No. 26-1309

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Sandoz Inc.,

Plaintiff-Appellant,

v.

Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Virginia
Case No. 2:25-cv-00218-AWA-RJK

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation, and no corporation or publicly held company owns 10% or more of its stock. The Biotechnology Innovation Organization states that it has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

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INTEREST OF *AMICI CURIAE*

Pursuant to Federal Rule of Appellate Procedure 29, *amici curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO") submit this brief in support of Defendants-Appellees and affirmance.[1]

PhRMA is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies.[2] PhRMA member companies are laser-focused on developing innovative medicines that transform lives and create a healthier world, and PhRMA advocates for public policies encouraging innovation in lifesaving and life-enhancing new medicines. PhRMA members make significant contributions to serve these goals and have led the way in the search for new cures. Over the last decade, PhRMA member companies have invested more than $850 billion in the search for new treatments and cures, supporting nearly five million jobs in the United States. BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of

[1] No counsel for any party authored this brief in whole or in part, and no entity or person other than *amici*, their members, or their counsel made any monetary contribution intended to fund this brief's preparation or submission. The parties have consented to this filing.

[2] *See* www.phrma.org/about#members.

the world's largest biopharmaceutical companies—all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. Many of BIO's members are small companies that have yet to bring products to market or to attain profitability. These members rely heavily on venture capital and other private investment, based on and protected by strong intellectual property rights.

Amici's members have a substantial interest in this case because Plaintiff's suit seeks to transform routine conduct in the biopharmaceutical and biotech industries—including the licensing of patents and patent *applications*, prosecuting those patent applications to issuance, and *successfully* enforcing patents—into an antitrust violation. But licensing, prosecuting, and enforcing patents are foundational activities in which *Amici*'s members frequently engage to bring life-saving therapies to patients. To continue the extraordinary investments in research and development necessary to offer new life-saving treatments, innovators must be able to: 1) maintain strong intellectual property protection for their products, and 2) achieve some level of certainty and risk minimization with respect to the licensing of patent portfolios and the subsequent enforcement of those patents in court. *Amici* thus have a compelling interest in ensuring that courts do not adopt antitrust rules that deter the enforcement of patent rights that are required to spur the life-saving innovations that *Amici*'s members provide.

SUMMARY OF ARGUMENT

Appellant's position, if adopted, would have a profound chilling effect on the biopharmaceutical and biotech industries. The impact on the industries' abilities to deliver life-saving therapies arising from the resulting uncertainty and antitrust exposure is not some theoretical speculative risk. Licenses—including those involving patent rights before a patent has issued—are indispensable to the development of critical new therapies for patients. Most new therapies approved by the FDA did not originate within large biopharmaceutical and biotech companies but from third parties, including startups and emerging biotechnology firms, and reach patients through licensing arrangements. If parties to these commonplace and essential agreements must fear that their transactions could later trigger antitrust liability, investment, collaboration, and technology transfer will inevitably suffer. The result would be fewer new therapies reaching patients, along with increased costs and delays for those that do. As explained below, both established antitrust principles and sound public policy compel rejection of Appellant's position.

Before the instant lawsuit, appellees (collectively, "Amgen") prevailed in patent infringement litigation against appellant Sandoz Inc. relating to patents that covered Sandoz's biosimilar version of Enbrel. Rather than asserting antitrust counterclaims in that litigation, Sandoz waited several years after the conclusion of the litigation to allege that Amgen's mere *licensing and prosecution* of patent

applications, and subsequent enforcement of patents protecting Enbrel, violated the antitrust laws.

The District Court dismissed Sandoz's antitrust claims for failure to state a claim because the court correctly determined that: (i) Sandoz's antitrust claims should have been raised as compulsory counterclaims during the patent litigation; and (ii) the narrow exception articulated by the Supreme Court in *Mercoid Corp. v. MidContinent Inv. Co.*, 320 U.S. 661 (1944) did not permit Sandoz to bring these claims years later in a separate suit. This Court should affirm and clarify the District Court's opinion.

First, the Court should affirm because Sandoz's antitrust claims arise out of the same transaction—Amgen's licensing of patent applications from Roche—that was at the center of the patent litigation. *Burlington Industries v. Milliken & Co.*, 690 F.2d 380 (4th Cir. 1982) makes clear that the *Mercoid* exception to the rule that antitrust claims challenging a licensing transaction already litigated in a prior suit are compulsory counterclaims does not apply. Broadening the exception would strip patentees of the finality to which all litigants are entitled at the conclusion of a civil case, invite opportunistic relitigation of issues already resolved, impose severe burdens on both the courts and the parties, and ultimately severely impact the ability of the biopharmaceutical and biotech industries to introduce new therapies for patients.

