No. 26-1473

In the
United States Court of Appeals
for the Fourth Circuit

CAREFIRST OF MARYLAND, INC.; GROUP HOSPITALIZATION & MEDICAL SERVICES, INC.; CAREFIRST BLUECHOICE, INC., on behalf of themselves and all others similarly situated,
Plaintiffs-Appellees,

v.

AMGEN INC., AMGEN MANUFACTURING LIMITED LLC, AND IMMUNEX CORPORATION,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Virginia, Norfolk Division
(Hon. Arenda L. Wright Allen)
Civil Action No. 2:24-cv-00484

BRIEF OF THE AMERICAN ANTITRUST INSTITUTE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

DAVID O. FISHER
AMERICAN ANTITRUST INSTITUTE
1025 Connecticut Ave., NW
Washington, DC 20036
(202) 304-0195
dfisher@antitrustinstitute.org

Counsel for Amicus Curiae

August 14, 2026

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, amicus curiae the American Antitrust Institute states that it is a nonprofit, non-stock corporation organized under the laws of the District of Columbia. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTEREST OF AMICUS CURIAE[1]

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders.[2]

AAI has a particular interest in the sound development of Section 2 doctrine, which is central to preserving competition in concentrated markets, including markets for pharmaceutical products. AAI submits this brief to address unique issues of causation and implied immunities that are raised by Amgen's argument on appeal.

---

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amicus and its counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this brief.

[2] Individual views of members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issues presented in this appeal lay at the intersection of three fundamental national policies: free enterprise, as embodied in the Sherman and Clayton Acts; patent rights, as embodied in the Copyright and Patent Clause at Article I, Section 8 of the U.S. Constitution; and freedom of petition, as embodied in the First Amendment. While the latter two policies promote material progress[3] and ensure democratic governance,[4] respectively, the policy of free enterprise serves both material and democratic goals: it promotes "the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress" while also "providing an environment conducive to the preservation of our democratic political and social institutions." *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958).

[3] *Diamond v. Chakrabarty*, 447 U.S. 303, 307, 315 (1980) (Patent law provides "social and economic benefits" by "offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts.").

[4] *United States v. Cruikshank*, 92 U.S. 542, 552 (1876) ("The very idea of a government, republican in form, implies a right on the part of its citizens to . . . petition for a redress of grievances.").

The overlapping nature of these policies means that courts are often asked to determine which has primacy over a given set of facts, presenting challenges of interpretation and application. To assist courts in meeting these challenges, the Supreme Court has laid out two important principles relevant to this case: (1) antitrust plaintiffs face the same pleading standards applied in "all civil actions," *Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) (quoting Fed. R. Civ. P. 1), and (2) "[i]mplied antitrust immunity is not favored." *United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 719 (1975). Amgen seeks a holding which would violate those principles.

CareFirst alleges that Amgen agreed with Roche to grant Amgen exclusive rights to market etanercept, excluding Roche and every other potential competitor from the relevant market and causing injury in the form of higher prices. JA. 251–56, 262–68. The district court held that these allegations, accepted as true, state a claim for relief under the antitrust laws, including because CareFirst plausibly alleges that it paid higher prices as a direct result of Amgen's exclusive licensing agreement with Roche. J.A. 35–39. But Amgen argues on appeal that any overpayment was actually caused by a subsequent court order enforcing the patent rights. It also urges this Court to hold that its agreement with Roche can *never* give rise to antitrust liability, either by extending the *Noerr-Pennington* doctrine or by holding that such transactions are not exclusionary conduct as a matter of law. Response Br. at 15–28, 44–50.

To avoid forcing antitrust plaintiffs to disprove defendants' causation theory on a motion to dismiss, this Court should clarify that, once a plaintiff has plausibly pleaded that their injury was caused by the defendant's conduct, the existence of an intervening cause is a fact question not suitable for a motion to dismiss. In addition, to avoid disrupting the balance Congress and the Supreme Court has set between free enterprise, freedom of petition, and patent rights, it should reject both Amgen's invitation to expand *Noerr* immunity to cover the acquisition of a pending patent application and its invitation to immunize such acquisitions from antitrust scrutiny.

