

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.

No. 1:24-cv-01355-JDW (D. Del. Feb. 17, 2026) · No. 1:24-cv-01355-JDW · Decided February 17, 2026

SUMMARY

The U.S. District Court for the District of Delaware grants both parties leave to amend their pleadings in a patent infringement action. The court permits iRhythm Technologies to supplement its counterclaims with infringement claims concerning two patents issued after the pleadings deadline and permits Bardy Diagnostics to add inequitable conduct defenses and unenforceability counterclaims based on information obtained in discovery. The court finds good cause under Rule 16 and determines that the proposed amendments satisfy Rule 15 without undue prejudice or futility.

OPINION

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE BARDY DIAGNOSTICS, INC., Case No. 1:24-cv-01355-JDW v. IRHYTHM TECHNOLOGIES, INC., MEMORANDUM During litigation, there's an advantage to fixing the pleadings as early as possible so that everyone knows the issues in the case. But sometimes events outside of litigation make that impossible. And sometimes, parties don't know the facts upon which to base their legal claims until they get discovery.

This case prevents both issues. iRhythm Technologies, Inc. asks for leave to assert infringement claims about two patents that didn't issue until September 2025. And Bardy Diagnostics, Inc., asks for leave to assert an inequitable conduct defense for which it didn't have a factual predicate until it gathered information in discovery. Both requests are appropriate, and I will grant them both.

I. BACKGROUND A. Factual History Bardy filed this action in December 2024, asserting infringement of patents directed to iRhythm's wearable cardiac monitoring technology. iRhythm responded with counterclaims alleging that Bardy infringed iRhythm patents directed to Bardy's invention, the CAM patch.

On April 4, 2025, I entered a Scheduling Order setting June 2, 2025, as the deadline to amend pleadings. As the case progressed, both parties amended their pleadings to add newly issued patents from related families. iRhythm ultimately asserted five patents against Bardy, encompassing seventy-eight claims. Two of those patents, U.S. Patent Nos. 12,274,554 and 12,303,277, issued in April and May 2025.

Bardy did not assert inequitable conduct defenses at that time. In early September 2025, the United States Patent and Trademark Office issued iRhythm two additional patents, U.S. Patent

Nos. 12,402,819 and 12,408,856. Those patents arise from the same patent families as the patents that iRhythm is asserting in this case and concern the same accused product, the Bardy CAM patch.

After the PTO approved the claims, iRhythm notified Bardy of its intent to seek leave to amend its counterclaims and provided Bardy with the claims. iRhythm also raised the issue with me during a status conference in August 2025. During the same period, Bardy pursued discovery relating to the prosecution of the '554 and '277 patents.

In September 2025, Bardy deposed Dr. David Schmidt, who confirmed his substantive involvement in prosecuting those patents and his review of materials relating to Japanese Patent Publication JP 2004-121360, also known as Matsumura, and an expert declaration by Jason Heikenfeld that no one disclosed to the PTO during prosecution. Around the same time, iRhythm produced a privilege log identifying the role of its Director of Global Intellectual Property, Theodore Lopez, in prosecuting the patents and approving claims for filing with the PTO.

Bardy then sought to depose Mr. Lopez, but iRhythm represented that it would produce him for deposition only after inequitable conduct claims formally became part of the case. In October 2025, the PTO ordered reexamination of the '554 and '277 patents after finding that the full English translation of Matsumura raised a substantial new question of patentability.

Bardy served a proposed amended answer asserting inequitable conduct defenses and counterclaims later that month. B. Procedural History On September 5, 2025, iRhythm moved for leave to amend its counterclaims to assert the '819 and '856 patents.

On January 5, 2026, Bardy moved for leave to amend its answer to assert inequitable conduct defenses and counterclaims of unenforceability. Claim construction briefing concluded on November 26, 2025, and I held a hearing on January 15, 2026. Initial expert disclosures under Federal Rule of Civil Procedure 26(a)(2) are due on May 15, 2026. Fact discovery remains open until July 17, 2026, and I have not set a trial date.

Both motions are fully briefed and ripe for disposition. II. LEGAL STANDARD A. Rule 15 Federal Rule of Civil Procedure 15 governs the filing of both amended and supplemental pleadings. Fed. R. Civ. P. 15(a), (d). Rule 15(a) contemplates amendment of an existing pleading and is intended “to enable a party to assert matters that were overlooked or were unknown” when the original pleading was filed., 938 F.3d 69, 82 (3d Cir.

