

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-218-AWA-RJK

**BRIEF OF *AMICUS CURIAE* HONORABLE PAUL R. MICHEL
(RET.) IN SUPPORT OF DEFENDANTS-APPELLEES**

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INTEREST OF *AMICUS CURIAE*¹

The Honorable Paul R. Michel (ret.) served on the U.S. Court of Appeals for the Federal Circuit for over twenty-two years. From 2004 until his retirement in May 2010, he was the chief judge of the court. During his twenty-two years of judicial service, he heard thousands of appeals and authored over 800 opinions, touching on all aspects of the court's jurisdiction, including patent law.

Judge Michel's judicial work is frequently noted for its influence on patent law, but the Federal Circuit has regularly confronted complex antitrust issues. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998). From its inception, the Federal Circuit has tackled issues at the interface of antitrust and patent law. *See, e.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984).

¹ No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting this brief; and no person other than amicus or his counsel contributed money to fund preparing or submitting this brief. Fed. R. App. P. 29(a)(4)(E). All parties have consented to this brief's filing.

Since he retired from the Federal Circuit, Judge Michel has maintained an active role in the public dialogue about optimal policies governing intellectual property and U.S. innovation. He has authored or co-authored numerous articles touching on innovation policy. *See, e.g.*, Paul R. Michel & Matthew J. Dowd, *Patent Protection: A Crucial Antitrust Tool for Increasing Innovation*, TechReg Chronicle (Oct. 1, 2024); David Kappos & Hon. Paul R. Michel, *The Smallest Salable Patent-Practicing Unit: Observations on its Origins, Development, and Future*, 32 Berkeley Tech. L.J. 1433 (2018); Paul R. Michel & Matthew J. Dowd, *The Need for “Innovation Certainty” at the Crossroads of Patent and Antitrust Law*, CPI Antitrust Chronicle (Apr. 2017). Judge Michel has also been invited to testify before Congress on substantive patent law issues that are critical to the Nation’s economic health.

More recently, in cases addressing the patent-antitrust intersection, Judge Michel has submitted briefs as an amicus curiae in *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020), and *Simon & Simon, PC v. Align Technology, Inc.*, Nos. 24-1703, 24-1783 (9th Cir. filed Mar. 21, 2024) (pending; argued April 10, 2025). The Ninth Circuit’s

opinion in *FTC v. Qualcomm* favorably cited Judge Michel’s amicus brief. 969 F.3d at 997, 999 n.20.

Judge Michel is one of the nation’s leading patent law experts, having a unique combination of judicial experience, legal expertise, and the total absence of any financial conflicts of interest. He is currently a board member for Council for Innovation Promotion (“C4IP”)² and for Inventors Defense Alliance,³ among several other organizations.

His sole objective is to respectfully share his perspective as a true friend of the court to ensure that the U.S. legal system—including patent law and antitrust law—creates the optimal incentives for inventors, innovators, and investors. Judge Michel also offers his perspective on the present appeal to ensure that the U.S. innovation ecosystem remains competitive in the global marketplace.

SUMMARY OF THE ARGUMENT

This case presents an antitrust challenge seeking to undermine the finality of a patent-infringement judgment that was affirmed on appeal more than six years ago. The outcome of Sandoz’s antitrust claim would

² <https://c4ip.org>.

³ <https://inventorsdefense.org>.

collaterally unwind the Federal Circuit's decision, where that appeals court affirmed Amgen's valid patent rights and where Sandoz did not dispute infringement by its biosimilar product. That type of collateral attack should not be permitted for several reasons.

First, patent and antitrust laws promote innovation, competition, and the public interest in complementary ways. Those objectives are best served when related patent and antitrust disputes are litigated together. Rule 13(a)'s compulsory-counterclaim requirement furthers the important interests of finality, judicial economy, and certainty in patent rights by preventing parties from withholding logically and largely related claims, only to litigate those related claims years later.

