IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARDY DIAGNOSTICS, INC.,	)	
	)	
Plaintiff, Counter-Defendant	)	
	)	
v.	)	C.A. No. 24-1355 (JDW)
	)	
IRHYTHM TECHNOLOGIES, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant, Counter-Plaintiff.	)	

DEFENDANT IRHYTHM TECHNOLOGIES, INC.'S FIRST AMENDED COUNTERCLAIMS AND ANSWER TO PLAINTIFF BARDY DIAGNOSTICS, INC.'S FIRST AMENDED COMPLAINT

Defendant iRhythm Technologies, Inc. ("Defendant" or "iRhythm"), by and through its undersigned counsel, hereby answers the First Amended Complaint ("FAC") of Bardy Diagnostics, Inc. ("Plaintiff" or "Bardy") and asserts counterclaims as follows:

I. IRHYTHM'S COUNTERCLAIMS AGAINST BARDY

iRhythm asserts the following counterclaims against Bardy.

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising from Bardy's infringement of U.S. Patent Nos. 12,133,734 (the "'734 patent"), 12,245,859 (the "'859 patent"), and 12,245,860 (the "'860 patent") (collectively, the "iRhythm Asserted Patents").

2. iRhythm is the owner by assignment of the '734 patent. A copy of the '734 patent is attached as Exhibit 1.

3. iRhythm is the owner by assignment of the '859 patent. A copy of the '859 patent is attached as Exhibit 11.

WELCH ALLYN EXHIBIT 2003
iRhythm v. Welch Allyn
IPR2025-00377

4. iRhythm is the owner by assignment of the ’860 patent. A copy of the ’860 patent is attached as Exhibit 12.

THE PARTIES

5. iRhythm is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 699 8th Street, Suite 600, San Francisco, CA 94103.

6. On information and belief, Bardy is a corporation organized and existing under the laws of the State of Delaware since 2013.

7. On information and belief, Bardy has its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., including specifically 35 U.S.C. § 271.

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, as a corporation organized and existing under the laws of the state of Delaware, Bardy has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over Bardy. This Court also has personal jurisdiction over Bardy at least by virtue of Bardy filing the instant action in this Court.

11. On information and belief, Bardy is a commercial entity that makes, uses, advertises, offers for sale, and/or sells ECG monitors and ECG monitoring services. On

information and belief, Bardy manufactures, makes, uses, advertises, offers for sale, and/or sells the Carnation Ambulatory Monitor (the "CAM patch").

12. On information and belief, Bardy sells and offers to sell ECG monitors and ECG monitoring services, including the CAM patch, throughout the United States, including in this judicial district.

13. On information and belief, Bardy makes the CAM patch available to healthcare providers and patients in Delaware.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Bardy is incorporated in the State of Delaware and therefore resides in this judicial district.

BARDY AND BARDY'S CARNATION AMBULATORY MONITOR

15. On information and belief, Bardy is an ambulatory ECG monitoring solutions company founded in 2013, around 7 years after iRhythm was founded in 2006 and after iRhythm had already launched the Zio XT monitor. *See* https://www.bardydx.com/.

16. On information and belief, Bardy received FDA approval for the CAM patch no earlier than Dec. 22, 2014. *See* https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143067.pdf.

17. On information and belief, Bardy publicly launched and began commercializing the 2-day CAM patch in the United States no earlier than 2015.

18. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 2-day CAM patch in the United States.

