NO. 26-1309

IN THE 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-218-AWA-RJK

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING DEFENDANTS-APPELLEES AND AFFIRMANCE

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IDENTITY AND INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, it regularly appears as amicus curiae to defend patent owners' rights in the face of antitrust challenges. *See, e.g., FTC v. Actavis*, 570 U.S. 136 (2013); *Impax Labs., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022).

This appeal asks whether a party that lost a patent suit may avoid Rule 13(a) by recasting its prior patent-validity challenge as a Section 2 Sherman Act claim in a later action. The answer carries significant consequences for the reliability of patent judgments. WLF urges the Court to affirm settled principles of Rule 13(a) and res judicata and to reject Sandoz's attempts to conjure a sweeping exception to those rules.

* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Antitrust law does not permit one district court to function as an appellate tribunal for another. Sandoz's appeal is an assault on principles of judicial finality. A party can't ask a federal court to effectively overturn a sister court's determination of patent validity by recasting a rejected patent defense as an antitrust claim in a later action. But that is what Sandoz attempts here.

The underlying dispute is not new. In 1998, drug company Immunex licensed patents from another drug company, Roche, to commercialize "Enbrel" (also known as "etanercept")—a drug used to treat arthritis. After acquiring Immunex, Amgen licensed etanercept patent rights from Roche in 2004, including two etanercept patent applications. The applications, years later, issued as the '182 and '522 patents.

In 2016, Amgen asserted those patents against Sandoz and its biosimilar drug "Erelzi" in *Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366 (D.N.J. 2019). Sandoz sought to invalidate the '182 and '522 patents under a double-patenting theory that argued the patents improperly extended Amgen's "etanercept monopoly." *Immunex*, 395 F.

Supp. 3d at 409. That argument was litigated, rejected on the merits, affirmed on appeal, and left undisturbed by the Supreme Court. Sandoz now seeks a second bite at the apple—this time, reframing the same theory as a Section 2 claim and arguing that Amgen's acquisition of rights to the Roche patent applications constitutes unlawful monopolization. *See* Sandoz Br. 2 (referencing 15 U.S.C. § 2). Sandoz's maneuver fails for three reasons.

First, preclusion rules bar Sandoz's Section 2 claim. Rule 13(a) bars the claim because it arises from the same "transaction or occurrence" as the prior *Immunex* action. Res judicata also forecloses the claim because it is a collateral attack on a final judgment.

Second, Sandoz can't avoid Rule 13(a) by relying on *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944). Courts—including this Circuit—widely criticize that decision, interpret it narrowly, and limit it to its unusual facts. Expanding *Mercoid* as Sandoz suggests would weaken the finality of patent judgments, invite duplicative litigation, and create uncertainty over patent rights.

Third, even on the merits, Sandoz's theory fails because acquisition of patent applications is not exclusionary conduct under Section 2, and the *Immunex* judgment precludes Sandoz's claim to any antitrust injury.

Appeals are for appellate courts, not follow-on district court cases. This Court should affirm.

ARGUMENT

I. SANDOZ'S SECTION 2 CLAIM IS AN INVALID COLLATERAL ATTACK ON A FINAL JUDGMENT.

Sandoz asks this Court to undermine a basic principle: a party that litigates and loses an issue in federal court cannot evade that judgment by repackaging the same theory under a different statute in a new forum.

Immunex already addressed whether the '182 and '522 patents improperly extended Amgen's exclusive rights to the etanercept molecule. *See Immunex*, 395 F. Supp. 3d at 409. Sandoz argued in *Immunex* that "the Patents-in-Suit . . . should be invalidated because Immunex [now Amgen] has used [them] to obtain[ ] an unjustified timewise extension of its etanercept monopoly." *Id.* The parties litigated this question through trial and appeal. The *Immunex* court rejected Sandoz's arguments and issued a final judgment holding the patents valid and enforceable. *Id.* at 423; (JA 231–34).