Second, Sandoz's three specific policy arguments for permitting its antitrust claims almost eight years after the patent action are unpersuasive. Bifurcation is more concerned with trial management and potential jury confusion—not whether the related antitrust and patent claims can be brought in separate lawsuits years apart. The Federal Circuit's exclusive jurisdiction over patent appeals reflects Congress's desire for uniformity in patent law. It is in no way a suggestion that Congress intended that antitrust claims should not be decided by the Federal Circuit in

related patent litigation. Nor does Sandoz's ripeness argument hold water. To the contrary, parties should be encouraged to assert antitrust claims as soon as possible in related patent litigation involving largely the same or logically related facts and issues. If the antitrust claim is too early, no preclusion attaches, and the party can assert it later when it is ripe.

Third, *Mercoïd Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661 (1944), does not create a broad rule that antitrust counterclaims are typically permissive to related patent-infringement claims. *Mercoïd* has long been criticized as thinly reasoned and has been correctly cabined to its specific context by several courts, including the Fourth Circuit. A context-based application of *Mercoïd*—confined to its facts—better reflects the modern complementary relationship between patent and antitrust law, preserves Congress's objective of promoting certainty and uniformity in patent law, and prevents collateral attacks on patent judgments through antitrust actions filed years later based on substantially the same underlying facts and issues.

ARGUMENT

I. Related Patent and Antitrust Claims Should Be Litigated Together to Increase Innovation Incentives

Collateral attacks challenging valid intellectual property rights threaten the health of the Nation's innovation ecosystem. Such a threat is more pronounced when the attack comes years after a patent's validity is upheld by the Federal Circuit, the appellate court created by Congress to bring uniformity to patent law. These accepted principles make it even more important to consider the intertwined roles of patent and antitrust law in advancing the health of the innovation ecosystem.

Patent law and antitrust law, at their base, work in concert to improve the innovation ecosystem. "The patent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) (citing *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 866-67 (Fed. Cir. 1985)).

Unlike antitrust law, patent law is rooted in the Constitution, with it being the only personal right enumerated in the original Constitution. *See* U.S. Const. art. I, § 8, cl. 8. The First Congress recognized the

importance of patents when it enacted the Patent Act of 1790. Patent Act of 1790, ch. 7, 1 Stat. 109. Since that time, Congress has periodically revised the patent statutes to ensure that the law keeps up with innovation and optimizes the U.S. innovation ecosystem.

In 1890, Congress passed the Sherman Act as a reaction to its valid concerns about the robber barons of the oil, steel, and railroad industries. The terse statutes left much room for further jurisprudential development. “Since the Sherman Act was passed, the federal antitrust laws have cycled through extreme positions on the relationship between competition policy and the patent system.” Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio State L.J. 467, 468 (2015).

Conventional legal thought often treated patent law and antitrust law as being in irreconcilable conflict, but a more sophisticated and contemporary perspective understands them as complementary. *See generally* Jonathan M. Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (2021). Patents do grant an exclusive right and thus limit absolute competition in the short term, but they also facilitate monetary capitalization, which promotes

commercialization, thus leading to more products in the marketplace and thus more competition. *Id.* at 38; *see also* U.S. Dep’t of Justice & Fed. Trade. Comm’n, *Antitrust Guidelines for the Licensing of Intellectual Property*, at 5 (2017) (“Licensing, cross-licensing, or otherwise transferring intellectual property . . . can facilitate integration of the licensed property with complementary factors of production.”).⁴ Patents thus aid competition and reward innovative efforts with a limited grant of exclusivity—all of which increases investments in research and development with the attendant benefits that inure to the public. Dina Kallay, Deputy Assistant General, Dept. of Justice, Antitrust Division, *Fueling Innovation: Antitrust and Intellectual Property in Support of American Technological Leadership, Remarks Before the Center for Strategic and International Studies* (Mar. 25, 2026) (“A robust intellectual property regime plays a big role in promoting innovation and competition.”).⁵

Ultimately, antitrust law and patent law are tools that, when properly coordinated in a coherent fashion, encourage innovation and fair

⁴ <https://www.justice.gov/atr/IPguidelines/>.

⁵ <https://www.justice.gov/opa/speech/fueling-innovation-antitrust-and-intellectual-property-support-american-technological>.

competition. Courts have indeed recognized that the “aims and objectives of patent and antitrust laws . . . are actually complementary, as both are aimed at encouraging innovation, industry and competition.” *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990). In other words, the “primary interest of both intellectual property and antitrust law” is the “public interest.” *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1218 (9th Cir. 1997) (citing *Mercoide*, 320 U.S. at 665); *see also Qualcomm*, 969 F.3d at 988 (“Antitrust law, like patent law, is ‘aimed at encouraging innovation, industry, and competition.’” (quoting *Atari*, 897 F.2d at 1576)). “Despite the opportunities for conflict . . . , a central goal of both patent and antitrust law is the promotion of the public benefit through a competitive economy.” *Int’l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 427 (4th Cir. 1986).