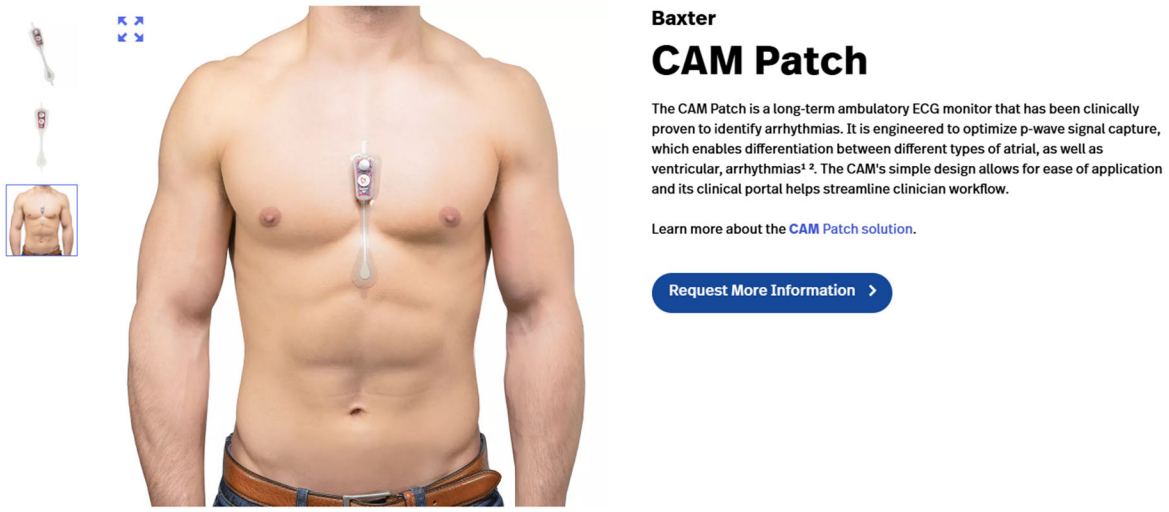
19. On information and belief, Bardy publicly launched and began commercializing the 7-day CAM patch in the United States no earlier than 2015.

20. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

21. On information and belief, Bardy publicly launched and began commercializing the 14-day CAM patch in the United States on or around January 23, 2020. *See* Exhibit 2, Bardy Diagnostics, Inc., "Bardy Diagnostics Announces Commercial Launch of the 14-day Carnation Ambulatory Monitor (CAM) Patch," PR Newswire (Jan. 23, 2020), https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-commercial-launch-of-the-14-day-carnation-ambulatory-monitor-cam-patch-300991978.html.

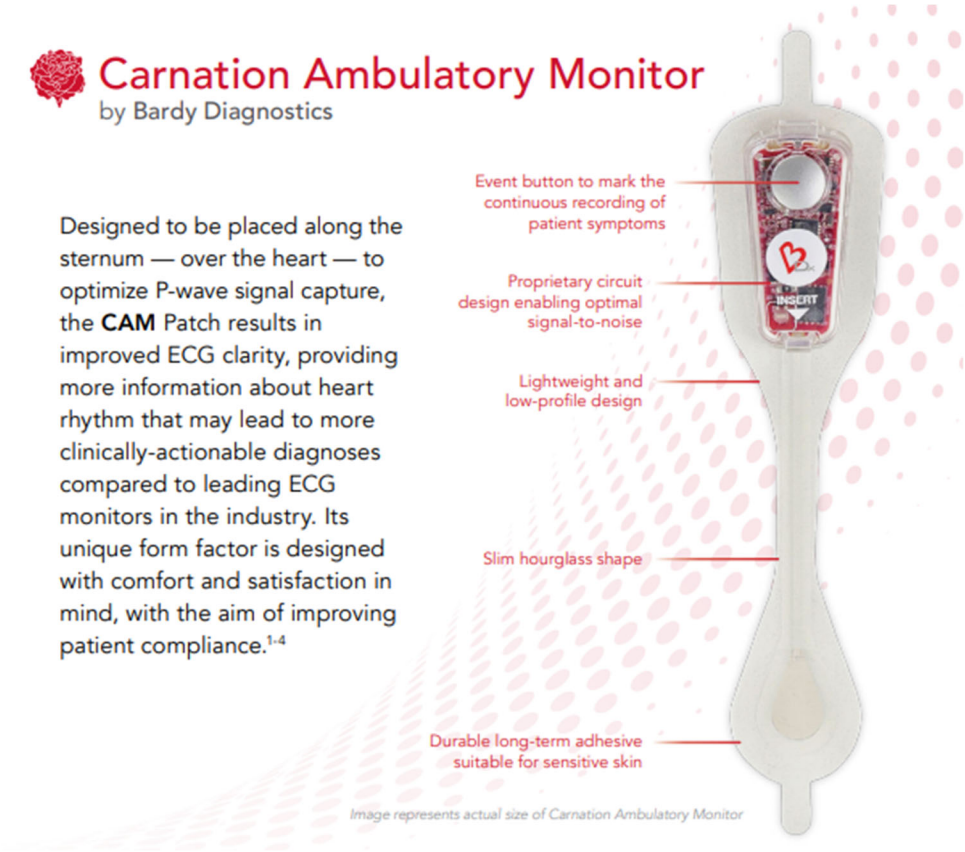
22. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