Second, this Court should reject the proposition—adopted in the related *CareFirst* proceedings—that patent-enforcement litigation may give rise to antitrust "injury" even where the *Noerr-Pennington* doctrine forecloses antitrust "liability." That distinction is illusory: causation of injury is itself an element of antitrust liability, and a rule permitting courts to treat the consequences of judicial injunctions as antitrust injury would effectively eviscerate the *Noerr-Pennington* doctrine's protections and expose patent holders to damages flowing from constitutionally protected petitioning activity. *See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961) ("[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out."). Exposing patent holders to antitrust liability beyond the well-established standards set by the *Noerr-Pennington* doctrine would dampen the incentives to pursue novel therapies.

Finally, this Court should not adopt Sandoz's position that Amgen's mere acquisition of rights to patent applications was potentially anticompetitive. Black letter law establishes that patent applications do not confer exclusionary rights. The District Court's apparent endorsement of Sandoz's position also introduces significant uncertainty into transactions involving patent licensing or acquisition and impedes the commercialization of life-saving therapies.

For these reasons, and those set forth more fully below, *Amici* urge this Court to affirm the District Court's holding that the *Mercoid* exception does not apply, to reinforce that antitrust damages cannot be predicated on the effects of prior judicial decisions, and to clarify that Amgen's acquisition of rights to patent applications cannot give rise to antitrust liability.

ARGUMENT

I. THE COURT SHOULD REJECT SANDOZ'S ATTEMPT TO EXPAND THE LIMITED *MERCOID* EXCEPTION TO THE COMPULSORY COUNTERCLAIM RULE.

A. The Compulsory Counterclaim Rule Applies to Sandoz's Antitrust Claims.

The compulsory counterclaim rule is designed to promote finality, prevent relitigation of the same disputes under different legal theories, and conserve judicial resources—all of which were advanced when the District Court correctly dismissed Sandoz's federal antitrust claim on the basis that Sandoz should have raised it as a compulsory counterclaim in the parties' earlier patent-infringement litigation. *Sandoz Inc. v. Amgen Inc.*, No. 2:25-cv-218, 2026 WL 822807, at *11–12 (E.D. Va. Feb. 17, 2026). This Court applies a four-part test to assess whether a counterclaim is compulsory under Rule 13(a): (1) whether the issues of fact and law are largely the same; (2) whether res judicata would bar a subsequent suit absent the rule; (3) whether substantially the same evidence supports or refutes both claims; and

(4) whether there is a logical relationship between the two. *Painter v. Harvey*, 863 F.2d 329, 331 (4th Cir. 1988).

The District Court engaged in detailed analysis and concluded that the first factor was neutral, the second, third, and fourth factors supported a finding that Sandoz's antitrust claim was a compulsory counterclaim, and no factor favored Sandoz. *See* JA26–28 (noting that Sandoz's "present antitrust claim" and its prior defense in the patent infringement suit are premised on the same core theory). Sandoz seeks to bypass this Court's four-part test based on *Mercoid*. *See, e.g.*, Sandoz Opening Br. 12. *Mercoid* created a narrow exception to Rule 13(a)'s compulsory counterclaim rule for antitrust claims where the antitrust allegations were based on patent *misuse*. JA29–30. The District Court properly declined to extend *Mercoid* to the facts of this case, where there is no allegation of patent misuse. The Court should reject Sandoz's renewed attempt to broaden *Mercoid*.

Binding precedent from this Court supports the District Court's well-reasoned opinion. In *Burlington*, this Court held that an antitrust claim is a compulsory counterclaim to a suit brought to enforce—and to obtain a declaratory judgment on the enforceability of—the very licensing agreement that the antitrust claim challenged. *See Burlington*, 690 F.2d at 389 (holding that claims which "arose out of the very transaction which was the subject matter of [the plaintiff's] complaint" are compulsory counterclaims under Rule 13(a)). That transaction-based

inquiry controls, and is satisfied here because Sandoz's present antitrust claim and its prior patent defense are premised on the same transaction, *see* JA26–28, and share substantially the same facts, evidence, and logical relationship, *see Painter*, 863 F.2d at 331. This Court has explained that *Mercoid* "does not require a different conclusion" because *Mercoid*'s treatment of antitrust claims as merely permissive "has been read narrowly," and its "continuing validity is open to serious question." *Burlington.*, 690 F.2d at 389.[3] Accordingly, the fact that the parties' prior litigation sounded in patent infringement does not bring this case within the exception, particularly where Sandoz alleges no patent misuse. *Mercoid* is also distinguishable because the *Mercoid* complaint "did not demand a declaratory judgment on the issue of the enforceability of the patents or of any license agreement." *Id.*

B. Public Policy Considerations Compel Affirmance.

The compulsory counterclaim rule serves a critical function: preventing parties from relitigating the same disputes under different legal theories in successive lawsuits.