ARGUMENT

I. The Law Does Not Impose a Special Pleading Burden on Antitrust Plaintiffs.

The Supreme Court made clear in *Iqbal*—and this Court has repeatedly reinforced—that there is no heightened pleading standard for antitrust plaintiffs. *Iqbal*, 556 U.S. at 684; *Lowy v. Daniel Def., LLC*, 167 F.4th 175, 199 (4th Cir. 2026); *see also id.* at 212 (Quattlebaum, J., dissenting); *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 441 (4th Cir. 2015). Like any other plaintiff, antitrust plaintiffs need merely allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

This principle applies equally to a plaintiff's allegations establishing the elements of Article III standing, including that the defendants' injury is "fairly traceable to the defendant's allegedly unlawful conduct." *Allen v. Wright*, 468 U.S. 737, 751 (1984); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice."). This Article III standing requirement is often termed "*de facto* causality" or "causation-in-fact" to distinguish it from the proximate-cause requirement of a plaintiff's case on the merits. *See, e.g.*, *Dep't of Commerce v. New York*, 588 U.S. 752, 768 (2019) ("Because Article III 'requires no more than *de facto* causality,' traceability is satisfied here.") (quoting *Block v. Meese*, 793

F.2d 1303, 1309 (D.C. Cir. 1986) (Scalia, J.)); *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 548 (1983) (Marshall, J., dissenting) (distinguishing cause-in-fact from proximate cause).

At the same time, courts have imposed additional, more specific requirements on private antitrust plaintiffs in the form of "antitrust standing," subsumed within which is the requirement of "antitrust injury," or "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 310–11 (4th Cir. 2007) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (cleaned up)); *see also Steves & Sons, Inc. v. Jeld-Wen, Inc.*, 988 F.3d 690, 703, 710–11 (4th Cir. 2021) (same).

However, the antitrust-injury requirement does not alter the pleading standards laid out in *Twombly*. As in all motions to dismiss, a court assessing antitrust complaints must accept the plaintiffs' well-pleaded factual allegations as true and make all reasonable inferences in the plaintiff's favor, without resolving factual disputes. *E. I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 444, 448 (4th Cir.

2011). This requires that the court accept as true plaintiffs' well-pleaded factual allegations of *both* causation-in-fact and antitrust injury. Holding otherwise would impose a heightened pleading standard on antitrust plaintiffs in violation of *Iqbal* and *Twombly*.

A. Antitrust Plaintiffs Need Only Plausibly Allege Causation.

CareFirst alleges that Amgen's exclusivity agreement with Roche contributed to higher prices because it prevented Roche and other would-be competitors from licensing Roche's patents and entering the market. J.A. 264–65, ¶ 151 (alleging that, without the exclusive license agreement, Roche would have licensed the patent to another competitor or used it itself). Amgen presents its own competing theory: that any overpayment by CareFirst was caused by subsequent court orders enjoining other manufacturers from entering the market for etanercept, not by its agreement with Roche. Opening Br. at 16–24. But CareFirst is not required to disprove Amgen's competing causation theory on a motion to dismiss.

In order to establish causation on the merits, an antitrust plaintiff is required to prove that a defendant's antitrust violation was a "material cause" of its injury; it need not "exhaust all possible alternative sources of injury." *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n.9 (1969). Requiring more would "effectively deny private remedies, for multiple causes always effect everyone." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 338a2 (5th ed. 2025). Accordingly, courts of appeals have allowed plaintiffs to prove their case without disproving other potential sources of injury. *Switzer Bros., Inc. v. Locklin*, 297 F.2d 39, 47 (7th Cir. 1961) ("A violation of the antitrust laws is answerable in treble damages for injury to another . . . even though other factors may have contributed to the injury") (listing cases).

Because they are highly fact-specific, causation questions are typically reserved for the factfinder. *Exxon Co. v. Sofec, Inc.*, 517 U.S. 830, 840–41 (1996) ("The issues of proximate causation and superseding cause involve application of law to fact, which is left to the factfinder."); *Peckham v. Cont'l Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990) ("Causation questions . . . are normally grist for the jury's mill."). Accordingly, this Court has held that, to survive a motion to dismiss, an antitrust plaintiff's well-pleaded factual allegations must show that it is "reasonably probable" that defendant's alleged violation caused its injury. *Va. Vermiculite, Ltd. v. W.R. Grace & Co.*, 156 F.3d 535, 540 (4th

Cir. 1998). This standard "is particularly justified in this context because in antitrust cases, where 'the proof is largely in the hands of the alleged conspirators,' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Id.* (quoting *Hosp. Bldg. Co. v. Trustees of the Rex Hosp.*, 425 U.S. 738, 746 (1976)).