23. The CAM patch is an ambulatory ECG monitor that adheres to a user's chest. *See, e.g.*, Exhibit 3, https://www.hillrom.com/en/products/cam-patch/.



24. As shown below, the CAM patch includes electrodes that capture p-wave signals, "which enables differentiation between different types of atrial, as well as ventricular, arrhythmias." *Id.*; *see also* Exhibit 4, https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf. The CAM patch includes a purportedly "proprietary circuit" in a housing that is electronically connected to an electrode

located on the patch. Exhibit 5, https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf.



25. On information and belief, and according to Bardy, the CAM patch provides a "[d]urable" adhesion that can last "[u]p to 2, 7, or 14 days." *See* Exhibit 4.

Technical Specifications 13

TECHNICAL SPECIFICATIONS

ITEM	SPECIFICATION
Performance Characteristics	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 days
Shelf life	24 months

26. On information and belief, and according to Bardy, the CAM patch "captures P-wave signals" from the heart using electrodes and transmits those to a purportedly "[p]roprietary circuit" located on the patch. Exhibit 5; *see also* Exhibit 6, https://www.bardydx.com/wp-content/uploads/2023/07/DN000697B-BDx_CAM_SpecSheet.pdf.

27. Given the facts alleged in this counterclaim, both stated above and set forth below and in Exhibit 7, 13, and 14, Bardy's CAM patch directly infringes the claims of the iRhythm Asserted Patents, literally or under the doctrine of equivalents.

FIRST COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,133,734

28. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 27 of Section I of iRhythm's Counterclaims and Answer.

29. The '734 patent duly and legally issued on November 5, 2024.

30. iRhythm owns all right, title, and interest in the '734 patent by assignment.

31. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 7, Bardy directly infringes at least claim 1 of the '734 patent, either literally or under the doctrine of equivalents.

32. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '734 patent.

33. On information and belief, Bardy has had knowledge of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '734 patent.

34. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the ’734 patent since at least February 28, 2025, when iRhythm’s counsel sent the claim chart attached as Exhibit 7 to this counterclaim to Bardy’s counsel.

35. On information and belief, despite having knowledge of the ’734 patent and knowledge that the CAM patch infringes at least claim 1 of the ’734 patent since at least February 28, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

36. Bardy has willfully infringed the ’734 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the ’734 patent and knowledge that the CAM patch infringes at least claim 1 of the ’734 patent.

37. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

38. This case is exceptional under 35 U.S.C. § 285, including due to Bardy’s willful infringement of the ’734 patent.

39. Bardy’s acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

40. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

SECOND COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,859

41. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 27 of Section I of iRhythm's Counterclaims and Answer.

42. The '859 patent duly and legally issued on March 11, 2025.

43. iRhythm owns all right, title, and interest in the '859 patent by assignment.

44. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 13, Bardy directly infringes at least claim 1 of the '859 patent, either literally or under the doctrine of equivalents.

45. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '859 patent.

46. On information and belief, Bardy has had knowledge of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '859 patent.

47. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 13 to this counterclaim to Bardy's counsel.

48. On information and belief, despite having knowledge of the '859 patent and knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

49. Bardy has willfully infringed the ’859 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the ’859 patent and knowledge that the CAM patch infringes at least claim 1 of the ’859 patent.

50. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

51. This case is exceptional under 35 U.S.C. § 285, including due to Bardy’s willful infringement of the ’859 patent.

52. Bardy’s acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

53. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

THIRD COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,860

54. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 27 of Section I of iRhythm’s Counterclaims and Answer.