[3] The Fourth Circuit's approach aligns with numerous other courts that have addressed the same issue. *See Critical-Vac Filtration Corp. v. Minuteman Int'l, Inc.*, 233 F.3d 697, 702–03 & n.6 (2d Cir. 2000) (recognizing that the Second and Fourth Circuits, as well as numerous district courts, have "serious[ly] critici[zed]" and narrowed *Mercoid*, and drawing a "distinction between claims of patent *misuse* and claims of patent *invalidity*").

According to Sandoz, Amgen engaged in an anticompetitive "scheme to acquire, prosecute, and enforce" patent rights from Roche. JA100. In the prior patent case, Sandoz advanced a materially similar claim under the patent laws, arguing that the Patent Act "prevent[ed]" Amgen from obtaining "separate patents" that "effectively extend the life of patent protection." *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1056 (Fed. Cir. 2020). The court rejected Sandoz's arguments. Now, years later, Sandoz has repackaged its failed arguments into an antitrust claim. The compulsory counterclaim rule exists precisely to prevent this kind of do-over.

Permitting Sandoz's approach would send a troubling signal that patent defendants dissatisfied with the outcome of a fully litigated infringement case can try to relitigate the same underlying transaction years later under the antitrust laws, which carry the specter of treble damages, joint and several liability, and attorneys' fees. That result would "defeat the entire point of the compulsory counterclaim rule," which is to prevent "duplicati[ve]" suits from becoming a "drain on limited judicial resources." *Painter*, 863 F.2d at 332.

The practical consequences of jettisoning the compulsory counterclaim rule for the biopharmaceutical and biotech industries—and thus patients—are particularly severe. It would expose innovators to two rounds of expensive and time-consuming litigation for every marketed product. To maintain exclusivity, an innovator would first need to bring suit to establish infringement of its patents and

defend against invalidity challenges. If the innovator loses, exclusivity is destroyed and the ability to recoup its investment to fund future research and development projects is extinguished. But even if the innovator wins on the patent merits, the reward would be a potential second lawsuit that reframes the same transaction as an antitrust violation. This Court should not permit that inequitable result, which would discourage innovation by reducing the investments in the biopharmaceutical industry that allow it to provide life-saving medicines.

None of the policy objections Sandoz interposes justifies departing from the District Court's adherence to the binding *Burlington* framework. Sandoz argues that treating antitrust claims as compulsory counterclaims would create inefficiency by forcing their simultaneous litigation with patent claims and routing antitrust appeals to the Federal Circuit. Sandoz Opening Br. 25–28. But Sandoz conflates the obligation to *file* a counterclaim with the obligation to *try* it simultaneously. The compulsory counterclaim rule requires only that the claim be asserted in the original action—it does not mandate simultaneous trial. Rule 42(b) gives district courts full authority to bifurcate and sever claims for trial, and as Sandoz's own authorities demonstrate, courts routinely exercise that authority to resolve patent issues first and defer antitrust claims for separate proceedings. *See Azurity Pharms., Inc. v. Bionpharma Inc.*, 650 F. Supp. 3d 269, 276 (D. Del. 2023); *see also Audio MPEG, Inc. v. Dell Inc.*, 254 F. Supp. 3d 798, 804 (E.D. Va. 2017) ("When applying [Rule

42(b)] to cases with patent claims and antitrust counterclaims, district courts frequently bifurcate the issues for trial."). Filing the antitrust claim as a counterclaim—even if it is immediately stayed—preserves it within the original action and puts the patentee on notice about those claims, while preventing the very outcome Sandoz seeks here: the loss of finality among the parties with relitigation of the same transaction in a different forum and the attendant costs of duplicative discovery and duplicative judicial resources.

Sandoz's invocation of Congress's creation of different appellate paths and venue statutes for patent and antitrust claims as evidence that antitrust claims should always be litigated separately from patent claims is also unavailing. *See* Sandoz Opening Br. 27–28. These structural features of the federal court system do not override Rule 13(a). Congress enacted the compulsory counterclaim rule knowing that different types of claims have different procedural characteristics. The rule applies to claims that arise from the same transaction or occurrence regardless of whether those claims involve different bodies of substantive law.