The fact-intensive nature of causation is particularly apparent in the context of generic delay claims in the pharmaceutical industry, where the timeline of generic entry in the but-for world is often complicated by a number of overlapping factors, including government action. In such cases, courts allow plaintiffs a chance to prove their causation theory whenever the defendant's allegedly anticompetitive conduct is a plausible cause for the delay of generic entry, even when additional factors of delay are known to exist. *See, e.g.*, *In re Suboxone Antitrust Litig.*, No. 2445, 2017 U.S. Dist. LEXIS 179101, at *49–50 (E.D. Pa. Oct. 30, 2017) (denying a motion to dismiss because, "[a]lthough Defendants may be able to prove that superseding acts have broken the chain of causation between their actions and Plaintiffs' alleged injuries, the well-pled allegations of the Amended Complaint permit the plausible inference that Defendants' alleged antitrust violation was a 'material cause' of the claimed injuries" and "the rules of pleading require no more") (quoting *Zenith*, 395 U.S. at 114 n.9); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 336 (D.R.I. 2017) (declining to dismiss generic delay claim because "the facts alleged in the Operative Complaints do not preclude the possibility" that an alleged reverse payment settlement "contributed to the [later] entry date" by "affect[ing] the FDA's . . . behavior during the approval process").

By insisting that CareFirst must disprove on a motion to dismiss that the factual cause of its injury is something other than government action or *Noerr*-protected conduct, Amgen's argument asks this Court to hold CareFirst to a pleading standard even higher than the standard of proof it would be held to at trial, where Amgen's burden is to show only that the anticompetitive conduct was one of several material causes of its overpayments. This Court should not do so.

B. Antitrust Plaintiffs Need Only Plausibly Allege Antitrust Injury.

Amgen attempts to get around *Twombly* by presenting its causation theory not as a merits question but as a component of antitrust injury. *See* Opening Br. at 29 (characterizing as "novel" district court's distinction between "antitrust injury" and "liability," and referring to the merits element of causation as "antitrust injury"); *id.* at 30 (arguing that "permitting government action to be a source of antitrust injury would permit government action to be a source of antitrust liability, which is impermissible . . . ."). But antitrust injury and antitrust liability are two separate inquiries, the former being a question of a plaintiff's standing to sue, not a question of defendant's liability.

The doctrine of antitrust injury is inferred from the text of Section 4 of the Clayton Act, which authorizes suit by "any person" injured "by reason of" conduct violating the antitrust laws. 15 U.S.C. § 15; *see also* 15 U.S.C. § 26 (providing for injunctive relief). The Supreme Court has held that the statutory language "is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated." *Mandeville Island Farms, Inc. v. Am. Crystal Sugar Co.*, 334 U.S. 219, 236 (1948) (noting that "[t]he statute does not confine its protection to consumers, or to purchasers, or to competitors, or to sellers.").

Interpreting this language, the Court reasoned that Congress legislated against the backdrop of the common-law principle that "a statutory cause of action extends only to plaintiffs whose interests 'fall within the zone of interests protected by the law invoked.'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (quoting *Allen*, 468 U.S., at 751).[5] Because the antitrust laws were intended to protect competition, an antitrust injury is one that "stems from a competition-reducing aspect or effect of the defendant's behavior." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (hereinafter "*ARCO*").

Properly construed, the antitrust injury doctrine thus asks only, as a matter of antitrust standing, whether the plaintiff's claimed injury is within the zone of interests of the Sherman and Clayton Acts such that the plaintiff "is entitled to a chance to prove its case." *Lexmark*, 572 U.S. at 140. That test "is not especially demanding" and "forecloses suit only when a plaintiff's interests are so marginally related to or

[5] Although the antitrust injury doctrine—and antitrust standing more generally, of which the doctrine forms a part—is sometimes described as a type of "prudential standing," that label is "misleading"; the doctrine arises as a matter of statutory interpretation. *Lexmark*, 572 U.S. at 125.

inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress authorized that plaintiff to sue." *Id.* at 130 (citation omitted); *but see id.* (noting that the breadth of the zone of interests varies according to context).

The zone-of-interest test is easily met here. CareFirst alleges that Amgen's exclusive licensing agreement with Roche excluded Roche and other would-be competitors from the relevant market, reducing competition and contributing to higher prices. J.A. 262–65. Its claimed injury therefore stems from the "competition-reducing" effect of Amgen's alleged conduct. *ARCO*, 495 U.S. at 344. As such, CareFirst "is entitled to a chance to prove its case" under this test, which Amgen does not dispute. *Lexmark*, 572 at U.S. 140.