55. The ’860 patent duly and legally issued on March 11, 2025.

56. iRhythm owns all right, title, and interest in the ’860 patent by assignment.

57. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 14, Bardy directly infringes at least claim 1 of the ’860 patent, either literally or under the doctrine of equivalents.

58. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the ’860 patent.

59. On information and belief, Bardy has had knowledge of the ’860 patent since at least March 21, 2025, when iRhythm’s counsel sent a letter to Bardy’s counsel identifying the ’860 patent.

60. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the ’860 patent since at least March 21, 2025, when iRhythm’s counsel sent the claim chart attached as Exhibit 14 to this counterclaim to Bardy’s counsel.

61. On information and belief, despite having knowledge of the ’860 patent and knowledge that the CAM patch infringes at least claim 1 of the ’860 patent since at least March 21, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

62. Bardy has willfully infringed the ’860 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the ’860 patent and knowledge that the CAM patch infringes at least claim 1 of the ’860 patent.

63. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

64. This case is exceptional under 35 U.S.C. § 285, including due to Bardy’s willful infringement of the ’860 patent.

65. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

66. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

RELIEF REQUESTED

WHEREFORE, iRhythm respectfully requests the following relief:

A. A judgment and order that Bardy has infringed the iRhythm Asserted Patents;

B. An order preliminarily and permanently enjoining and restraining Bardy, its officers, directors, agents, servants, employees, licensees, attorneys, and all other persons acting under or through them, directly or indirectly, from infringing the iRhythm Asserted Patents;

C. A judgment and order requiring that Bardy pay damages under 35 U.S.C. § 284, including an award up to three times iRhythm's damages, as well as prejudgment and post-judgment interest and costs and post-trial damages for any ongoing infringement;

D. A judgment and order that this case is exceptional and awarding iRhythm its attorneys' fees, costs, disbursements, and interest, as provided by law, including under 35 U.S.C. § 285;

E. A judgment that Bardy's infringement has been willful, and ordering Bardy to pay treble damages as provided by law; and

F. Such other and further relief as the Court may deem just and equitable.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, iRhythm respectfully requests a trial by jury in this action for all issues triable by a jury.

II. ANSWER

iRhythm, by and through its counsel, hereby answers the FAC as follows:

Nature of the Action[1]

1. iRhythm admits that Bardy purports to allege an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., including specifically 35 U.S.C. § 271. iRhythm denies that Bardy is entitled to the relief it seeks for any alleged infringement of U.S. Patent Nos. 12,161,473 (the "'473 patent") and 12,171,562 (the "'562 patent") (collectively, the "Asserted Patents"). iRhythm denies any remaining allegations of paragraph 1 of the FAC.

2. iRhythm admits that the '473 patent lists "Bardy Diagnostics, Inc." as an assignee. iRhythm further admits that Bardy purports to attach a copy of the '473 patent as Exhibit 1 to the FAC. iRhythm denies any remaining allegations of paragraph 2 of the FAC.

3. iRhythm admits that the '562 patent lists "Bardy Diagnostics, Inc." as an assignee. iRhythm further admits that Bardy purports to attach a copy of the '562 patent as Exhibit 2 to the FAC. iRhythm denies any remaining allegations of paragraph 3 of the FAC.

The Parties

4. iRhythm lacks knowledge or information to form a belief as to the truth or falsity of the allegations of paragraph 4 of the FAC and, on that basis, denies them.

5. iRhythm admits that it was incorporated in the State of Delaware on September 14, 2006. iRhythm denies any remaining allegations in paragraph 5 of the FAC.

6. iRhythm admits that its executive offices are located at 699 8th Street, Suite 600, San Francisco, CA 94103. iRhythm denies any remaining allegations in paragraph 6.

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[1] To the extent that Bardy intends the headings in its FAC to constitute allegations, iRhythm explicitly denies them. The headings in iRhythm's answer are not responses to the headings in Bardy's FAC.