II. CONDUCT CANNOT CAUSE ANTITRUST "INJURY" WHERE THERE IS NO COGNIZABLE ANTITRUST "LIABILITY."

Although the District Court properly dismissed Sandoz's complaint, its opinion adopts the erroneous conclusion from the related *CareFirst* case that Amgen's prosecution and successful enforcement of its patent rights "does not immunize Amgen from the allegedly anticompetitive conduct of purchasing the

Roche Patent Rights." JA22–23 (quoting *CareFirst of Md., Inc. v. Amgen, Inc.*, No. 2:24-cv-484, 2025 WL 4704542, at *11 (E.D. Va. Sept. 30, 2025), *appeal filed*, No. 26-1473 (4th Cir. Apr. 20, 2026)); *see also CareFirst of Md., Inc. v. Johnson & Johnson*, 745 F. Supp. 3d 288, 317 (E.D. Va. 2024) ("[T]here is a distinction between antitrust *liability* and antitrust *injury*."). Adopting the *CareFirst* standard would undermine constitutionally protected petitioning rights, expose patent holders to treble damages for lawfully enforcing their intellectual property, and chill the innovation that drives development of new therapies. This Court should confirm that prevailing on patent infringement claims in court—and, in this case, obtaining an injunction that blocks market entry—constitutes protected activity that breaks any chain of antitrust causation between the allegedly anticompetitive acquisition of rights to Roche's patent applications and the claimed competitive harm (here, exclusion of Sandoz's Enbrel biosimilar from the market). Accordingly, pre-injunction conduct (e.g., Amgen's acquisition of rights in various Roche patent applications) cannot form the basis of an antitrust violation.

A. Judicial Injunctions Break the Causal Chain of Antitrust Liability.

Antitrust injury requires a "reasonably probable causal link" between the anticompetitive conduct and the plaintiff's injury. *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 149 (4th Cir. 1990). Courts across multiple circuits have held that an independent, discretionary governmental

decision, including judicial decisions, as is the case here, severs any causal chain between the defendant's private conduct and the plaintiff's claimed harm from restraint of trade. *See Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001); *Sandy River Nursing Care v. Aetna Cas.*, 985 F.2d 1138, 1143–44 (1st Cir. 1993); *Sessions Tank Liners, Inc. v. Joor Mfg.*, 17 F.3d 295, 299–301 (9th Cir. 1994).[4]

This understanding of antitrust liability comports with *Noerr-Pennington* and its progeny. *See A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 251 (3d Cir. 2001) (holding that a party is "immune from antitrust liability whether or not the injuries are caused by the act of petitioning or are caused by government action which results from the petitioning"). That doctrine "guarantees citizens their First Amendment right to petition the government for redress without fear of antitrust liability," *Balt. Scrap Corp. v. David J. Joseph Co.*, 237 F.3d 394, 398 (4th Cir. 2001), regardless of whether the petitioning is "intended to eliminate competition," *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965).

[4] That principle applies with particular force here, where the injunctions barring Sandoz from selling its biosimilar etanercept product were not the ministerial entry of a private agreement between the parties, but rather the product of a full bench trial in which the court independently adjudicated patent validity and infringement, followed by appellate affirmance by the Federal Circuit and denial of certiorari by the Supreme Court. *See* JA13 (noting that "Sandoz and Amgen litigated the infringement claims through trial, and on August 9, 2019, after a bench trial, the [court] issued a decision upholding the validity of the '182 and '522 Patents," which was "affirmed" by the Federal Circuit, and for which "Sandoz's petition for *certiorari* to the U.S. Supreme Court was denied").

As the District Court correctly noted, the doctrine applies with full force to the forms of petitioning at issue here: it is well established that *Noerr-Pennington* "exempts from anti-trust liability any petitioning activity designed to influence legislative bodies or governmental agencies," including "patent prosecutions before the PTO" and "filing lawsuits" in court alleging patent infringement. JA22 (quoting *N.C. Elec. Membership Corp. v. Carolina Power & Light*, 666 F.2d 50, 52 (4th Cir. 1981)). And the immunity extends beyond the act of petitioning itself to encompass the governmental response that petitioning produces. Stated differently, a party that invokes the judicial process is shielded from antitrust liability for the consequences of the court's decision. *See Noerr*, 365 U.S. at 136; *Balt. Scrap*, 237 F.3d at 399 ("[T]he rights of petition and association trump any anticompetitive effects that might occur from asking the government for redress.").