Amgen's conflation of antitrust injury with the merits question of causation may have been influenced by this Court's precedents treating "causation" under the rubric of antitrust injury. *See, e.g.*, *Jeld-Wen*, 988 F.3d at 710 (describing antitrust injury as encompassing "(1) the 'causal connection' between the plaintiff's injury and an antitrust violation, and (2) whether the plaintiff's injury 'was of a type that Congress sought to redress in providing a private remedy for violations of the antitrust laws.'") (quoting *Novell*, 505 F.3d at 311); *Novell*, 505 F.3d at 311 (citing *Brunswick*, 429 U.S. at 489). But both *Jeld-Wen* and *Novell* rely on an outdated reading of *Brunswick*, which the Court has since clarified. In *Lexmark*, the Supreme Court explained that, rather than an element of the threshold inquiry of antitrust standing, proximate causation is a merits element of a claim. *Lexmark*, 572 U.S. at 134, n.6 ("Proximate causation … is an element of the cause of action under the statute" which, "like any other element of a cause of action, . . . must be adequately alleged at the pleading stage.") (citing *Iqbal*, 556 U.S. at 678–79)). By contrast, the zone-of-interest test, which is the remaining component of antitrust injury under this Court's pre-*Lexmark* reading of *Brunswick*, is "treated as … effectively jurisdictional" as a matter of antitrust standing. *Id*. at 128, n.4; *see Novell*, 505 F.3d at 311.[6]

---

[6] Notwithstanding their use of the general term "causation" in the context of antitrust injury, *Jeld-Wen* and *Novell* are best understood as referring to proximate cause, not cause-in-fact. *See Lexmark*, 134 ("[T]he zone-of-interests test and the proximate-cause requirement suppl[y] the relevant limits on who may sue"). Cause-in-fact is already encapsulated by Article III's standing requirement, so it would be redundant to include it as an antitrust standing requirement (via antitrust injury) as well.

That distinction, however, is not relevant for applying *Twombly* to plaintiff's allegations in this case. Even under this Court's pre-*Lexmark* cases that treat proximate causation as a component of antitrust injury, a plaintiff need only plead factual allegations that plausibly establish proximate cause. *Lexmark*, 572 U.S. at 134, n.6. ("If a plaintiff's allegations, taken as true, are insufficient to establish proximate causation, then the complaint must be dismissed; if they are sufficient, then the plaintiff is entitled to an opportunity to prove them.") (citing *Iqbal*, 556 U.S. at 678–79). That burden is clearly met where, as here, the "causal connection between [plaintiff's] injuries and [defendant's] alleged antitrust violation" is "straightforward" because the alleged violation "would have naturally tended" to cause the injury alleged. *Novell*, 505 F.3d at 316.

Applying *Twombly*'s plausibility standard to the plaintiff's allegations of causation takes on special importance in instances where, as here, the alleged anticompetitive scheme includes conduct protected under *Noerr*. If courts were required to parse out the various potential causes of the plaintiff's claimed injury—those subject to *Noerr* immunity and those not—in order to decide the threshold question of antitrust injury, they would be forced to determine the exact causes of the plaintiff's injury without the benefit of a factual record. For this reason, the Third Circuit and district courts in this Circuit have reasoned that *Noerr* provides immunity only "against *liability* stemming from antitrust injuries flowing from valid petitioning," not immunity from suit. *A.D. Bedell Wholesale Co.., Inc. v. Philip Morris Inc.*, 263 F.3d 252, 267 (3d. Cir. 2001) (holding that plaintiffs "properly pleaded an antitrust injury" but that defendants were immune from liability under *Noerr*); *Carefirst of Md., Inc. v. Johnson & Johnson*, 745 F. Supp. 3d 288, 317 (E.D. Va. 2024) (hereinafter "J&J") ("*Noerr-Pennington* stands for the proposition that litigation enforcing lawfully acquired patents cannot serve as a basis for antitrust liability. It does not, however, serve as a bar to asserting that patent enforcement litigation constitutes antitrust injury."); *see also Acoustic Sys., Inc. v. Wenger Corp.*, 207 F.3d 287, 294–95 (5th Cir. 2000) ("Although the *Noerr-Pennington* doctrine is frequently referred to as an 'antitrust immunity,' it provides only a defense to liability, not an immunity from suit.") (listing cases); *Nunag-Tanedo v. E. Baton Rouge Parish Sch. Bd.*, 711 F.3d 1136, 1140 (9th Cir. 2013) ("The *Noerr-Pennington* doctrine . . . does not confer a right not to stand trial.") (listing cases).