This contemporary understanding of the patent-antitrust dynamic highlights the outdated and troubling view of the district court in *Zero Technologies, LLC v. Clorox Co.*, 713 F. Supp. 3d 40 (E.D. Pa. 2024). Sandoz relies heavily on *Zero Technologies* in its brief, Sandoz Br. 3-4, 24-27, but there is good reason to be skeptical of that heavy reliance. One red-flag point in the *Zero Technologies* decision is where the court

asserted that “a patent comes at a great social cost.” *Id.* at 69. That bald contention about “great social cost” is not accurate, however. Courts and the academic literature have thoroughly detailed the net benefit to societal growth and the advancement of innovation. The tenor of the *Zero Technologies* opinion unfortunately harkens back to outdated views of patents, such as the obsolete view that a patent by itself confers market power on a patent owner. *See Ill. Tool Works Inc. v. Indep. Ink Inc.*, 547 U.S. 28, 45 (2006) (“Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.”).

In short, a collateral attack on validly enforced patent rights—raised for the first time years after the underlying patent dispute—threatens the vitality of the innovation ecosystem. Patent and antitrust principles should work in concert. Of course, not all antitrust disputes will be so intertwined with the patent issues, but when they are, the law must encourage resolution in concert in order to align the complementary roles of patents and antitrust enforcement in innovation policy.

II. Sandoz's Policy Arguments are Not Persuasive

In its opening brief, Sandoz presents three specific policy-based contentions on why antitrust claims should not be considered compulsory counterclaims to patent-infringement claims. Sandoz Br. 25; *see also* Amgen Br. 40-42. Sandoz refers to these points as “crucial policy considerations” that “*Mercoïd* advances.” Sandoz Br. 25. An examination of Sandoz's points, however, shows that they do not advance the contention that adjudicating largely related patent and antitrust claims years apart and in separate appellate courts is beneficial.

A. Bifurcation Does Not Indicate that Related Patent and Antitrust Claims Should Be Litigated Separately

The first reason Sandoz advances is that “district courts regularly bifurcate trial of patent and antitrust claims” and that is supposedly evidence that antitrust claims need not be asserted when related patent-infringement claims are brought. Sandoz Br. 25-27.⁶ Sandoz reads too

⁶ Sandoz largely repeats several policy points presented in *Hydranautics v. FilmTec Corp.*, 70 F.3d 533, 536-37 (9th Cir. 1995), in support of that court's conclusion that certain antitrust counterclaims were not compulsory. Several courts have cited the *Hydranautics* points over the past thirty years, including *Zero Technologies*, 713 F. Supp. 3d at 68-69, but few have explored the validity of the *Hydranautics* points. As explained herein, *Hydranautics* is less persuasive than it first appears.

much into bifurcation, which is mainly a procedural tool used for “convenience, to avoid prejudice, or to expedite and economize.” Fed. R. Civ. P. 42(b). It does not override the need for finality in disputes between the same parties over logically related issues.

Bifurcation allows a court to manage related claims that are properly raised together. It is not, by itself, a justification for litigating related claims by years apart. In the patent/antitrust context, bifurcation is often employed to avoid jury confusion. *See, e.g., Audio MPEG, Inc. v. Dell Inc.*, 254 F. Supp. 3d 798, 806 (E.D. Va. 2017) (“In the interest of a just disposition of the litigation, the Court must consider whether bifurcation would improve the jury’s comprehension of the issues.”); *Indivior Inc. v. Dr. Reddy’s Lab’s S.A.*, No. 17-CV-7106 (KM)(CLW), 2020 WL 2139540, at *3 (D.N.J. May 5, 2020) (recognizing that “bifurcation will prevent the potential for significant juror confusion”).