However, the District Court accepted the erroneous proposition that activity occurring prior to the patent-enforcement litigation may create antitrust "injury" even if the *Noerr-Pennington* doctrine forecloses antitrust "liability." *Amgen*, 2025 WL 4704542, at *15–16 (relying on *Johnson & Johnson*, 745 F. Supp. 3d at 317); JA22–23 (adopting same analysis). But antitrust injury is not a freestanding concept divorced from the elements of an antitrust claim; it is one of the elements. A plaintiff asserting monopolization must establish "possession of monopoly power in a relevant market, willful acquisition or maintenance of that power in an exclusionary

manner, and causal . . . injury." *Advanced Health-Care Servs.*, 910 F.2d at 147. Because causation of the injury is a prerequisite to liability, a rule that permits activity pre-dating government action to serve as the source of antitrust "injury" necessarily permits it to serve as a predicate for antitrust liability.[5] This is precisely what *Noerr-Pennington* forbids.

B. Sandoz's Theory Risks Transforming Patent Enforcement Victories into Antitrust Exposure.

Adopting Sandoz's position would invite open-ended antitrust litigation against any company that acquires or licenses patent rights and later succeeds in enforcing them. Under Sandoz's logic, an antitrust plaintiff need only identify some pre-petitioning activity—in this case, a routine patent licensing agreement executed more than a decade before the injunctions issued—and then claim that all downstream consequences of the patentee's successful enforcement of its patent rights are attributable to that earlier conduct. Although a plaintiff would still have to establish market power and point to some arguably anticompetitive act, those requirements offer little protection where, as here, the theory recasts a lawful license as anticompetitive conduct and treats the results of successful, court-sanctioned enforcement as the resulting injury. This would eviscerate *Noerr-Pennington*'s

[5] This would not apply to claims based solely on pre-litigation conduct. Rather it is limited to situations where, as here, the plaintiff's theory challenges patent licensing transactions based on later successfully prosecuting and enforcing those patents.

protections and dissuade would-be petitioners from exercising their First Amendment rights.

The antitrust laws were never intended to become a mechanism for punishing successful petitioning divorced from actual competitive harm. Yet that is precisely what Sandoz's theory would accomplish. Overbroad liability theories of this kind allow opportunistic plaintiffs to manufacture significant legal exposure based on legitimate conduct. Many companies may be forced to settle these frivolous claims rather than mount an expensive and time-consuming defense on the merits given the high stakes.

C. Overbroad Antitrust Exposure Would Chill Patent Enforcement and Licensing in the Biopharmaceutical Industry—the Very Activities Congress Designed the Patent System to Encourage.

Noerr-Pennington's protections are essential in the context of biopharmaceutical and biotech patents that are the lifeblood of those industries. Innovators must be able to enforce their patent rights in court, including by seeking injunctions, without the threat that plaintiffs will later recast their success as an antitrust violation. Allowing conduct that pre-dates the successful enforcement of patent rights in court to serve as a basis for antitrust liability would undermine the constitutional protection of *Noerr-Pennington* immunity and weaken the robust patent protections necessary to spur the life-saving innovations that the biopharmaceutical industry provides. In fact, licensing and acquisitions are an

indispensable part of the discovery and commercialization of new medicines across every stage of the development pipeline. Alexander Schuhmacher et al., *Investigating the Origins of Recent Pharmaceutical Innovation*, 22 Nature Revs. Drug Discovery 781, 781–82 (2023), https://bit.ly/3RknAv5 (systematic analysis of every new molecular entity and new therapeutic biologic approved by the FDA between 2015 and 2021 for the top 20 biopharmaceutical companies found that 65% originated externally and 28% were invented internally); Murray Aitken et al., IQVIA Inst. for Human Data Science, *Global Trends in R&D: Overview Through 2021*, at 3 (2022), https://bit.ly/449HSKL (emerging biopharmaceutical companies account for a record 65% of the molecules in the industry's R&D pipeline, up from less than 50% in 2016).[6]

The biopharmaceutical and biotech industries rely on the bargain embodied in the Patent Act: innovators commit extraordinary resources to develop and commercialize drugs in exchange for the limited, government-sanctioned monopoly provided by their patent rights. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,

[6] *See also* Bart Van de Vyver et al., McKinsey & Co., *Pulse Check: Key Trends Shaping Biopharma Dealmaking in 2025* (June 20, 2025), http://bit.ly/4f58UIh ("Since 2018, more than 70 percent of new molecular entity (NME) revenues have come from externally sourced products. Many of these innovations originate in small labs with no capacity to effectively bring them to market." (footnote omitted)); *Pharmaceutical Licensing Agreements: The Complete IP Valuation, Deal Architecture, and Strategy Guide for Pharma/Biotech Leaders*, DrugPatentWatch (Mar. 19, 2026), https://bit.ly/449GXtN (global pharmaceutical licensing market projected to reach $560 billion by 2030 as a result of "mounting R&D costs, the complexity of biologics development, and the geographic fragmentation of prescription drug markets").