2019) (quoting 6 Charles Alan Wright & Arthur Miller, Federal Practice and Procedure § 1473 (3d ed. 2019)). By contrast, Rule 15(d) contemplates a supplemental pleading that sets out “any transaction, occurrence, or event that happened the date of the pleading to be supplemented.” Fed. R. Civ. P. 15(d) (emphasis added);, 938 F.3d at 82.

The standard for granting leave under both rules is essentially the same. 6 Wright & Miller, *supra*, § 1504 (citing, 409 F. Supp. 2d 552, 558 (D. Del. Jan. 13, 2006)). “The decision to grant or deny leave to amend lies within the discretion of the court.”, No. CV 18-654-SB-SRF, 2021 WL 6883231, at *4 (D. Del. Feb. 10, 2021) (citations omitted).

Under Rule 15, courts should “freely give leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). This liberal amendment regime helps effectuate the “general policy embodied in the Federal Rules favoring resolution of cases on their merits.”, 875 F.3d 140, 149 (3d Cir. 2017). “Leave to amend must generally be granted unless equitable considerations render it otherwise unjust.”, 434 F.3d 196, 204 (3d Cir.

2006). “Among the grounds that could justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice, and futility.”, 213 F.3d 113, 115 (3d Cir. 2000). An amendment is futile when it “fails to state a claim upon which relief can be granted, or advances a claim or defense that is legally insufficient on its face.”, 56 F. Supp.3d 613, 622 (D.

Del. 2014) (cleaned-up);, 213 F.3d at 115. A “proposed amendment is not futile [where it] would withstand a motion to dismiss.”, 677 F.3d 519, 545 (3d Cir. 2012). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.”, 809 F.3d 780, 786 (3d Cir. 2016).

B. Rule 16 If a motion to amend satisfies Rule 15, but the motion comes after the deadline that a scheduling order sets for amendments, the moving party must also satisfy Rule 16(b)(4) of the Federal Rules of Civil Procedure., 225 F.3d 330, 340 (3d Cir. 2000). Rule 16(b)(4) provides that “[a] schedule maybe modified only for good cause and with the judge's consent.” Fed.

R. Civ. P. 16(b)(4). While Rule 15(a)(2) focuses on the question of prejudice to the non-moving party, Rule 16(b)(4) “focuses on the moving party's burden to show due diligence.”, 614 F.3d 57, 84 (3d Cir. 2010);, C.A. No. 08-132-JJF, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010).

Thus, good cause is established if the amendment is not unduly delayed, i.e., if the movant shows that it acted diligently in filing its motion to amend. If the movant satisfies that requirement of Rule 16, leave to amend should be granted unless there is a reason to deny leave, such as bad faith, prejudice to the non-moving party, or futility of the claims., 371 U.S. at 182; Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir.

1997). III. ANALYSIS A. iRhythm’s Motion iRhythm seeks leave to amend its counterclaims to assert infringement of the ’819 and ’856 patents, which issued in early September 2025. Good cause exists to modify the scheduling order to permit iRhythm to supplement its counterclaims.

The ’819 and ’856 patents did not exist when the pleadings closed. iRhythm could not have asserted infringement of issued patents before they issued, and iRhythm moved promptly once

issuance was imminent. Additionally, Bardy cannot claim surprise or lack of notice because iRhythm provided Bardy advance notice of its intent to seek leave to amend its counterclaims shortly after learning that the patents would issue.

That notice is consistent with diligence. Bardy argues that iRhythm could have applied for these patents sooner. It does not cite to any case, however, that finds a lack of diligence in applying for or prosecuting a patent as a basis to deny leave to modify a scheduling order in court. And Bardy's inability to identify any such case is not surprising because its argument conflates patent prosecution strategy with diligence.

Rule 16 does not require a party to predict future issuance of patents or to amend pleadings based on speculative future rights. Nor does it impose rules about a party's timing in applying for a patent. The relevant inquiry is whether the moving party acted reasonably once the basis for amendment existed. iRhythm did, so I will amend the scheduling order to permit iRhythm's amendment request.

On the question of amendment, the governing rule is Rule 15(d), not Rule 15(a), because the amended counterclaims purport to add patents that issued after the original complaint and counterclaims were filed., Civ. No. 09–80, 2010 WL 1609899, *2–3 (D. Del. Apr. 20, 2010). Leave to supplement is appropriate under Rule 15(d) because the proposed supplemental counterclaims arise from the same patent families as the patents that iRhythm is asserting, share common specifications, and accuse the same Bardy product at issue in this case.

Courts in other districts have found that “there is substantial authority for allowing supplemental pleadings where the new infringement claims relate to the same technology or to new patents containing similar claims as those in the original patent.” 669 F.Supp.2d 227, 237 n. 12 (D.Conn.2009) (collecting cases). Allowing supplementation will not unduly prejudice Bardy, as the newly issued patents do not introduce a different accused product, a new technology, or a materially different theory of infringement.