In other instances, a court bifurcates the antitrust counterclaim from the patent claim not because they are unrelated but because “resolution of the patent infringement issues may render [the] antitrust [c]ounterclaim moot, thereby serving the interests of judicial economy.” *Otsuka Pharm. Co. v. Torrent Pharm. Ltd.*, 118 F. Supp. 3d 646, 659

(D.N.J. 2015); *see also Shenzhen Smoore Tech. Co. v. Next Level Ventures, LLC*, No. 2:22-CV-07646-AB-AGR, 2024 WL 5317246, at *3 (C.D. Cal. Dec. 4, 2024) (denying bifurcation but agreeing “that, in cases where resolving issues of patent validity and infringement before addressing the antitrust counterclaim may render the antitrust claim moot, a stay likely promotes judicial economy” (internal quotation omitted)). In short, bifurcation for trial says little about whether an antitrust counterclaim is logically related and thus compulsory to a patent-infringement claim.

Moreover, bifurcation in many instances involved antitrust claims that were compulsory counterclaims. *See, e.g., In re Innotron Diagnostics*, 800 F.2d 1077, 1078 (Fed. Cir. 1986) (consolidating and staying cases in view of argument that patent infringement claim was compulsory to antitrust claim); *see also Ingevity Corp. v. BASF Corp.*, No. 18-CV-1391-RGA, 2020 WL 1329604, at *2 (D. Del. Mar. 23, 2020) (bifurcating tortious interference and antitrust counterclaims).

Sandoz’s reasoning and its reliance on *Hydranautics v. FilmTec Corp.*, 70 F.3d 533 (9th Cir. 1995), urge that bifurcation is indicative of counterclaims that are not related enough to be compulsory. But experience and precedent indicate otherwise, as courts routinely bifurcate

compulsory counterclaims. That happens because bifurcation is concerned less with the “compulsory” nature of the counterclaim and more with judicial economy, pragmatic considerations, and the need to avoid jury confusion given the evidentiary overlap and complexity of related patent and antitrust claims.

Even antitrust claims that rest on other bases that are less “patent-intensive,” such as “patent misuse,” will frequently, if not always, involve deciding core patent-law issues. *See, e.g., Princo Corp. v. ITC*, 616 F.3d 1318, 1327 (Fed. Cir. 2010) (en banc) (addressing misuse claims requiring the purchase of unpatented products as a condition for a license). Such situations will often involve logically related issues of patent law, such as whether “the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects.” *Id.* at 1328.

Of course, not every antitrust counterclaim is so intertwined with the patent-law issues. With standard-essential patents, for instance, antitrust claims can be unrelated and separate from any fundamental patent-law issues, such as the patent’s scope. Instead, the antitrust claim rests on distinct conduct, such as whether a patent owner “deceptively

failed to disclose to the SSO [*i.e.*, the standard setting organization] the patent interests it held in four technologies that were standardized.” *Rambus Inc. v. FTC*, 522 F.3d 456, 459 (D.C. Cir. 2008). Antitrust disputes in the pharmaceutical context likewise do not always implicate substantive patent-law questions. *E.g.*, *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 125 (4th Cir. 2021) (alleging that a drug company “extended its patent monopoly for its branded drug Tracleer—a drug to treat pulmonary artery hypertension—beyond the patent’s expiration date” by refusing to sell drug samples to generic companies).

Nevertheless, experience teaches that piecemeal litigation of intertwined, logically related patent and antitrust claims undermines certainty in patent rights—and thus impairs innovation. It creates multiple bites at the apple. The two bites are most troubling when taken years apart, even though an infringer could have raised its Sherman Act claims when defending against the patent-infringement suit.

B. Sandoz’s Position Would Undermine Congress’s Mandate for Patent-Law Uniformity

Next, Sandoz points to “*Mercoïd*’s holding that antitrust counterclaims are merely permissive” as “honor[ing] Congress’s purpose of providing ‘different appellate paths for those two kinds of actions.’”