7. iRhythm admits that the website https://investors.irhythmtech.com/resources/investor-faqs/default.aspx states that "iRhythm is a leading digital health care company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, iRhythm distills data from millions of heartbeats into clinically actionable information. Through a relentless focus on patient care, iRhythm's vision is to deliver better data, better insights, and better health for all." iRhythm denies any remaining allegations of paragraph 7 of the FAC.

8. iRhythm admits that iRhythm's 2023 Form 10-K, available at https://www.sec.gov/Archives/edgar/data/1388658/000138865824000014/irtc-20231231.htm, states that iRhythm "offer[s] remote cardiac monitoring technology and also function[s] as [a] diagnostic service provider[]." iRhythm denies any remaining allegations of paragraph 8 of the FAC.

9. iRhythm admits that both iRhythm and Bardy offer remote cardiac monitoring technology. iRhythm denies any remaining allegations of paragraph 9 of the FAC.

Jurisdiction and Venue

10. iRhythm admits that Bardy purports to allege a cause of action arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* iRhythm admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. iRhythm admits that it is incorporated in the State of Delaware. For the purposes of this case only, iRhythm admits that this court has personal jurisdiction over it. iRhythm denies the remaining allegations of paragraph 11 of the FAC.

12. iRhythm admits that it offers remote cardiac monitoring technology, such as the Zio Next-Generation Monitor. iRhythm denies any remaining allegations of paragraph 12 of the FAC.

13. iRhythm admits that the Zio Next-Generation Monitor is available to healthcare providers and patients in Delaware. iRhythm denies any remaining allegations of paragraph 13 of the FAC.

14. The statements set forth in paragraph 14 constitute legal conclusions. To the extent a response is required, iRhythm admits that it is incorporated in the State of Delaware and that venue is proper in this judicial district under 28 U.S.C. § 1400(b). iRhythm denies any remaining allegations of paragraph 14 of the FAC.

Background and Ambulatory Cardiac Monitoring Devices Market

15. iRhythm admits that paragraph 15 of the FAC includes a graphic from Exhibit 3 to the FAC, which purports to have the title "Ambulatory Cardiac Monitoring Devices Market Size, Share & Trends Analysis Report by Device Type (ECG Devices, Holter Monitors, Event Monitors), By End-Use, By Regions, And Segment Forecasts (2023-2030)." iRhythm admits that the graphic in paragraph 15 of the FAC includes the categories ECG Devices, Holter Monitors, Event Monitors, Implantable Loop Recorders, and Mobile Cardiac Telemetry. iRhythm denies any remaining allegations of paragraph 15 of the FAC.

16. iRhythm admits that Exhibit 3 to the FAC states that "[t]he ECG devices segment accounted for the largest market share of 38.9% in 2022" and that "[t]he demand for ECG devices is expected to grow due to the increasing incidences of cardiovascular disease & hypertension worldwide, coupled with the ease of access, continuous monitoring, and high accuracy capabilities of the device." iRhythm further admits that Exhibit 3 to the FAC states that "[a]ccording to a study

conducted by the WHO, 17.9 million people die every year due to cardiovascular diseases, which accounts for 32% of the total deaths globally." iRhythm denies any remaining allegations of paragraph 16 of the FAC.

17. iRhythm admits that Bardy offers remote cardiac monitoring technology. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations of paragraph 17 of the FAC and, on that basis, denies them.

18. iRhythm admits that Bardy offers remote cardiac monitoring technology and sells the Carnation Ambulatory Monitor. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations of paragraph 18 of the FAC and, on that basis, denies them.

19. iRhythm admits that the traditional 12-lead ECG monitor had several drawbacks. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations of paragraph 19 of the FAC and, on that basis, denies them.

20. iRhythm denies that the CAM™ Patch was revolutionary. iRhythm admits that Bardy's instructions for use for the CAM™ Patch teach to attach it to a patient's chest and that it may be worn for up to 14 days. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations of the paragraph 20 of the FAC and, on that basis, denies them.

21. iRhythm denies that the '473 patent or the '562 patent claim priority to any patent application that was filed on September 23, 2013. iRhythm denies that that the '473 patent or the '562 patent disclose any body-worn ambulatory ECG monitor that was new or innovative. iRhythm denies any remaining allegations of paragraph 21 of the FAC.