489 U.S. 141, 150–51 (1989). *Amici* members have invested more than $850 billion in the search for new treatments and cures over the last decade, and the industry spent more than $100 billion annually on R&D from 2021-2024.[7] On average, a manufacturer will spend nearly $3 billion developing a single new medicine,[8] with a failure rate exceeding 99.98% in preclinical testing.[9] Yet only one in five approved drugs will ever generate revenues that exceed average development costs.[10]

Innovators can only support these significant upfront investments if their inventions are protected by a predictable system of patent and antitrust enforcement. The Hatch-Waxman Act and the Biologics Price Competition and Innovation Act created deliberate frameworks in which patent disputes are resolved through litigation before generic or biosimilar entry, with the understanding that valid patent rights will be enforced in order to continue to incentivize investment in novel therapies. The ability to petition courts to enforce patent-protected exclusivity

[7] PhRMA, *2025 PhRMA Annual Membership Survey* 3 tbl. 1 (July 14, 2025), https://bit.ly/43tk1VM.

[8] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/30UAIdg.

[9] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK; *see also* Aroon D. Hingorani et al., *Improving the Odds of Drug Development Success Through Human Genomics: Modelling Study*, 9 Sci. Reps. 18911, at 2 (2019), https://bit.ly/4tPPOej (discussing failure rate of over 96%).

[10] John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010), https://bit.ly/4tY8RmW.

against infringing products, and to rely on the finality of the resulting judgments, is a central pillar of that system. This system of pharmaceutical innovation has helped countless patients over the decades. Since 2000, nearly 900 new medicines have been approved by the FDA[11] and, in 2025 alone, PhRMA members received FDA approval for 52 medicines.[12]

Sandoz's theory would undermine predictability by creating a regime in which successful patent enforcement action carries with it the specter of follow-on antitrust liability. An innovator that obtains an injunction after prevailing in court on the merits could face the prospect of a second round of costly litigation—years later, and potentially in a different jurisdiction—in which it must defend the very patent rights that a court previously upheld. That uncertainty alone would alter investment calculations, particularly for biologics and other high-cost therapies where development timelines stretch over a decade or more. And because antitrust litigation in the pharmaceutical context tends to involve complex economic testimony, expert witnesses, and extensive document discovery, the burden on both parties and the courts would be substantial.

[11] PhRMA, *Future of Medicine*, https://bit.ly/42UI5AQ (last visited June 5, 2026).

[12] Kristen Booze, PhRMA, *Advancing Patient Care: A Look at New Medicines Approved in 2025* (Jan. 30, 2026), https://bit.ly/4dtfdFV (noting that 14 of the approvals were for oncology drugs).

As this Court has recognized, courts "should hesitate to apply antitrust sanctions" where doing so would "discourage innovation and investment." *Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 427 (4th Cir. 1986). That admonition applies with full force here.

III. AMGEN'S LICENSING OF PATENT RIGHTS CANNOT TRIGGER ANTITRUST LIABILITY.

As explained above, the District Court correctly dismissed Sandoz's complaint for failure to state a claim. However, the District Court's opinion incorporated its flawed holding from the related *CareFirst* case that the plaintiff had "'plausibly alleged anticompetitive conduct pursuant to Federal Rule of Civil Procedure 12(b)(6)' based upon [Amgen's] acquisition of the Roche Patent Rights," which included a pending U.S. patent application. JA23 (quoting *Amgen*, 2025 WL 4704542, at *14); *accord* JA2–5. This Court should clarify that Amgen did not engage in anticompetitive behavior when it acquired these rights from Roche.