Amgen's argument that a plaintiff harmed by *Noerr*-protected conduct cannot establish antitrust standing (because it cannot establish antitrust injury) leads to absurd results. Because antitrust injury is "a necessary element of standing in the antitrust context," *Jeld-Wen, Inc.*, 988 F.3d at 709, the defendant could not obtain a binding judgment in a case where it prevails on the merits of causation; both it and the judicial system would have to face serial lawsuits by other plaintiffs for conduct that does not violate the antitrust laws. *Cf. Kohen v. Pac. Inv. Mgmt. Co. LLC & PIMCO Funds*, 571 F.3d 672, 677 (7th Cir. 2009) (Posner, J.) (Article III standing established at the pleading stage "is not lost when at trial the plaintiff fails to substantiate the allegation of injury; instead the suit is dismissed on the merits"; "to say that if a plaintiff loses his case, this shows that he had no standing to sue … would be an absurd result.").

Moreover, courts could not hold that a plaintiff has established antitrust injury but subsequently rule in favor of the defendant on the merits, because the plaintiff will have proved the merits causation in the course of establishing standing. Yet, courts routinely find antitrust injury sufficient to confer standing and then subsequently rule in favor of the defendants on merits issues. *See, e.g.*, *Eichorn v. AT&T Corp.*, 248 F.3d 131, 142, 145–46 (3d Cir. 2001) (holding plaintiffs suffered antitrust injury but that defendant did not in fact violate the antitrust laws); *Willow Creek Fuels, Inc. v. Farm & Home Oil Co.*, No. 08-5417, 2009 U.S. Dist. LEXIS 85400, at *9–10 (E.D. Pa. Sept. 18, 2009) (plaintiff adequately alleged antitrust injury but failed to adequately allege the agreement element of a conspiracy). The reverse is also true. Plaintiffs often fail the antitrust injury test even when a violation on the merits is confirmed as a matter of law. *ARCO*, 495 U.S. at 346 (competitor-plaintiff lacked antitrust injury despite per se illegality of alleged maximum price fixing).

Here, CareFirst has adequately pleaded the causation component of antitrust injury under this Court's pre-*Lexmark* precedent. Its complaint alleges that Amgen's exclusive licensing agreement with Roche is a material cause of the higher prices it paid. This is sufficient at the pleading stage whether or not the agreement *in fact* had the effect of thwarting competition, whether or not CareFirst *in fact* paid higher prices than it otherwise would have, and indeed whether or not Amgen is immune from liability under the *Noerr-Pennington* doctrine.

II. Implied Antitrust Immunities Are Not Favored.

In passing the Sherman Act, Congress used the fullest extent of its authority to establish a "national policy in favor of competition" that has an "indispensable role . . . in the maintenance of a free economy." *S. Motor Carriers Rate Conf. v. United State*s, 471 U.S. 48, 57, 68 (1985) (Stevens, J., dissenting). As a result, the Supreme Court has consistently reaffirmed that "[i]mplied antitrust immunities . . . are disfavored, and any exemptions from the antitrust laws are to be strictly construed." *Id.* at 67–68; *Carnation Co. v. Pac. Westbound Conf.*, 383 U.S. 213, 217–18 (1966) ("'[R]epeals of the antitrust laws by implication . . . are strongly disfavored'" because "antitrust . . . [is] a fundamental national economic policy[.]") (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 350– 51 (1963)); *FTC v. Phoebe Putney Health Sys., Inc.*, 568 U.S. 216, 225 (2013) ("[G]iven the fundamental national values of free enterprise and economic competition that are embodied in the federal antitrust laws, . . . repeals by implication" are "disfavored.") (quoting *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 636

(1992)). Because Congress in a valid exercise of its legislative authority has established free enterprise as a national policy, "the antitrust laws will not be displaced unless it appears that the antitrust and regulatory provisions are plainly repugnant." *City of Lafayette v. La. Power & Light Co.*, 435 U.S. 389, 398–99 (1978).

Along with state-action immunity, which is rooted in state sovereignty, *Phoebe*, 568 U.S. at 224–25, the protection for petitioning activity recognized in *Noerr* is one of only two policies the Court has ever found to be "sufficiently weighty" to imply an immunity from liability under the antitrust laws. *City of Lafayette*, 435 U.S. at 399–400. Meanwhile, although a patent is best understood as a limited, legal right to assert a monopoly over a patented invention, the Court has consistently held that patent rights do *not* provide "any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). Moreover, "the Court has struck down overly restrictive patent licensing agreements" like the one at issue in this case. *FTC v. Actavis, Inc.*, 570 U.S. 136, 150 (2013).