22. iRhythm admits that the American Heart Association reports that atrial fibrillation is an irregular heartbeat or arrhythmia; that atrial fibrillation can lead to blood clots, stroke, heart failure, and other heart-related complications; and that "more than 12 million people are projected to have AFib by 2030." *See* https://www.heart.org/en/health-topics/atrial-fibrillation/what-is-atrial-fibrillation-afib-or-af. iRhythm denies any remaining allegations of paragraph 22 of the FAC.

23. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations of paragraph 23 of the FAC and, on that basis, denies them.

24. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations of the paragraph 24 of the FAC and, on that basis, denies them.

25. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations of the paragraph 25 of the FAC and, on that basis, denies them.

26. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations of the paragraph 26 of the FAC and, on that basis, denies them.

27. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations of the paragraph 27 of the FAC and, on that basis, denies them.

The Asserted Patents

28. iRhythm admits that the '473 and the '562 patent each list "Bardy Diagnostics, Inc." as an assignee. iRhythm lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations of paragraph 28 of the FAC and, on that basis, denies them.

29. iRhythm admits that the ’473 patent lists “Dec. 10, 2024” as its issue date, “Electrocardiography Patch” as its title, and “Bardy Diagnostics, Inc.” as an assignee. iRhythm denies any remaining allegations of paragraph 29 of the FAC.

30. iRhythm admits that the ’473 patent purports to claim an “electrocardiography patch.” To the extent there are any remaining factual allegations in this paragraph, iRhythm denies them.

31. iRhythm admits that the ’562 patent lists “Dec. 24, 2024” as its issue date and “Bardy Diagnostics, Inc.” as an assignee. iRhythm denies that the ’562 patent lists “Electrocardiography Patch” as its title. iRhythm denies any remaining allegations of paragraph 31 of the FAC.

32. iRhythm admits that the ’562 patent purports to claim an “electrocardiography monitoring device.” To the extent there are any remaining factual allegations in this paragraph, iRhythm denies them.

iRhythm

33. iRhythm admits that Uday Kumar was a founder of iRhythm. iRhythm admits that it was incorporated in 2006. iRhythm admits that it manufactures and offers remote cardiac monitoring technology, such as the Zio Next-Generation Monitor. iRhythm denies any remaining allegations of paragraph 33 of the FAC.

34. iRhythm admits that the website https://investors.irhythmtech.com/resources/investor-faqs/default.aspx states that “[c]ombining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, iRhythm distills data from millions of heartbeats into clinically actionable information.” iRhythm denies any remaining allegations of paragraph 34 of the FAC.

35. iRhythm admits that it manufactures and offers remote cardiac monitoring technology, such as the Zio AT Monitor, Zio XT Monitor, and Zio Next-Generation Monitor. iRhythm denies any remaining allegations of paragraph 35 of the FAC.

36. iRhythm admits that on July 18, 2012, it received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the Zio® Patch, which was later called the Zio XT ECG Monitoring System. iRhythm denies any remaining allegations of paragraph 36 of the FAC.

37. iRhythm admits that on June 2, 2017, it received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the Zio QX ECG Monitoring System, which was later called the Zio AT ECG Monitoring System. iRhythm denies any remaining allegations of paragraph 37 of the FAC.

38. iRhythm admits that on May 21, 2021, it received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the Zio Monitor. iRhythm denies any remaining allegations of paragraph 38 of the FAC.

iRhythm's Next Generation Zio Monitor

39. iRhythm admits that Exhibit 9 to the FAC, an article written by Amanda Pedersen, states that "iRhythm Technologies recently launched its next-generation Zio monitor and enhanced Zio long-term continuous monitoring service in the United States. The San Francisco, CA-based company touts an improved form factor with the new wearable heart monitoring device, which is 23% thinner, 62% lighter, and 72% smaller compared to previous generations of the technology." iRhythm admits that Exhibit 9 of the FAC is a third-party article that attributes the following quote to Mark Day: "So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the

housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it.… So, we innovated a different way, which was to integrate it into the ECG tracings themselves." iRhythm denies any remaining allegations of paragraph 39 of the FAC.