Sandoz now advances the same theory but masks it as a Section 2 claim. (JA 093). It alleges that "Amgen's acquisition of the [patents] was for the purpose, and has had the consequence of, unlawfully extending and maintaining Amgen's monopoly in the market for etanercept . . . ." *Id*. Sandoz's attempt at a redo is foreclosed by Rule 13(a) and res judicata.

Rule 13(a) requires a defendant to assert any counterclaim arising from the same "transaction or occurrence" as the plaintiff's claim. Fed. R. Civ. P. 13(a). And a defendant that fails to do so is barred from raising the counterclaim in a later action. *See Q Int'l Courier Inc. v. Smoak*, 441 F.3d 214, 219 (4th Cir. 2006) ("If the claims asserted in the second action would have been considered compulsory counterclaims . . . the claims will be precluded in the second action").

Courts determine whether Rule 13(a) applies by examining the extent to which facts, law, and evidence overlap in the two suits and whether res judicata independently bars the claim. *See Painter v. Harvey*, 863 F.2d 329, 331 (4th Cir. 1988). The district court properly dismissed Sandoz's Section 2 claim under Rule 13(a). The claim rests on the same conduct and core theory as that litigated in *Immunex*—the assertion that

the '182 and '522 patents improperly extended Amgen's exclusive rights to etanercept.

Rule 13(a) works to ensure that all related disputes are resolved in a "single judicial proceeding"—not relitigated in successive suits. *Frank M. McDermott, Ltd. v. Moretz*, 898 F.2d 418, 420 (4th Cir. 1990). Permitting Sandoz to proceed with its Section 2 claim would defeat this purpose and create a pathway for endless relitigation of patent disputes. Rule 13(a) forecloses that gambit.

Res judicata reinforces this point and the district court's dismissal. *See Q Int'l Courier*, 441 F.3d at 219 (Rule 13(a) asks in part "whether res judicata would bar a subsequent suit on the counterclaim"). Res judicata bars a counterclaim when pursuing it "would nullify [an] initial judgment or would impair rights established in the initial action." *In re Iannochino*, 242 F.3d 36, 42 (1st Cir. 2001) (applying Restatement (Second) of Judgments § 22(2)(b)); *Jones v. HSBC Bank USA, N.A.*, 444 F. App'x 640, 644 n.3 (4th Cir. 2011) (same). Yet that is exactly what Sandoz seeks here: to undo the exclusivity conferred by patents already adjudicated as valid. (JA 272) ("Sandoz seeks . . . to enjoin Amgen's exclusive use of the . . . Patent Rights").

Sandoz tries to avoid these preclusion rules by arguing that its patent-validity challenge in *Immunex* was a "defense," and not part of Amgen's infringement claim. Sandoz Br. 30-32. But there's no difference in that distinction.

None of Sandoz's cases permits a party that litigated and lost on patent validity to relitigate that same issue in a later action under a new label. *See* Sandoz Br. 31–32. Patent validity is not collateral to infringement; it is central to it. A patentee cannot prevail in an infringement action unless the asserted patent survives validity challenges. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) (explaining that patent statute provides remedies to a patent holder who "proves infringement of a valid patent"); *Gamehancement LLC v. Footage Firm, Inc.*, 801 F. Supp. 2d 3d 578, 588 (E.D. Va. 2025) ("[A] plausible claim for relief in a patent infringement case necessarily requires a valid patent."). Sandoz's effort to invalidate the '182 and '522 patents in *Immunex* was thus a case-defining issue. Sandoz cannot relitigate it now through a different statutory label. *See, e.g., Nash Cnty. Bd. of Educ. v. Biltmore Co.*, 640 F.2d 484, 488 (4th Cir. 1981) (res judicata turns on the subject matter of the suits, not whether they involve

different statutes); *Greer v. Bd. of Trs. of Univ. of D.C.*, No. 24-710, 2025 WL 1186259, at *1 (D.D.C. Feb. 7, 2025) (a party who "applies a different label to the same conduct" remains "barred by res judicata").