Considering the "fundamental national values" embodied in the antitrust laws, *Phoebe*, 568 U.S. at 225, and the narrow limits on *Noerr* immunity and patent-right exemptions reflecting the careful balance drawn by Congress and the Supreme Court between free enterprise and other national policies, this Court should decline Amgen's invitation to extend *Noerr* immunity to—or otherwise exempt from antitrust scrutiny—the commercial act of acquiring a pending patent application.

A. This Court Should Not Extend *Noerr* Immunity to an Exclusive Licensing Agreement Between Patentees.

1. The right to petition does not supersede enforcement of the antitrust laws.

The right to petition, and subsequently *Noerr* immunity, "is one of the freedoms protected by the Bill of Rights," and the antitrust laws cannot be construed "to invade these freedoms." *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138 (1961). Its importance, however, does not override the antitrust laws, and courts cannot overlook the antitrust laws' importance in deciding *Noerr* immunity cases. *See Ernest W. Hahn, Inc. v. Codding*, 615 F.2d 830, 842–43 (9th Cir. 1980) ("We acknowledge the First Amendment underpinnings of the *Noerr-Pennington* doctrine .... Nevertheless, this court should not underestimate the importance of the Sherman Act and the interests which it protects.").

In short, the right to petition and its tensions with antitrust law are treated the same as any other set of laws. *Nunag-Tanedo*, 711 F.3d at 1141 ("The Petition Clause of the First Amendment, which *Noerr–Pennington* is designed to safeguard, does not enjoy a special status, or confer any greater immunity, than that provided by other First Amendment guarantees."). And this right is "unavailing to prevent antitrust enforcement" unless the petitioner demonstrates that the policies underlying *Noerr* are not just "implicat[ed]" but rather "severely … impinge[d] upon." *City of Lafayette,* 435 U.S. at 400.

To that end, the right to petition that undergirds *Noerr* immunity is not absolute. *Segni v. Com. Off. of Spain*, 816 F.2d 344, 346 (7th Cir. 1987) (citing *McDonald v. Smith*, 472 U.S. 479, 484–85 (1984)). Immunities from suit, such as the absolute immunity applied to certain public officials, rely on the notion that the very litigation itself, not just a judgment, may have negative impacts which the immunity is designed to protect against. *See, e.g.*, *Nixon v. Fitzgerald*, 457 U.S. 731, 752, n.32 (1982). This logic does not apply to *Noerr* immunity and, thus, there is no categorical rule requiring dismissal at the motion to dismiss stage, even to protect against a potential chill of the right to petition. *Acoustic Sys.,* 207 F.3d at 294–95; *Nunag-Tanedo*, 711 F.3d at 1140.

To be sure, it is well-settled that the *Noerr-Pennington* doctrine immunizes private actors from antitrust liability for petitioning activities undertaken in an attempt to secure government action, even if that government action would restrain trade. *Noerr*, 365 U.S. at 135–36; *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965). The Supreme Court has recognized that in our representative democracy, "[i]t is neither unusual nor illegal for people to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors." *Noerr*, 365 U.S. at 139. The Sherman Act does not regulate this form of petitioning as it is political conduct and not the kind of trade restraint subject to antitrust prohibitions. *Id.* at 140. But for conduct to be immunized by *Noerr*, it has to be "directed toward obtaining *governmental action*." *Id.* at 140 (emphasis added). Otherwise, it does not fulfill the policy reasons behind *Noerr*'s existence.[7]

2. The acquisition of a patent application is not "incidental" to the exercise of protected petitioning.

CareFirst alleges that Amgen violated the antitrust laws by entering into a horizontal agreement with its only current competitor, Roche, by which Roche transferred intellectual property, Roche's patent application, and agreed not to compete against Amgen. Even though Amgen later engaged in petitioning conduct to obtain a patent and later enforced its right to exclude competitors, the acquisition was a commercial transaction that involved no petitioning activity. As such, it is not protected by *Noerr*.

