7th Cir. 2007) (holding Noerr-Pennington is "understood as an application of the [F]irst [A]mendment's [S]peech and [P]etitioning [C]lauses"); see also E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 138-39 (1961)

[1] No party asserts that the vaccine is unsafe or ineffective.

(holding that subjecting a company's "political activity" but "not business activity" to the antitrust laws would be an "unjustified" congressional invasion into the Bill of Rights). Because, however, the First Amendment's Petitioning Clause does not tolerate abusing government process, the Supreme Court has created the "sham exception" to Noerr-Pennington. Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993) ("PRE"). This exception strips immunity from a litigant whose petitioning activity is both (1) "objectively baseless" and (2) subjectively motivated by anticompetitive aims to abuse the governmental process. Id.

Related to the notion that immunity should not be conferred to disingenuous actors, some circuits have recognized another exception to Noerr-Pennington immunity known as the misrepresentation or fraud exception.[2] This exception is based on the idea

[2] Eight federal circuit courts have recognized or otherwise suggested that a misrepresentation exception to Noerr-Pennington exists, with some treating it as distinct from the sham exception and others applying it as an exception within the sham exception. The Courts of Appeal for the First, Fifth, Ninth, and Eleventh Circuits have expressly recognized a distinct misrepresentation exception. See Amphastar Pharms., Inc. v. Momenta Pharms., Inc., 850 F.3d 52, 56 (1st Cir. 2017) ("Noerr-Pennington immunity . . . has a well-established exception for knowing misrepresentations, at least in the administrative and adjudicatory contexts." (internal quotation marks, citation, and alteration omitted)); Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1062-63 (9th Cir. 1998); St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am., 795 F.2d 948, 955 (11th Cir. 1986) ("When a governmental agency . . . is acting judicially" then "[m]isrepresentations . . . do not enjoy Noerr immunity."); Woods Expl. & Producing Co. v. Aluminum Co. of Am., 438 F.2d 1286, 1298 (5th Cir. 1971) (holding that the filing of false documents related to requests to transport gas to a state agency was not immunized because the "conduct was not action designed to influence policy" and "abuse of the administrative process . . . does not justify antitrust immunity"). On different occasions, the Court of Appeals for the Seventh Circuit has seemingly treated the misrepresentation exception as both distinct from the sham exception and incorporated therein. See U.S. Futures Exch., L.L.C. v. Bd. of Trade of the City of Chicago, Inc., 953 F.3d 955, 960 (7th Cir. 2020) ("Fraudulent misrepresentations made in an adjudicative proceeding before an administrative agency

that a party does not have a First Amendment right to misrepresent material facts while petitioning for government action during an adjudicative proceeding. As the Court of Appeals for the Ninth Circuit observed, a petitioner's misrepresentations to a government agency "deprive[s] the entire [adjudicative] proceeding of its legitimacy." Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1062-63 (9th Cir. 1998). The circuit courts that recognize the misrepresentation exception derive it from the Supreme Court's suggestion in an antitrust case that "[m]isrepresentations . . . are not immunized when used in the adjudicatory process." Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513

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are not protected from antitrust liability."); Mercatus Grp., LLC v. Lake Forest Hosp., 641 F.3d 834, 843 (7th Cir. 2011) (explaining when "a misrepresentation renders an adjudicative proceeding a sham"). The Court of Appeals for the Sixth Circuit has applied the misrepresentation as part of the sham exception. See Potters Med. Ctr. v. City Hosp. Ass'n, 800 F.2d 568, 580-81 (6th Cir. 1986) ("[K]nowing and willful submission of false facts to a government agency falls within the sham exception to the Noerr-Pennington doctrine. Such knowingly false submissions or intentional misrepresentations constitute an abuse of government process[.]" (internal citations omitted)). The Court of Appeals for the Fourth Circuit has noted that the exception may exist, but it did not reach the issue as the plaintiff there failed to establish any material fraud or deceit. See Balt. Scrap Corp. v. David J. Joseph Co., 237 F.3d 394, 401-02 (4th Cir. 2001) (noting that whether a misrepresentation exception to Noerr-Pennington exists is an open question, but that if one does, "it extends only to the type of fraud that deprives [an adjudicative proceeding] of its legitimacy"). Likewise, the Court of Appeals for the District of Columbia Circuit, in determining whether Noerr-Pennington applied to certain common law tort claims outside of the antitrust context, has suggested that the doctrine would not extend immunity to an entity's misrepresentations. See Whelan v. Abell, 48 F.3d 1247, 1254-55 (D.C. Cir. 1995) ("However broad the First Amendment right to petition may be, it cannot be stretched to cover petitions based on known falsehoods . . . . [A] knowing assertion of false claims is not protected by Noerr-Pennington[.]").