Sandoz also insists that its Section 2 claim rests not on "alleged patent invalidity," but on Amgen's "unlawful acquisition of Roche's patent applications," which extended "its monopoly." Sandoz Br. 23, 38. But that distinction is illusory. Sandoz seeks to enjoin Amgen's exclusive use of the patents. (JA 272). By definition, a patent is a grant of lawful exclusivity. *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) ("The basic right concomitant to the grant of a patent is the right of exclusivity."); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."). To deny Amgen the exclusivity conferred by the patents is, in substance, to agree that the patents are invalid. Indeed, if a party that lost a patent-validity challenge may later attack the same exclusionary rights through a collateral antitrust suit, final patent-validity judgments would lose much of their force.

II. SANDOZ'S *MERCOID* ARGUMENT FAILS.

Sandoz contends that *Mercoid* exempts antitrust claims from Rule 13(a) whenever an earlier case involved patent-infringement claims. *See* Sandoz Br. 15-17. Sandoz's position is wrong under Fourth Circuit precedent, reads *Mercoid* far too broadly, and would seriously disrupt the patent system.

A. There is no "*Mercoid* exception."

Mercoid does not create an exception to Rule 13(a). Its unusual circumstances and sparse treatment of counterclaim rules show why.

In *Mercoid*, a patentee who had licensed the manufacture of components for its patented furnace system sued a homeowner for infringement after he installed the system using parts made by Mercoid, an unlicensed manufacturer. 320 U.S. at 663. Mercoid—who had funded the homeowner's defense *but was not a party to the suit*—later asserted an antitrust counterclaim when the patentee sued it directly. *Id*. at 663-64, 669. Although the Supreme Court ultimately allowed the antitrust claim to proceed (*id*. at 671–72), nothing in the opinion supports Sandoz's sweeping exception.

The opinion's discussion of counterclaim rules is cursory and never mentions Rule 13(a). Instead, the Court simply assumed that "Rule 13(b)," governing permissive counterclaims, applied. *Id.* at 671. Mercoid's non-party status in the first action should have resolved the preclusion issue by itself. As Wright & Miller explain, the Court's "discussion of whether the counterclaim was compulsory in the first action was entirely unnecessary" because Mercoid "had not been a party to it." Wright & Miller, *Federal Practice & Procedure* § 1412. *Mercoid* supplies no governing counterclaim principle, much less a categorical rule allowing parties bound by the judgment to evade Rule 13(a) in patent cases by later packaging the dispute as an antitrust action. *See Critical-Vac Filtration Corp. v. Minuteman Int'l, Inc.*, 233 F.3d 697, 702 (2d Cir. 2000) (explaining that *Mercoid* must be read narrowly because the opinion does not "discuss the principles on which its decision rested") (cleaned up).

The Fourth Circuit has long recognized that *Mercoid* is an anomaly that does not create a broad exception to Rule 13(a). In *Burlington Indus. v. Milliken & Co.*, 690 F.2d 380 (4th Cir. 1982), this Court declared that *Mercoid* "has been read narrowly," and its continuing validity is "open to serious question." *Id.* at 389.

Other courts agree and have consistently limited *Mercoid* to its unique facts, rejecting efforts to transform it into an escape hatch from Rule 13(a). *See Critical-Vac*, 233 F.3d at 702; *Martino v. McDonald's Sys., Inc.*, 598 F.2d 1079, 1086 (7th Cir. 1979) (limiting *Mercoid* to its facts—"[n]othing in *Mercoid* justifies [appellant's] argument that *Mercoid* generally prohibits application of res judicata in antitrust claims"); *USM Corp. v. SPS Tech., Inc.*, 102 F.R.D. 167, 169–70 (N.D. Ill. 1984) ("[T]he majority of courts . . . have held that antitrust claims are compulsory counterclaims."); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 932 (D. Del. 1991) ("*Mercoid* has been widely and severely criticized."); *see also* John J. Barnhardt III, *Counterclaiming in Patent Infringement Litigation*, 15 AIPLA Q.J. 175, 182 (1987) ("[M]ost courts restrict *Mercoid* to its facts.").