The Supreme Court's decision in *Allied Tube* controls. There, the Court rejected the argument that a private agreement, reached in the

---

[7] Subsequently the Court has recognized a so-called "sham exception," *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 512 (1972), and several circuits have recognized a "fraudulent misrepresentations exception," neither of which apply here. *U.S. Futures Exch., L.L.C. v. Bd. of Trade*, 953 F.3d 955, 960 (7th Cir., 2020); *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1262 (9th Cir. 1982). Both exceptions reflect the judgement that speech which is not subject to the First Amendment's strongest protections is not entitled to immunity from antitrust liability.

context of a standard setting organization, to exclude a competitor's product from the standard, became protected because defendants later needed to petition government officials to have the standard incorporated into state and local building codes. *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492, 505–07 (1988). The adoption of the standard, like the agreement giving Amgen the exclusive right to Roche's intellectual property, involved no petitioning activity. *Id.* at 507. Rather, it was "commercial activity with a political impact." *Id.* "Just as the antitrust laws should not regulate political activities 'simply because those activities have a commercial impact,' so the antitrust laws should not necessarily immunize what are in essence commercial activities simply because they have a political impact." *Id.* (quoting *Noerr*, 365 U.S. at 141). Because Amgen's conduct was commercial, its assertion that potential antitrust liability here would chill protected petitioning activity simply has no purchase. *See* Opening Br. at 26–27.

Amgen's position is not saved by characterizing its monopolistic acquisition as "incidental" to its later petitioning activity. Opening Br. at 44–45. The implications of Amgen's position are staggering, as the

Supreme Court explained in *Allied Tube*: "If all such conduct were immunized then, for example, competitors would be free to enter into horizontal price agreements as long as they wished to propose that price as an appropriate level for governmental ratemaking or price supports." 486 U.S. at 503. Under Amgen's approach, parties to a merger agreement under Section 7 of the Clayton Act, 15 U.S.C. § 18, could claim *Noerr* protection simply because they had to petition the government for clearance to merge under the provisions of the Hart-Scott-Rodino Act, 15 U.S.C. § 18a ("HSR Act"), or because they later had to defend their proposed merger in federal court.

Indeed, Amgen's interpretation could nullify the HSR regulation, adopted in 2013 (after the 2004 agreement at issue here), that requires certain exclusive patent licenses to be noticed to the FTC for antitrust review. 16 C.F.R. §§ 801.1(o), 802.[8] If the FTC were to conclude that the exclusive license agreement violated the antitrust laws, Amgen's position would suggest that the FTC could not challenge the license

[8] The D.C. Circuit rejected the pharmaceutical industry's challenge to the rule. *Pharm. Research & Mfrs. of Am. v. FTC*, 790 F.3d 198 (D.C. Cir. 2015).

because the acquisition of patent rights would be incidental to *Noerr*-protected petitioning activity, which is an absurd result.

Amgen also analogizes its agreement to pre-litigation conduct such as litigation funding or pre-suit letters. Opening Br. at 46. Some circuits have immunized such pre-litigation conduct as incidental to petitioning activity. *See Primetime 24 Joint Venture v. NBC*, 219 F.3d 92, 100 (2d Cir. 2000) (listing cases holding litigation, threats of litigation, and settlement offers are protected by *Noerr*); *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1560 (11th Cir.1992) (threats of litigation); *Sosa v. DIRECTV, Inc.*, 437 F.3d 923, 936–37 (9th Cir. 2006) (litigation funding). No court, however, has held that the purchase of a competitor's intellectual property can be immunized by later petitioning the government for a patent using that intellectual property. To the contrary, courts have rejected granting *Noerr* immunity to otherwise illegal conduct on the basis that the defendant later engaged in protected petitioning. *See, e.g.*, *Alvarado v. W. Range Ass'n*, Case No. 3:22-cv-00249-MMD-CLB, 2023 U.S. Dist. LEXIS 122127 at *9–11 (D. Nev. Mar. 21, 2023) (citing *Clipper Exxpress*, 690 F.2d at 1263).

In the time since the Court's decision in *Allied Tube*, no court has extended *Noerr-Pennington* immunity to a patent licensing agreement on the basis of potential downstream incidental effects on petitioning that may result. And with good reason. Further extension of *Noerr-Pennington* immunity to other possible categories of "incidental" conduct is unnecessary to fulfill the policy purposes for its existence and "contravenes the maxim that exemptions from the antitrust laws must be construed narrowly." *Indian Head, Inc. v. Allied Tube & Conduit Corp.*, 817 F.2d 938, 945 (2d Cir. 1987) *aff'd*, 484 U.S. 814 (1987) (quoting *Union Labor Life Insurance Co. v. Pireno*, 458 U.S. 119, 126 (1982)).