Sandoz Br. 27 (quoting *Zero Techs.*, 713 F. Supp. 3d at 68). That contention appears to misapprehend the purpose of the “different appellate paths” for patent law and antitrust law.⁷

In 1982, Congress created the Federal Circuit to remedy a long-standing problem of the lack of uniformity in patent law. See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982); H.R. Rep. No. 97-312, at 20-21 (1981); S. Rep. No. 97-275, at 5 (1981). Thus, for almost forty-five years, per Congress’s plan, the Federal Circuit has had exclusive appellate jurisdiction on cases arising under patent law. See generally Donald R. Dunner, *The U.S. Court of Appeals for the Federal Circuit: Its Critical Role in the Revitalization of U.S. Patent Jurisprudence, Past, Present, and Future*, 43 Loy. L.A. L. Rev. 775 (2010).⁸

⁷ The *Zero Technologies* decision repeats the policy points stated earlier in *Hydranautics*, 70 F.3d at 536. But the *Hydranautics* opinion did not explore the main reasons why Congress established the Federal Circuit’s exclusive jurisdiction over appeals of patent cases.

⁸ <https://digitalcommons.lmu.edu/llr/vol43/iss3/17/>. Of course, there can be cases that do not arise under the patent laws yet still involve predicate patent-law issues. See *Holmes Grp. Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826 (2002); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988). In 2011, Congress reaffirmed its desire for patent issues to be decided by the Federal Circuit when it amended 28 U.S.C. § 1295(1)(a) to legislatively overrule *Holmes Group*. See *Vermont v.*

In contrast, appeals of antitrust cases are—and have been from the inception of the Sherman Act—decided by the different regional appellate courts. 15 U.S.C. § 29; *see also Christianson*, 486 U.S. at 812 (“[A] monopolization claim . . . does not ‘arise under’ federal patent law.”); *Mayor of Baltimore*, 995 F.3d at 128. Since 1890, the various appellate courts have not infrequently reached different views on how to interpret and apply the various antitrust statutes.

Looking deeper, the *Hydranautics* case misstates Congress’s intention when attempting to summarize, in a sentence, Congress’s intent behind establishing the Federal Circuit. There, the Ninth Circuit wrote that “Congress has provided for regional courts of appeals to decide antitrust appeals, and for the [F]ederal [C]ircuit to decide patent appeals.” 70 F.3d at 536. But that paints an incomplete picture because it incorrectly suggests that Congress intended all antitrust claims to be decided by the regional circuits on appeal.

To the contrary, it was understood that a case “arising under” patent law that also included an antitrust claim would be decided by the

MPHJ Tech. Invs., LLC, 803 F.3d 635, 643-44 (Fed. Cir. 2015) (summarizing the “*Holmes Group* fix”).

Federal Circuit, and that Congress was aware of that when it established the Federal Circuit. Section 1338 provides district courts with exclusive jurisdiction over “any civil action arising under any Act of Congress relating to patents.” 28 U.S.C. § 1338. And the Federal Circuit was given exclusive jurisdiction of appeals “if the jurisdiction of that court was based, in whole or in part, on section 1338.” 28 U.S.C. § 1295(a)(1) (1982). Thus, since 1982, Congress understood and intended that patent cases with related antitrust claims would be appealed to the Federal Circuit. *See also* H.R. Rep. No. 97-312, at 41 (1981) (expecting that courts would develop “guidelines” that “would continue to provide a consistent jurisprudence and a uniform body of patent law created over time by the Court of Appeals for the Federal Circuit or by its reviewing court, the Supreme Court of the United States”).

Sandoz also presses a misplaced concern about purportedly “generat[ing] a difference between the antitrust law generally applicable within each regional circuit, and antitrust law in . . . patent infringement cases.” Sandoz Br. 27. This is not a valid concern because the Federal Circuit applies regional circuit law to antitrust issues, even when they impact issues of patent law. *Nobelpharma*, 141 F.3d at 1067 (“As a

general proposition, when reviewing a district court’s judgment involving federal antitrust law, we are guided by the law of the regional circuit in which that district court sits.”). This approach by the Federal Circuit has existed since its outset and leads to a consistent application of antitrust law, while maintaining Congress’s overarching intent to provide uniformity within patent law. *See Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 507 (Fed. Cir. 2012); *Am. Hoist*, 725 F.2d at 1366-67 (applying Ninth Circuit law to an antitrust claim).

All this reinforces the need to maintain patent-law uniformity, per Congress’s plan, when assessing whether a logically related antitrust counterclaim is compulsory. Here, one issue raised is whether the two licensed patent applications granted any rights to Amgen when they were licensed. *See Sandoz Br. 5-6, 33-35; Amgen Br. 53-58*. The parties appear to dispute the legal significance of those licensed rights, and that dispute implicates a fundamental patent-law issue.