This approach follows directly from Rule 13(a) itself. Like all Federal Rules of Civil Procedure, Rule 13(a) carries the force of a federal statute, and its text contains no exception for antitrust claims in patent litigation. *Bright v. United States*, 603 F.3d 1273, 1279 (Fed. Cir. 2010). Courts may not create an atextual carveout from a decision that neither mentions Rule 13(a) nor explains its reasoning. *See Bus. Guides, Inc. v.*

Chromatic Commc'ns Enters., Inc., 498 U.S. 533, 540 (1991) (emphasizing that the Federal Rules of Civil Procedure are to be given "their plain meaning"). The Supreme Court's decision in *SEC v. Jarkesy*, 603 U.S. 109 (2024) reinforces this point: courts should not extend a thin, criticized, and analytically opaque exception beyond its facts. 603 U.S. at 138–39 n.4 (declining to apply *Atlas Roofing* exception beyond its facts where the decision lacked substance, was widely criticized, and relied on "circular" reasoning).

And *Mercoid*'s facts are easily distinguishable here. It was a patent-misuse case where a patentee sought to leverage patent rights to control unpatented goods, not an attempt to relitigate patent validity after a final judgment. Sandoz's reliance on a handful of out-of-circuit cases (Sandoz Br. 16) underscores this contrast. In those cases, the antitrust claims generally rested on allegations of sham litigation akin to malicious prosecution and arose either while patent validity was still being litigated or after invalidity had already been established. This case is the opposite: the *Immunex* court fully adjudicated the validity of the '182 and '522 patents and upheld Amgen's exclusivity rights, which Sandoz now seeks to collaterally attack.

No court has invoked *Mercoid* to "justify allowing a party to launch a collateral attack on a ruling in the first action, the effect of which would be to alter the judgment in that action." *Cummins, Inc. v. TAS Distributing Co, Inc.* 700 F.3d 1329, 1338 (Fed. Cir. 2012) (internal cites and quotes omitted). This Court should not be the first.

B. Accepting Sandoz's *Mercoid* theory would disrupt the patent system.

Not only is Sandoz's proposed *Mercoid* exception unsupported by law, but it would also create an antitrust end-run around patent litigation, with serious practical consequences.

First, it would invite collateral attacks on sister-court judgments. The *Immunex* court upheld the '182 and '522 patents, found infringement, and entered an injunction barring Sandoz's product. That judgment remains in force. Sandoz's Section 2 claim would declare the patents' exclusionary effect unlawful, and in practical terms, nullify the *Immunex* judgment. The law does not allow that.

One district court cannot undo another's final judgment through a follow-on suit. *See, e.g.*, *Celotex Corp. v. Edwards*, 514 U.S. 300, 313 (1995) ("[i]t is for the court of first instance to determine the question of the validity of the law, and until its decision is reversed for error . . .

either by itself or by a higher court, its orders based on its decision are to be respected"); *Alley v. U.S. Dep't of Health & Hum. Servs.*, 590 F.3d 1195, 1203 (11th Cir. 2009) (explaining in FOIA case that "[a]n injunction issued by one court" cannot be "collaterally attacked in another court" through another statute) (collecting cases). But Sandoz's reading of *Mercoid* would invite such unlawful interference as a matter of course.

Second, Sandoz's position would unsettle final judgments on patent validity—judgments on which the "public at large" depends. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993). Under Sandoz's theory, unsuccessful patent challengers could seek second-round litigation under a different statute and in a different court. Patent owners should not be forced into double litigation on the same patent.

Patent litigation is notoriously protracted and costly. It costs about $3.6 million—give or take—to litigate a patent case with more than $25 million at stake. *See* American Intellectual Property Law Association, *AIPLA 2025 Report of Economic Survey* at 34 (2025). And this figure omits the substantial business costs that never appear on an invoice—diverted personnel, "lost opportunities, diminished innovation, and eroded shareholder value." DrugPatentWatch, *The Cost of Combat:*

Deconstructing Drug Patent Litigation in the Pharmaceutical Age (Feb. 2, 2026), https://perma.cc/2CPZ-ASF9.