Furthermore, extending *Noerr* as Amgen proposes would go beyond what is needed to protect the right to petition and immunize a wide range of anticompetitive conduct. *See* Diane MacArthur, *The Limitations of the* Noerr-Pennington *Doctrine as a Defense for Political Activity in Restraint of Trade*, 12 Loy. U. Chi. L.J. 773, 811 (1981) (Because "[a]ll types of anticompetitive activity contain an element of expression[,] . . . [t]o permit the *Noerr-Pennington* doctrine to protect all expressive conduct in restraint of trade would . . . severely undermine the effectiveness of the Sherman Act."). This concern is heightened in the pharmaceutical sector, where anticompetitive schemes often involve petitioning activity. *See* Lisa Orucevic, *A Machete for the Patent Thicket: Using* Noerr-Pennington *Doctrine's Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies*, 75 Vand. L. Rev. 277, 285 (2022) (explaining how "[t]he combination of *Noerr-Pennington* antitrust immunity with existing patent law protections" provides monopolists "a perfect cocktail for exploitation.")

B. Patent Law and Antitrust Law Are Complimentary Systems Designed to Encourage Innovation for the Benefit of Consumers.

As an alternative to its argument that its agreement with Roche is protected under *Noerr-Pennington*, Amgen urges this Court to hold, in order to avoid disincentivizing innovation, that the acquisition of a pending patent application can never be exclusionary conduct actionable under the antitrust laws. Opening Br. 41–44, 54–56. But the antirust laws also serve to promote innovation. *See generally* Richard J. Gilbert & A. Douglas Melamed, *Innovation Under Section 2 of the Sherman Act*, 84 Antitrust L.J. 1 (2021) (examining role of Section 2 enforcement in promoting innovation). A blanket exemption from antitrust scrutiny for transactions involving pending patent applications would create a new antitrust exemption for patent holders and their licensees beyond the fixed terms of their patent without any corresponding benefit to innovation.

Patent law and antitrust law are complimentary systems designed to encourage innovation for the benefit of consumers. *See* Robert Pitofsky, *Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property*, 68 Antitrust L. J. 913, 919 (2001) (examining "traditional balance between intellectual property and antitrust" and its role in promoting innovation). While patent law incentivizes innovation by offering limited monopolies, *Actavis*, 570 U.S. at 161 (Roberts, J., dissenting), antitrust law encourages innovation through competition. Indeed, the Constitution's Patent Clause "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance[ment]" in innovation. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

Here, the competition-reducing implications of the exclusive licensing agreement between Amgen and Roche are clear: CareFirst alleges that, by acquiring an exclusive license to Roche's pending patent applications, Amgen both excluded Roche, its competitor, from the market, and gained the power to prevent other, would-be competitors from licensing that patent and entering the market. But, as the court recognized in *J&J*, "[i]t is easy to see how a monopolist's acquisition of exclusive rights over processes to make competitor goods … has the potential to harm competition," 745 F. Supp. at 315, even in ways not addressed by this case. Firms may also use licenses to pending patent applications as a way to raise rivals' costs. *See* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs To Achieve Power Over Price*, 96 Yale L.J. 209, 236–38 (1986) (explaining how a firm can exclude rivals or gain market share in violation of antitrust law by depriving them of patentable technology that is a critical input). And of course, as explained in CareFirst's brief, a monopolist's transactions involving pending patent applications have consistently been scrutinized as a potential basis for antitrust liability under Section 2. Response Br. at 19–24.

To get around these obvious examples of how pending patent applications can be used anticompetitively, Amgen contends that protecting the acquisition of a pending patent application from antitrust liability is necessary to protect innovation. Response Br. at 55–56. But immunizing the transfer of rights to a pending patent application between competitors as Amgen proposes could result in decreases in research and development spending and pharmaceutical innovation more broadly. *See* Orucevic at 319–21 (arguing that increasing competition between pharmaceutical companies correlates to more innovation and more research). If companies are granted antitrust immunity for acquiring patent applications, they will be able to extend their monopolies well beyond the patent term without any corresponding innovation benefit. This may lead to firms' focusing their investments on buying up patent applications and extending their monopoly rather than developing new drugs. While a general rule of free alienability of patents and patent applications serves the innovation-promoting functions of patent law, extending that rule so far as to prevent anticompetitive scrutiny of two patentees' exclusive licensing agreement does not serve that goal. This Court should decline Amgen's invitation to create a new, wide immunity that would upset the balance between patent law and antitrust law.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the district court.

Dated: August 14, 2026

Respectfully submitted,

/s/ *David O. Fisher*
David O. Fisher
American Antitrust Institute
1025 Connecticut Ave., NW
Suite 1000
Washington, DC 20036
(202) 304-0195
dfisher@antitrustinstitute.org

Counsel for Amicus Curiae
American Antitrust Institute