As a matter of law, when Amgen exclusively licensed the two applications in 2004, the patent applications did impart any right to exclude. A patent application does not grant a right to exclude; that comes only with a granted patent. 35 U.S.C. § 154(a) (a “patent” is “a grant . . . of

the right to exclude others”). For that reason, a patent application cannot create a threat of infringement. *See GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 482-83 (Fed. Cir. 1996) (“A declaratory judgment of ‘invalidity’ or ‘noninfringement’ with respect to Elk’s pending patent application would have had no legal meaning or effect.”). Other courts have recognized the same. *E.g., Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 714 (7th Cir. 2022) (Easterbrook, J.) (“Patent applications, successful or not, do not impose costs on rivals; only issued patents do so.”).⁹

C. Sandoz’s Ripeness Concern is a Non-Issue

Lastly, Sandoz asserts that “treating antitrust claims as compulsory counterclaims in patent infringement litigation would force

⁹ The two patent applications at issue were filed before U.S. patent applications were published by the Patent Office. Prior to 1999, patent applications were not published and were therefore not publicly accessible until patent issuance. In 1999, U.S. patent law was amended to provide for the publication of pending patent applications. Additionally, Congress provided limited provisional rights in connection with a published patent application. 35 U.S.C. § 154(d). Section 154(d) provides for a “reasonable royalty” for pre-issuance infringement, strictly contingent upon actual notice and the patent eventually being granted with claims that are “substantially identical” to the published application. *Id.*; *see also* Matthew J. Dowd & Justin Crotty, *The Limited Impact of Provisional Rights*, Law360 (Feb. 11, 2016).

defendants to bring unripe antitrust claims that have yet to accrue or risk losing their ability to pursue antitrust claims in the patent infringement context altogether.” Sandoz Br. 28. This concern is a non-issue. If a claim of any type is not ripe, the court lacks jurisdiction to rule on its merits, and there will be no estoppel effect.

The “basic rationale” of the ripeness doctrine “is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements.” *Abbott Laby’s v. Gardner*, 387 U.S. 136, 148 (1967). The problem of ripeness “is best seen in a twofold aspect, requiring [a court] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Id.* at 149.

“The ripeness doctrine is ‘drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.’” *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 808 (2003) (quoting *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 57, n.18 (1993)); *Whitaker v. Monroe Staffing Servs., LLC*, 42 F.4th 200, 206 (4th Cir. 2022) (“The doctrine of ripeness arises from the case or controversy requirement of Article III.”).

A case is not ripe for judicial determination “if the plaintiff has not yet suffered injury and any future impact remains wholly speculative.” *Doe v. Va. Dep’t of State Police*, 713 F.3d 745, 758 (4th Cir. 2013) (citation and internal quotation marks omitted). In contrast, the ripeness requirement is met when the “controversy is final and not dependent on future uncertainties.” *Id.* at 772-73 (citation omitted).

At its root, ripeness is a constitutional limitation on federal-court jurisdiction; it is a thus threshold question of whether a claim is justiciable. *Scoggins v. Lee’s Crossing Homeowners Ass’n*, 718 F.3d 262, 269 (4th Cir. 2013). “Without jurisdiction the court cannot proceed at all in any cause.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94-95 (1998) (citation and internal quotation marks omitted).

Here, Sandoz’s ripeness-requirement argument is misplaced for at least two reasons. First, if a party involved in a patent litigation brings an antitrust counterclaim and the court deems the counterclaim not ripe, no preclusive effect attaches. There will be no adjudication on the merits of the antitrust counterclaim, and the party will be free to assert the antitrust claim once it has suffered an antitrust injury and the future impact is not “wholly speculative.” *Doe*, 713 F.3d at 758.

Second, incentivizing parties to bring antitrust claims early—even if not yet ripe—is beneficial. If the alleged antitrust violator is put on notice of the potential violation, that party will have its own incentives to ensure that its course of conduct is not violative of the antitrust laws.