(1972).[3, 4] For the exception to apply, the misrepresentation must have been (1) "intentionally made, with knowledge of its falsity[,]" and (2) "material, in the sense that it actually altered the outcome of the proceeding." Mercatus Grp., LLC v. Lake Forest Hosp., 641 F.3d 834, 843 (7th Cir. 2011) (citing, inter alia, Cheminor, 168 F.3d at 124).

B

Although our Court has not expressly recognized a misrepresentation exception, our precedent does not foreclose it. Our caselaw counsels against tolerating a party's material misrepresentations in petitioning activity during an adjudicative proceeding. In Cheminor, for example, we declined to decide whether a misrepresentation exception exists outside of the sham exception but observed, within the confines of the sham exception, that "a material misrepresentation that affects the very core of a litigant's . . . case will preclude Noerr-Pennington immunity[.]" 168 F.3d at 124 (emphasis omitted).

Less than four months after Cheminor, we made a statement in Armstrong Surgical Center, Inc. v. Armstrong County Memorial Hospital, that, read out of context, could be

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[3] See also Cal. Motor Transp. Co., 404 U.S. at 513 ("There are many [] forms of illegal and reprehensible practice which may corrupt the administrative or judicial processes and which may result in antitrust violations. Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process . . . . Insofar as the administrative or judicial processes are involved, actions of that kind cannot acquire immunity by seeking refuge under the umbrella of 'political expression.'"). More than two decades later, the Supreme Court again noted the possibility of a misrepresentation exception. See PRE, 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.").

[4] See supra note 1. Although Woods Exploration & Producing Co. was decided before California Motor, its view that Noerr-Pennington protects "action designed to influence policy" but not "abuse of the administrative process" echoes California Motor. 438 F.2d at 1298.

viewed as foreclosing a misrepresentation exception. See 185 F.3d 154, 162-63 (3d Cir. 1999). Specifically, we stated that

> the Sherman Act [] forecloses liability predicated on anticompetitive injuries that are inflicted by states acting as regulators. Liability for injuries caused by such state action is precluded even where it is alleged that a private party urging the action did so by bribery, deceit or other wrongful conduct that may have affected the decision making process.

Id. Putting aside whether that dispute arose in the legislative or adjudicative context,[5] this quoted language appears at the conclusion of the Court's discussion of a Supreme Court case that seemingly rejected a misrepresentation exception in legislative-type proceedings, namely a zoning board's enactment of an ordinance. Id. at 161-62 (discussing City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365 (1991)). Thus, the Armstrong Court's use of the phrase "states acting as regulators" within its discussion of a state body acting in a legislative context shows that it was speaking of proceedings where an agency is engaged in promulgating regulations, rather than where an agency enforces regulations against a particular entity in a judicial-like adjudicative setting. Id. at 162. This matters because the misrepresentation exception applies only to adjudicative, as opposed to legislative, proceedings. See U.S. Futures Exch., L.L.C. v. Bd. of Trade of the City of Chicago, Inc., 953 F.3d 955, 960 (7th Cir. 2020); see also Cal. Motor Transp. Co., 404 U.S. at 513 (distinguishing between the "political arena" and an "adjudicatory process"). Therefore, the above quoted language in Armstrong reflects

[5] Armstrong involved antitrust claims that arose after the state health department denied a medical practice a certificate of need that was required to operate in the state. 185 F.3d at 156-57.

only the uncontroversial rule that there is no misrepresentation exception in legislative proceedings, which accords with our sister circuits.[6]

Accordingly, I would recognize a misrepresentation exception to Noerr-Pennington in the context of adjudicative proceedings.

C

Because the misrepresentation exception applies only in the adjudicative context, I consider next whether Merck's petitioning activity occurred in an adjudicative or legislative proceeding. To determine whether a proceeding is adjudicative or legislative for Noerr-Pennington immunity purposes, courts consider:

> (1) the general nature of the authority exercised by the agency; (2) the formality of the agency's fact-finding process; (3) the extent to which fact gathering is subject to political influence; (4) whether the agency received any testimony under oath, affirmation, or penalty of perjury; and (5) whether the agency acted ultimately as a matter of discretionary authority or instead acted in accordance with more definite standards subject to judicial review.

U.S. Futures Exch., L.L.C., 953 F.3d at 960; see also Mercatus Grp., LLC, 641 F.3d at 844-48 (noting that whether an agency is acting in an adjudicative or legislative capacity is circumstance dependent).