A. Patent Applications Confer No Exclusionary Rights.

As an initial matter, it is axiomatic that patent applications provide no exclusionary rights. The Patent Act provides that "[e]very *patent* shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude" and that "such grant shall be for a term *beginning on the date on which the patent issues*." *See* 35 U.S.C. § 154(a)(1)–(2) (emphases added). It follows that no exclusionary right exists prior to "the date on which the patent issues," i.e., when the applicant

possesses only an unenforceable patent application. *See In re Forest*, 134 F.4th 1198, 1200 (Fed. Cir. 2025) ("These exclusionary rights begin when the patent issues and end twenty years after the application date or applicable priority date.").[13] Indeed, a patent application is nothing more than a request that the United States Patent and Trademark Office ("USPTO") issue a patent containing the claims set forth in the patent application. Unless the USPTO determines that a patent should issue, there is no cognizable right to exclude, no ability to enforce that right against competitors, and no power to block market entry.

An applicant's ability to obtain an issued patent from a patent application is far from certain. And there is no guarantee that any patent that does issue will contain claims that cover the scope sought in the originally-filed patent application. That is because independent experts at the USPTO evaluate each patent application in light of the disclosure in the specification and the pertinent prior art to determine whether

[13] The Patent Act's grant of so-called "provisional rights" further confirms this understanding. *See* 35 U.S.C. § 154(d). Provisional rights begin to run on the date a patent application is published, but they are not exclusionary and they do not attach until a patent actually issues. *In re Forest*, 134 F.4th at 1200 (explaining that "provisional rights [i.e., a reasonable royalty] run from when the application is published until the patent issues. . . . Provisional rights are thus less robust than section 154(a) exclusionary rights, and they are 'provisional' in the sense that the rights end and are replaced by the statutory exclusionary rights once a patent issues. Importantly, provisional rights do not materialize until the Patent Office issues a patent." (cleaned up)). For this reason, the Federal Circuit expressly distinguished between provisional rights for a published patent application and exclusionary rights for an issued patent. *Id.* at 1202 ("[P]rovisional rights attach to 'the invention as claimed in the published patent application,' 35 U.S.C. § 154(d)(1)(A)(i)–(ii), whereas exclusionary rights attach to the issued patent, 35 U.S.C. § 154(a)(1).").

the claims should be allowed and, if so, what their scope can be. *See generally* 37 C.F.R. § 1.104(a) ("On taking up an application for examination . . . , the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application . . . with the applicable statutes and rules and to the patentability of the invention as claimed . . . ."). "If the invention is not considered patentable, or not considered patentable as claimed, the claims, or those considered unpatentable will be rejected." *Id*. § 1.104(c)(1).

As a result of the USPTO's examination process, a substantial percentage of applications never mature into issued patents. This is especially true for patent applications in the pharmaceutical space.[14] Accordingly, the acquisition of rights to a pending application constitutes nothing more than the purchase of a contingent, uncertain interest that may never mature into an exclusionary right. It strains credulity to conclude that such a transaction could give rise to antitrust liability.

[14] *See, e.g.*, Michael Carley et al., *What Is the Probability of Receiving a U.S. Patent?*, 17 Yale J. L. & Tech. 203, 212 (2015), https://perma.cc/Y6QB-NN5C (reporting, based on analysis of 2.15 million U.S. patent applications from 1996 through mid-2013, that patent "[a]pplications in Drugs and Medical Instruments have the lowest average allowance rate of 42.8%").

B. Sandoz's Approach Would Inject Needless Uncertainty into Routine Business Transactions.

Adopting Sandoz's analysis also would make it impossible to determine at the time of the transaction whether an acquisition or license to a patent portfolio exposes the participants to future antitrust liability. That is because patent prosecution is not a ministerial path from application to issuance. An applicant submits proposed claims, and a USPTO examiner reviews those claims for compliance with the Patent Act. If the examiner rejects the claims, the applicant may amend the claims to address the examiner's patentability concerns or to claim different aspects of the disclosed invention (e.g., the crystalline form of the active ingredient or the dosing schedule). There can be, and often are, multiple rounds of claim amendments by the applicant and rejections by the examiner. Because the examiner may reject the claims as filed, suggest amendments, or allow only amended claims, neither the ultimate issuance of a patent nor the claim scope is predictable. The patent that does issue, if any, may contain claims that cover a materially different scope than the claims that were pending when the application was acquired.