Beyond these two points, the cases Sandoz cites strongly suggest that its antitrust claim was ripe when Amgen successfully asserted the two patents in 2016, which was later affirmed by the Federal Circuit in 2020. For instance, Sandoz quotes *Go Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 177 (4th Cir. 2007), as standing for the proposition that “[an antitrust] cause of action generally accrues when a defendant commits an act that causes economic harm to a plaintiff.” Sandoz Br. 28. Here, Sandoz’s harm appears to fit into that formulation because, as Sandoz argues, it was harmed by the injunction entered in 2016 and affirmed by the Federal Circuit in 2020. Sandoz Br. 10 (“Sandoz’s complaint alleged significant antitrust injury flowing from the exclusion of biosimilar competition in the U.S. etanercept market.”).

Indeed, Sandoz’s allegations largely show that its alleged harm is tied to Amgen’s acquisition of the exclusive patent-application rights in

2004 and then to Amgen's subsequent successful enforcement in 2016 of the two patents. Sandoz Br. 5-8.

Finally, the analogy of the antitrust claims to civil claims for malicious prosecution might apply in some instances but seems inapt here. When "[t]he antitrust claim attacks the patent infringement lawsuit itself as the wrong which furnishes the basis for antitrust damages," *Hydranautics*, 70 F.3d at 536-37, that can indeed be similar to a malicious-prosecution claim. But those typically are cases asserting "sham litigation," where the suit was brought to enforce a patent with objective knowledge that the patent is invalid or not infringed, and the litigation is conducted subjectively for anti-competitive purposes. *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1343 (Fed. Cir. 2014); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998).

Here, in contrast, Sandoz does not assert that the prior patent litigation was a sham. See Sandoz Br. 9-11. Sandoz's action instead is, as alleged, tied to Amgen's successful prosecution of the two patent applications and then the later successful enforcement of the two patents against Sandoz's biosimilar product. *Id.*

In short, Sandoz's current lawsuit presents a collateral attack on the outcome of Amgen's 2016 patent litigation, and the three policy reasons advanced by Sandoz are insufficient justification for such an attack. The stronger policy considerations weigh towards a conclusion that Sandoz's antitrust challenge should have been raised in Amgen's patent-infringement suit in 2016. *See generally Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049 (Fed. Cir. 2020). To allow otherwise undercuts the critical need for innovation certainty and litigation finality.

III. *Mercoïd* Should Be Understood as a Narrow Exception When Patent and Antitrust Claims Relate to Largely the Same Issues and Facts

Sandoz seeks to apply *Mercoïd* broadly. *Mercoïd* deemed the specific antitrust claim at issue to be permissive, but multiple reasons warrant a narrow application of *Mercoïd* and distinguish that case from the present dispute.

First, the Supreme Court's reasoning in *Mercoïd* is murky, to say the least. Courts have recognized as much. *See, e.g., Critical-Vac Filtration Corp. v. Minuteman Int'l, Inc.*, 233 F.3d 697, 702 n.6 (2d Cir. 2000) ("It bears noting that, for generations, the *Mercoïd* decision has been subject to serious criticism by the courts and by the commentators");

Burlington Indus., Inc. v. Miliken & Co., 690 F.2d 380, 389 (4th Cir. 1982) (“The [*Mercoïd*] opinion has been read narrowly in this respect, and its continuing validity is open to serious question.”); *United States v. Eastport S.S. Corp.*, 255 F.2d 795, 805 (2d Cir. 1958) (“In view of the criticism which the decision has received and the failure of the Court to discuss the principles upon which the decision rests, we think that *Mercoïd* cannot be taken as precedent for other than its own limited facts.”); *Zero Techs.*, 713 F. Supp 3d at 67 (noting that “the *Mercoïd* Court never discussed the principles upon which its decision rested, leading some courts to conclude that its holding is limited to the facts of the case”).

Indeed, courts recognized almost immediately the infirmities in *Mercoïd*’s reasoning. *E.g.*, *Addressograph-Multigraph Corp. v. Cooper*, 156 F.2d 483, 488 (2d Cir. 1946) (Clark, J., dissenting) (“The [*Mercoïd*] Court was there sharply divided, and the reaches of the decision cannot yet be considered clearly defined.”); *Douglas v. Wisc. Alumni Research Found.*, 81 F. Supp. 167, 170 (N.D. Ill. 1948) (“A consideration of the nature of a compulsory counterclaim would appear to indicate certain inherent weaknesses in the rationale of the *Mercoïd* decision.”).