In addition, any additional discovery will largely overlap with discovery already contemplated. Although supplementation will require additional contentions and some incremental claim construction, that modest burden is not undue, particularly where iRhythm proposed a measured schedule that integrates the new patents without displacing existing deadlines. There is also no indication of bad faith or dilatory motive. iRhythm did not wait to spring these new patents on Bardy.

After the PTO approved the claims, iRhythm notified Bardy of its intent to seek leave and provided copies of the claims. It raised the issue with the Court at the August 2025 status conference and filed its Motion within days of the '819 patent issuing. And when iRhythm filed its

Motion, fact discovery remained open, expert discovery had not begun, claim construction proceedings were underway but incomplete, and no trial date had been set.

Prejudice must be assessed as of that point in time. Any increased difficulty resulting from the passage of time while the Motion was pending cannot fairly be attributed to iRhythm and does not justify denial of leave. Judicial economy further supports supplementation. Resolving infringement disputes concerning closely related patents in a single action avoids duplicative discovery and the risk of inconsistent rulings.

Allowing the '819 and '856 patents to proceed in this case will conserve judicial and party resources; the alternative would require the parties to initiate a separate action involving the same technology and accused product. B. Bardy's Motion "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.", 649 F.3d 1276, 1285 (Fed.

Cir. 2011). A claim for inequitable conduct requires that (a) "the patentee acted with the specific intent to deceive" the PTO and (b) the material withheld from the PTO satisfies "but-for materiality," meaning the PTO would not have allowed a claim had it known of the undisclosed material., 649 F.3d at 1290-91. A party claiming inequitable conduct ordinarily must show that the patentee "withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing.", 735 F.3d 1333, 1345 (Fed.

Cir. 2013). Because Bardy seeks leave to amend its affirmative defenses to assert inequitable conduct before the PTO, the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applies to its allegations. Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.

Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." "[I]nequitable conduct, while a broader concept than fraud, must be pled with particularity" under Rule 9(b)., 575 F.3d 1312, 1326 (Fed. Cir. 2009). Good cause exists to modify the scheduling order to permit Bardy to seek to assert its inequitable conduct defense because Bardy could not reasonably have met the amendment deadline despite diligence. iRhythm asserted the '554 and '277 patents shortly before and after that deadline, and Bardy did not yet possess the discovery necessary to plead inequitable conduct with the particularity Rule 9(b) requires.

Only after taking a key deposition and reviewing prosecution-related materials did Bardy have a factual basis to seek to amend. That sequence demonstrates diligence, not delay. Courts routinely find good cause under Rule 16 where, as here, a party waits to amend until discovery supplies the facts necessary to satisfy Rule 9(b). 270 F.Supp.2d 484, 487-89 (D.

Del. Dec. 16, 2003). iRhythm argues that Bardy knew the relevant references earlier and therefore should have amended sooner. That argument overlooks the nature of inequitable conduct pleading. Bardy needed to do more than identify prior art; it needed a factual basis to allege knowledge,

materiality, and intent by specific individuals. Bardy obtained that information through discovery, after the amendment deadline.

Bardy's proposed amended answer pleads inequitable conduct with sufficient particularity to avoid futility. Bardy alleges that Mr. Lopez and Dr. Schmidt, both of whom owed duties of candor, knew of the Heikenfeld Declaration and the English translation of Matsumura during prosecution of the '554 and '277 patents, appreciated their relevance to patentability, and chose not to disclose them.

Bardy further alleges that those same materials later prompted reexamination, reinforcing their materiality. Taken as true, those allegations permit a reasonable inference of inequitable conduct that satisfies Rule 9(b). At this stage, Bardy need not prove that inference or eliminate competing explanations. Nor will amendment unduly prejudice iRhythm.

The defenses concern only the '554 and '277 patents, which iRhythm added near the amendment deadline. Bardy gave advance notice of its intent to amend and shared a draft pleading before filing. The relevant evidence, including prosecution history and the knowledge of iRhythm personnel, lies largely within iRhythm's control. Allowing amendment will not require the parties to redo completed work or drastically disrupt the schedule.

IV. CONCLUSION iRhythm has shown good cause to supplement its counterclaims, and its proposed amendment satisfies Rule 15. Bardy has also shown good cause to amend its answer, and its proposed inequitable conduct defenses and counterclaims are neither futile nor unduly prejudicial. I will grant both motions for leave to amend. An appropriate Order follows. BY THE COURT: JOSHUA D. WOLSON, J. February 17, 2026