The record here shows that Merck's communications with the FDA occurred in the adjudicative context. Specifically, (1) the nature of the proceeding was similar to a

[6] Moreover, a close reading of Armstrong shows that this statement was dicta because the ultimate holding was based on the absence of evidence to suggest that the misrepresentations there were material, Armstrong Surgical Ctr., Inc., 185 F.3d at 163, and thus the statement was not necessary for the Court's holding. See Tyler v. Cain, 533 U.S. 656, 663 n.4 (2001) (noting that dictum is "not binding" and is different from a holding, with dictum not being necessary to the end result (citation omitted)).

judicial proceeding in that the FDA was evaluating the evidence to determine whether, and to what extent, to impose sanctions on Merck; (2) the factfinding was conducted by independent, subject-matter experts; (3) the decision-making was made by unelected experts, not subject to the whims of political pressure; (4) false statements to the FDA are subject to criminal penalties, see 18 U.S.C. § 1001; and (5) the threatened actions in the FDA's Warning Letter would have been subject to judicial review, see 21 C.F.R. § 12.140 (procedures for judicial review of the FDA Commissioner's final decisions). See U.S. Futures Exch., L.L.C., 953 F.3d at 960; cf. St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am., 795 F.2d 948, 950-55 (11th Cir. 1986) (concluding that an antitrust case based on alleged misrepresentations to a state licensing authority could move forward because the agency acted more judicially than legislatively).

Accordingly, because (1) there is a misrepresentation exception to Noerr-Pennington immunity for petitioning activity in adjudicative proceedings; (2) the exception may apply here because Merck's communications with the FDA occurred in an adjudicative setting; and (3) there are factual disputes about whether Merck knowingly and intentionally made material misrepresentations to the FDA, I would affirm the order denying Merck summary judgment and allow a jury to resolve those disputes and, based upon those findings, allow the District Court to determine whether an exception bars Merck from being cloaked with Noerr-Pennington immunity.[7] See Rock River

[7] Although the briefing and oral argument focused on the sham exception, the briefs mention the misrepresentation exception. Thus, it is fairly before us, and "[w]e may affirm on any ground supported by the record as long as the appellee did not waive – as opposed to forfeit – the issue." Montemuro v. Jim Thorpe Area Sch. Dist., 99 F.4th

Commc'ns, Inc. v. Universal Music Grp., Inc., 745 F.3d 343, 352 (9th Cir. 2014) (noting that it is premature and "not appropriate" to rule on exceptions to Noerr-Pennington "where the facts are disputed" (characterizing Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1253-54 (9th Cir. 1982))).

II

Separately, even if we were to ignore Merck's petitioning activity with respect to its Form 483, Warning Letter, and BDPR communications with the FDA,[8] the remaining facts, viewed in Plaintiffs' favor, provide a basis for a reasonable jury to find that Merck engaged in unlawful anticompetitive behavior.[9] In short, the record, viewed in Plaintiffs' favor, shows that (1) Merck's MMR-II label was approved in the 1970s and was continually used thereafter; (2) decades after the label was approved, Merck learned that the public-facing label may not be accurate with respect to the seroconversion rate[10] and

639, 646 (3d Cir. 2024) (quotation marks, italics, and alteration omitted). Moreover, Appellee's suggestion that the misrepresentation exception is not recognized in this Circuit was not a waiver as it was not an "intentional relinquishment or abandonment of a known right" because the statement was premised upon an incorrect understanding of our precedent. Id. (internal quotation marks and citation omitted).

[8] Merck seeks to invoke Noerr-Pennnington immunity only for these three activities.

[9] I am not treating Noerr-Pennington as an evidentiary rule, see Majority Op. at *24, but rather, I am examining the record to determine whether there is a basis for antitrust liability without regard to Merck's three FDA petitioning activities at issue in this case.

[10] Merck knew that data suggested that its mumps vaccine was not providing the protection its label suggested against the types of virus strains people would likely encounter.

potency/shelf-life claims,[11] and withheld that information from the public;[12] and (3) Merck was reluctant to modify the claims on its approved label because doing so would make it easier for its competitor, GSK, to enter the market and cut into Merck's monopoly and profits.[13] Therefore, focusing only on what Merck learned about potential

[11] Specifically, Merck's internal documents show that it knew that even after overfilling the vaccine, it could not guarantee that by end-expiry its potency claims on its label would be accurate. Indeed, Merck's scientist who was tasked with developing the assay used to support its label claims designed the assay with that goal in mind and "without considering the impact on accuracy." App. 5133-34. Moreover, Merck acknowledged internally that there was no correlation between the ELISA assay it designed and the results from the more accurate PRN assay. Accordingly, there are factual disputes about whether Merck's label claims were supported by the science.

[12] Merck was aware that the public would want to know this information and that disclosure about sub-potent vaccine lots could have resulted in a recall, vaccine tracing, and large numbers of revaccinations.

