

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.

CASE DETAILS

COURT	United States District Court for the District of Delaware
WRITING FOR THE COURT	Joshua D. Wolson
JURISDICTION	U.S. District Court for the District of Delaware
DECIDED	February 17, 2026
DOCKET	1:24-cv-01355-JDW
DISPOSITION	other
PROCEDURAL POSTURE	Both parties moved for leave to amend their pleadings after the scheduling-order deadline. iRhythm sought leave to supplement its counterclaims to add infringement claims concerning two patents issued after the pleadings deadline. Bardy sought leave to amend its answer to add inequitable-conduct defenses and related unenforceability counterclaims based on information obtained in discovery.
STANDARD OF REVIEW	Leave to amend or supplement under Federal Rule of Civil Procedure 15 is committed to the court's discretion. When a motion is filed after the scheduling-order deadline, the movant must also show good cause under Rule 16(b)(4), principally by demonstrating diligence. Futility is assessed under the applicable pleading standard, including Rule 9(b) for inequitable-conduct allegations.
PRECEDENTIAL VALUE	unpublished, nonprecedential district court memorandum

PARTIES

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

TOPICS

motion to amend

civil procedure

patent infringement

affirmative defenses

patent prosecution

PRACTICE AREAS

civil procedure

patent law

patent infringement

commercial litigation

QUESTIONS PRESENTED

1. Whether iRhythm showed good cause under Rule 16(b)(4) to modify the scheduling order and could supplement its counterclaims under Rule 15(d) to assert infringement claims concerning patents issued after the pleadings deadline.
2. Whether iRhythm's proposed supplemental infringement claims arose sufficiently from the same transactions or occurrences, technology, patent families, and accused product to warrant supplementation under Rule 15(d).
3. Whether Bardy showed good cause under Rule 16(b)(4) to amend its answer after the deadline when discovery supplied the factual basis needed to plead inequitable conduct with the particularity required by Rule 9(b).
4. Whether Bardy's proposed inequitable-conduct defenses and unenforceability counterclaims were futile or unduly prejudicial.

HOLDINGS

1. Good cause existed under Rule 16(b)(4) to permit iRhythm to amend because the two patents did not exist when the pleadings closed and iRhythm acted reasonably and promptly once the basis for amendment existed.
2. Rule 15(d), rather than Rule 15(a), governed iRhythm's request, and supplementation was appropriate because the new patent claims involved the same patent families, common specifications, and the same accused product without undue prejudice.
3. Bardy showed good cause under Rule 16(b)(4) because it could not reasonably have pleaded inequitable conduct with the particularity required by Rule 9(b) before obtaining the necessary discovery.
4. The proposed inequitable-conduct allegations were pleaded with sufficient particularity to avoid futility under Rule 9(b).

KEY QUOTATIONS

"The relevant inquiry is whether the moving party acted reasonably once the basis for amendment existed."
(III.A)

“Bardy needed to do more than identify prior art; it needed a factual basis to allege knowledge, materiality, and intent by specific individuals.” (III.B)

“I will grant both motions for leave to amend.” (IV)

FACTUAL BACKGROUND

Bardy sued iRhythm over wearable cardiac-monitoring technology, and iRhythm counterclaimed for infringement of patents relating to Bardy's CAM patch. Two additional iRhythm patents issued in September 2025 and concerned the same patent families, specifications, and accused product. During discovery, Bardy obtained information concerning the prosecution of two previously asserted patents, including the involvement of iRhythm personnel and allegedly undisclosed materials, and the PTO later ordered reexamination after finding that a translation of Matsumura raised a substantial new question of patentability.

PROCEDURAL HISTORY

Bardy filed the patent-infringement action in December 2024, and iRhythm asserted patent-infringement counterclaims. The court entered a scheduling order setting June 2, 2025, as the deadline to amend pleadings. iRhythm moved on September 5, 2025, to add claims concerning newly issued patents, and Bardy moved on January 5, 2026, to add inequitable-conduct defenses and counterclaims. After briefing and a January 15, 2026 hearing, the court granted both motions.

DISPOSITION

other

CASES CITED

- 938 F.3d 69, 82 (3d Cir. 2019)
- 409 F. Supp. 2d 552, 558 (D. Del. Jan. 13, 2006)
- 875 F.3d 140, 149 (3d Cir. 2017)
- 434 F.3d 196, 204 (3d Cir. 2006)
- 213 F.3d 113, 115 (3d Cir. 2000)
- 56 F. Supp. 3d 613, 622 (D. Del. 2014)
- 677 F.3d 519, 545 (3d Cir. 2012)
- 809 F.3d 780, 786 (3d Cir. 2016)
- 225 F.3d 330, 340 (3d Cir. 2000)
- 614 F.3d 57, 84 (3d Cir. 2010)
- 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010)
- 371 U.S. at 182
- Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997)
- 2010 WL 1609899, at *2-*3 (D. Del. Apr. 20, 2010)
- 669 F. Supp. 2d 227, 237 n. 12 (D. Conn. 2009)

- 649 F.3d 1276, 1285 (Fed. Cir. 2011)
- 649 F.3d 1276, 1290-91 (Fed. Cir. 2011)
- 735 F.3d 1333, 1345 (Fed. Cir. 2013)
- 575 F.3d 1312, 1326 (Fed. Cir. 2009)
- 270 F. Supp. 2d 484, 487-89 (D. Del. Dec. 16, 2003)

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