The possibility of relitigating validity and exclusivity rights—years later and under the guise of antitrust—would inject pervasive uncertainty into the patent system. As one commentator observes, "[u]ncertainty, especially in the validity and thus value of a patent, is bad for technological advancement because it results in an increased risk for investment in new technologies, which in turn potentially stifles further innovation." Lidiya Mishchenko, *Alice: Through the Formalist Looking-Glass*, 97 JPTOS 214, 215 (2015). Businesses rely on final patent judgments to make long-term investment and commercialization decisions.

But Sandoz's position would severely undermine the finality of these judgments, invite serial litigation over issues already conclusively resolved, and create prolonged uncertainty over a firm's patent rights. This Court should refuse to adopt a novel rule that invites so much mischief.

III. SANDOZ'S SECTION 2 CLAIM FAILS ON THE MERITS.

Even setting aside the dispositive procedural issues, Sandoz's Section 2 claim fails on the merits.

Because the *Noerr-Pennington* doctrine forecloses any challenge to Amgen's patent-prosecution or enforcement activity, Sandoz attempts to reframe this case around Amgen's acquisition of "Roche's patent *applications*." *See* Sandoz Br. 23 (emphasis added). It then points to the later *Immunex* judgment—which bars Sandoz from marketing Erelzi until 2029—as the supposed antitrust injury. Sandoz's reframing attempt collapses for two reasons.

First, acquiring patent applications is not exclusionary conduct under Section 2. *See 2311 Racing LLC v. NASCAR*, 139 F.4th 404, 410 (4th Cir. 2025) (explaining that a Section 2 claim requires conduct to "exclude rivals on some basis other than efficiency"). A pending patent application confers no enforceable right to exclude. *See Marsh v. Nichols, Shepard & Co.*, 128 U.S. 605, 612 (1888) ("Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce"); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1581 (Fed. Cir. 1997) (agreeing with government that "the right to exclude does not inure

until the patent issues"); *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("Filing an application is no guarantee any patent will issue and a very substantial percentage of applications never result in patents").

Indeed, treating the acquisition of patent applications as actionable monopolization would make investment in early-stage intellectual property legally perilous. It would demand that firms speculate about whether a valid patent would issue, whether the issued patent would materially differ from the application, and whether the resulting patent might someday intersect with a competitor's product or process. Such a rule would demand diligence bordering on clairvoyance, slow transactions, chill investment in companies selling their IP, and undermine the Supreme Court's instruction to "safeguard incentives to innovate." *Verizon Commc'ns Inc. v. Trinko*, 540 U.S. 398, 407 (2004).

Second, the *Immunex* judgment cannot supply Sandoz's antitrust injury. A court order upholding patent validity and entering an injunction is a judicial act, not anticompetitive conduct by a private party. Sandoz thus can't recast the consequences of that judgment as antitrust injury attributable to Amgen. *See, e.g., Andrx Pharm., Inc. v.*

Biovail Corp. Int'l, 256 F.3d 799, 818 (D.C. Cir. 2001) ("If anticompetitive harm is caused by the decision of a court . . . no private restraint of trade occurs because the intervening government action breaks the causal chain"); *A.D. Bedell Wholesale Co. v. Philip Morris, Inc.*, 263 F.3d 239, 251 (3d Cir. 2001) ("parties are immune from liability arising from the antitrust injuries caused by government action which results from [ ] petitioning").

This government-action rule should apply here. When a court grants relief, the resulting order carries the government's imprimatur and breaks the causal chain between the petitioning party and the alleged competitive harm. Otherwise, a firm could face antitrust liability for consequences created—and expressly approved—by the government itself. That result would convert judicial relief into antitrust exposure and erode the ability of parties to rely on final judgments.

CONCLUSION

Sandoz's claims are procedurally barred, legally flawed, and incompatible with fundamental principles of finality and comity. The law does not permit re-litigation by relabeling. The Court should enforce Rule 13(a), respect the finality of judgments, and affirm.

Respectfully submitted,

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July 6, 2026

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,445 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it uses 14-point Century Schoolbook font.

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CERTIFICATE OF SERVICE

I certify that on July 6, 2026, I filed the above brief with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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