An example illustrates the confusion that Sandoz's reasoning would cause. Assume that the '790 and '791 Applications did not contain claims that covered etanercept, the active ingredient in Enbrel, at the time that Amgen acquired rights to

those applications from Roche.[15] If the USPTO granted patents on the '790 and '791 Applications in their original form (i.e., without claims that read on Enbrel biosimilars), presumably Sandoz would agree that the acquisition of rights to those patent applications was not anticompetitive. So, too, if the USPTO never granted patents on the '790 and '791 Applications at all, even if the claims in the pending applications were amended during prosecution to read on an Enbrel biosimilar. But if the '790 and '791 Applications were later amended to contain claims that cover Enbrel biosimilars and the USPTO eventually granted patents on those applications then, according to Sandoz, Amgen's acquisition of rights to the '790 and '791 Applications becomes anticompetitive.

This cannot be right. Such a rule would allow events occurring years later to retroactively transform an otherwise legal transaction into a violation of the antitrust laws. What's more, the legality would turn not on the parties' conduct (or even intent) at the time of the transaction but rather on the unknown—and unknowable—future decisions of an independent patent examiner at the USPTO regarding the permissible scope and validity of the amended claims in the patent application.

Introducing this level of risk and uncertainty into routine business transactions runs counter to the Supreme Court's guidance, which "ha[s] repeatedly emphasized

[15] The District Court noted in the *CareFirst* case that this issue was "extensively litigate[d]" and "is a factual determination." *Amgen*, 2025 WL 4704542, at *14 n.20.

the importance of clear rules in antitrust law." *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 452 (2009). That is because of the "'significant costs' in 'business certainty and litigation efficiency'" associated with antitrust litigation, *Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289 (1985), and its potential to "chill the very conduct the antitrust laws are designed to protect," *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986).

C. Policy Considerations Require Rejection of Sandoz's Position.

Any suggestion that the mere acquisition of rights to patents or patent applications opens the door to antitrust liability would wreak havoc on the biopharmaceutical and biotech industries because it would inevitably diminish or destroy the incentive to innovate that is required to bring new life-saving therapies to market. As demonstrated above, companies in these fields regularly license and purchase patent rights, as they facilitate the ability to introduce innovative therapies faster, cheaper, and with less risk. Accordingly, it is not surprising that these kinds of transactions are expressly contemplated by the Patent Act,[16] which Congress passed pursuant to the Constitution's authorization "To promote the Progress of . . .

[16] *See, e.g.*, 35 U.S.C. § 261 ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.'" *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966) (quoting U.S. Const. art. I, § 8, cl. 8).

Consider, for example, a startup company developing a promising new technology that lacks the financial resources or expertise to navigate the clinical trial and FDA approval process. That company would benefit financially from licensing or selling its patent rights to an entity that has the expertise and financial wherewithal to obtain regulatory approval and commercialize the product, and the public would benefit from the product being introduced.

But Sandoz's approach would impose staggering costs, introduce profound uncertainty into this standard practice, and ultimately reduce or eliminate altogether the investment incentives that deliver life-saving treatments to patients. It is not uncommon for patent licensing or acquisition deals to include dozens of patents and applications. If this Court adopted Sandoz's analysis, parties would be forced to assess not only the scope of existing rights for all patents in the portfolio, but also the speculative future contours of all patent applications still under examination. This would require a significant increase in the diligence costs for each deal because antitrust and patent attorneys would need to pore over every patent application to determine whether it contains claims that could cover future competing products. Antitrust and patent counsel would also need to determine whether the specification

of each patent application would support amendments to the claims that could cover future competing products and, if so, how likely it is that a future examiner at the USPTO would grant claims with the requested scope. The challenge is exacerbated for potential licensees because the licensor often retains control over prosecution of the licensed patent applications. This leaves the licensee trying to predict during diligence not just what rejections an examiner may issue years in the future, but also how the licensor will respond to those future, unknown rejections.

This would devastate the very innovation ecosystem the patent system is designed to promote. There would be fewer patent acquisition and licensing transactions and thus fewer products that are commercialized based on those transactions. For the deals that do go through despite the heightened antitrust risk environment, the additional scrutiny required during diligence would significantly delay the timelines and increase the costs. In the end, consumers would be left with fewer, more expensive therapies, and they would be forced to wait longer for those therapies to become available, if ever.

* * *

CONCLUSION

For the foregoing reasons, *Amici* urge this Court to affirm dismissal of Sandoz's claims for failure to state a claim, to confirm that antitrust damages cannot be based on the effects flowing from judicial decisions, and to clarify that the acquisition of rights to patent applications cannot give rise to antitrust liability.

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Respectfully submitted,

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This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 6,458 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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I hereby certify that on July 6, 2026, the foregoing brief was filed with the Clerk of Court for the U.S. Court of Appeals for the Fourth Circuit and served on all counsel who have entered an appearance in this action via the Court's CM/ECF system.

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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