[13] See, e.g., App. 5031 (Merck presentation noting that "[r]elaxing the criteria for success would lower the bar for the competition"); App. 5037 (Merck email noting "lowering the seroconversion rate in the label would help GSK"); App. 5379 (Merck memo noting its decisions about whether to pursue label and testing changes could "facilitate licensure of Priorix"); App. 4962 (Merck report noting commercial impacts of reducing shelf life); App. 7716 (Merck email noting "concern if [GSK] has better sensitivity and higher seroconversion rates – competition??"); App. 4840 (Merck Defense Action Plan noting MMR-II was "under threat of significant change and disruption due to" GSK); App. 4844 (Merck likewise noting MMR-II was "under imminent threat"); App. 5195 (Merck acknowledging that Priorix's licensure would "significantly increase competition"); App. 5291 (Merck noting its "defensive activity"); App. 4840-42 (Merck Defense Action Plan Background); App. 5291-92 (Merck email regarding strategy in light of GSK licensing efforts).

For every month that Merck maintained its monopoly by keeping GSK out of the market, it earned an additional $10 million in revenue. In light of Merck's financial interest in keeping GSK out of the market, a reasonable jury could conclude that Merck knowingly stood by its label's misrepresentations to (1) make it harder for GSK to gain FDA approval and thus (2) thwart competition. Evidence that GSK paused developing its MMR vaccine after it could not mirror Merck's label corroborates such a conclusion. To be sure, other factors could have contributed to the GSK vaccine's pause, e.g., budget constraints. However, a jury could reasonably conclude that GSK's budget would not have been prohibitively constrained were it not for extra-high costs of matching Merck's

inaccuracies on its label after the label was approved[14] and its internal reaction to that data, including withholding information about the label's inaccuracies from the public to protect Merck's monopoly,[15] the record viewed in Plaintiffs' favor would permit a reasonable jury to find that Merck violated the antitrust laws by engaging in anticompetitive acts that are "on some basis other than the merits." LePage's Inc. v. 3M, 324 F.3d 141, 147 (3d Cir. 2003) (en banc).[16]

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misleading label. Accordingly, a jury should decide whether Merck's misrepresentations or omissions, or GSK's own business decisions, delayed GSK's entry into the market.

[14] Plaintiffs do not assert that Merck made any knowing misrepresentations in connection with its FDA communications associated with the original approval of MMR-II. Nor do they do not seek to hold Merck liable for any petitioning activity arising from those communications. This is a critical distinction because Merck's decision to continue to include misrepresentations on its public-facing label is divorced from any petitioning activity associated with the label's original approval as the misrepresentations and omissions at issue here occurred only after the label was already approved. Therefore, the original petitioning activity is independent from Merck's decision to maintain its label for the express purpose of preventing GSK from entering into the mumps vaccine market.

[15] See, e.g., App. 5506 (Merck email noting data suggested it would "need to get [a] label change").

[16] Additionally, viewing the facts in Plaintiffs' favor, a reasonable jury could find that Merck's actions caused Plaintiffs' injuries because (1) GSK was clearly "willing and able to supply [Priorix] but for [Merck's] exclusionary conduct[,]" Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 862 (D.C. Cir. 2008); and (2) Plaintiffs' injury—lack of price erosion and therefore higher prices for the mumps vaccine—was directly related to Merck's successful efforts to keep GSK out of the marketplace. Moreover, contrary to my Colleagues' assertion, see Maj. Op. at *27, a reasonable jury viewing the facts in Plaintiffs' favor could conclude that the need for the FDA to approve a license for GSK's vaccine before GSK could enter the market does not break the chain of causation because (1) the FDA was not an intervening actor because GSK put its licensing efforts on hold due in part to the challenges it faced mirroring Merck's allegedly misleading label even before going through the FDA approval process; and (2) GSK's delayed market entry, based on the FDA's requirement that it mirror Merck's label claim, was a foreseeable consequence of Merck's alleged label misrepresentations, see In re Flonase Antitrust Litig., 798 F. Supp. 2d 619, 629 (E.D. Pa. 2011) ("Intervening conduct does not sever the chain of causation [] where that conduct was in turn proximately caused by the defendant's antitrust violation. Intervening conduct also does not sever the chain of

III

For the foregoing reasons, I would affirm the District Court's order denying Merck summary judgment and as a result, respectfully dissent.

causation where that conduct was a foreseeable consequence of the original antitrust violation."); see also In re Suboxone Antitrust Litig., 622 F. Supp. 3d 22, 78 (E.D. Pa. 2022) (same). The jury may also consider whether the actions of the FDA broke the chain of causation.