Professor Charles Alan Wright, in 1954, summarized the problem with *Mercoïd* quite succinctly when describing how counterclaims are typically compulsory when they “meet the test of logical relation”:

Indeed the only really troublesome case is a United States Supreme Court decision [i.e., *Mercoïd*] in which the Court interjected a casual dictum that a claim for misuse of a patent in violation of the anti-trust laws is only a permissive counterclaim in an action for infringement of the patent. The Court could have reached the same result quite simply, since the company now sought to be barred had not been a party to the prior suit, and thus could not possibly have run afoul of the compulsory counterclaim rule.

Charles A. Wright, *Estoppel by Rule: The Compulsory Counter-Claim under Modern Pleading*, 38 Minn. L. Rev. 423, 441 (1954) (footnote omitted).¹⁰

Another legal commentator has referred to *Mercoïd* as “cryptic” and “mysterious.” Teague Donahey, *Antitrust Counterclaims in Patent Infringement Litigation: Clarifying the Supreme Court’s Enigmatic Mercoïd Decision*, 81 J. Pat & Trademark Off. Soc’y 493, 495, 505 (1998). Various explanations for *Mercoïd*’s “cryptic” holding have been offered, ranging

¹⁰ <https://journals.law.umn.edu/mlr/vol38/iss5/estoppel-by-rule-the-compulsory-counter-claim-under-modern-pleading>.

from a misreading of the law to *Mercoïd* being an intentional expansion of the reach of antitrust law. *Id.* at 505-16.

These significant, lingering questions about *Mercoïd* have led to varying interpretations among the circuits. On the one hand, this Circuit, the Second Circuit, and the Federal Circuit have held that the *Mercoïd* exception is narrow and limited to the facts of that case. *Cummins, Inc. v. TAS Distrib. Co., Inc.*, 700 F.3d 1329, 1337-38 (Fed. Cir. 2012) (“The *Mercoïd* case, however, is much narrower than *Cummins* suggests.”); *Glitsch, Inc. v. Koch Eng’g Co.*, 216 F.3d 1382, 1386 (Fed. Cir. 2000) (“[T]he rationale of *Mercoïd* does not 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.”); *Burlington*, 690 F.2d at 389; *Eastport*, 255 F.2d at 805. On the other hand, the First, Fifth, Seventh, Eighth, and Ninth Circuits have adopted a broader reading of *Mercoïd*. See *Tank Insulation Int’l, Inc. v. Insultherm, Inc.*, 104 F.3d 83, 86 (5th Cir. 1997); *Hydranautics*, 70 F.3d at 536; *Agrashell, Inc. v. Hammons Prods. Co.*, 479 F.2d 269, 287 (8th Cir. 1973); *Fowler v. Sponge Prods. Corp.*, 246 F.2d 223, 227 (1st Cir. 1957) (holding that

antitrust-like claims for treble damages “appear to be permissible under *Mercoïd*”); *Switzer Bros. v. Locklin*, 207 F.2d 483, 488 (7th Cir. 1953).

There is good reason for this Court to faithfully apply its prior rulings and to not expand *Mercoïd* beyond its limited facts and obscure reasoning. Here, the district court’s application of *Mercoïd* is more consistent with Rule 13(a) and the modern understanding of the important complementary nature of the patent and antitrust laws, as well as the importance of avoiding collateral attacks on issues that undermine innovation certainty.

In the end, even putting aside the opaqueness of *Mercoïd*, the outcome here must consider and should favor the strong policy interest of innovation certainty. The root cause of Sandoz’s perceived antitrust injury appears squarely tied to Amgen’s enforcement in 2016 of the two patents upheld as valid the *Immunex* case and the facts concerning alleged monopolization are significantly intertwined with the invalidity defense raised therein.

IV. Conclusion

Sandoz’s collateral attack on the outcome of the 2016 patent litigation undermines confidence in the innovation marketplace. It will

encourage parties to delay challenges that are highly related to the enforcement of valid patent rights and will subject patentees to prolonged uncertainty about their rights. That result is not in accordance with the important goal of providing certainty in court rulings and patent rights. This is precisely the result that the creation of the Federal Circuit and Rule 13(a) were implemented to avoid.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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