40. iRhythm admits that paragraph 40 of the FAC purports to include a graphic from Exhibit 4 to the FAC, but the graphic appears differently between the two sources. iRhythm admits that it describes the Next-Generation Zio Monitor on its website, accessible at https://www.irhythmtech.com/. iRhythm denies any remaining allegations of paragraph 40 of the FAC.

41. iRhythm admits that paragraph 41 of the FAC purports to include a graphic from Exhibit 11 to the FAC that identifies two electrodes labelled "Electrode – acquires ECG data" and portions that are identified as "Adhesive wings – adheres the Zio monitor to the upper-left chest." iRhythm admits Exhibit 11 to the FAC states that "[t]he Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring." iRhythm denies any remaining allegations of paragraph 41 of the FAC.

42. iRhythm admits that Exhibit 11 to the FAC states that "[t]he Zio monitor is an ECG monitor that continuously records the electrical activity of the heart" and that is "intended to be worn continuously for a time period specified by a provider for up to 14 days." iRhythm admits that Exhibit 11 to the FAC states that "[a]fter conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it to iRhythm for processing" and that "[a]fter receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings." iRhythm denies any remaining allegations of paragraph 42 of the FAC.

43. iRhythm admits that paragraph 43 of the FAC purports to include two graphics from Exhibit 12 to the FAC. iRhythm admits that the Zio Monitor is available to healthcare providers and that healthcare providers can prescribe the Zio Monitor to patients. iRhythm denies any remaining allegations of paragraph 43 of the FAC.

44. Whether a product is made in the United States is a legal conclusion, including under Federal Trade Commission regulations. The allegation in this paragraph therefore states a legal conclusion to which no response is required.

45. iRhythm admits that Exhibit 13 to the FAC, a purported transcript of a discussion at the Citi Global Healthcare Conference, attributes the following quote to Daniel G. Wilson, who is identified as Chief Financial Officer of iRhythm Technologies, Inc.: "So, yeah, Zio MCT will be on the same form factor that Zio Monitor is on currently, XT and AT look – the legacy form factors for us look the same, but the internal componentry is different, so they're manufactured on separate lines. With MCT and Monitor, they will be the same exact product and manufactured on a single line." iRhythm denies any remaining allegations of paragraph 45 of the FAC.

46. iRhythm admits that Exhibit 13 to the FAC, a purported transcript of a discussion at the Citi Global Healthcare Conference, attributes the following quote to Daniel G. Wilson: "Zio MCT is now two years delayed from when we initially set that target in 2022.… Ultimately, we do need to get Zio MCT on the market to achieve that $1 billion target. It may be a bit delayed beyond 2027. If it's not 2027, it will be 2028 in terms of when we eclipse that $1 billion target." iRhythm admits that it will need to obtain the requisite regulatory clearance for Zio MCT before it is marketed in the United States. iRhythm denies any remaining allegations of paragraph 46 of the FAC.

COUNT I
[Alleged] Patent Infringement of U.S. Patent No. 12,161,473]

47. iRhythm incorporates by reference its responses to paragraphs 1 through 46 as if fully set forth herein.

48. iRhythm denies that it directly infringes, or has infringed, any claim of the ’473 patent, either literally or under the doctrine of equivalents. iRhythm denies any remaining allegations of paragraph 48 of the FAC.

49. iRhythm denies the allegations of paragraph 49 of the FAC.

50. iRhythm denies the allegations of paragraph 50 of the FAC.

COUNT II
[Alleged] Patent Infringement of U.S. Patent No. 12,171,562]

51. iRhythm incorporates by reference its responses to paragraphs 1 through 50 as if fully set forth herein.

52. iRhythm denies that it directly infringes, or has infringed, any claim of the ’562 patent, either literally or under the doctrine of equivalents. iRhythm denies any remaining allegations of paragraph 52 of the FAC.

53. iRhythm denies the allegations of paragraph 53 of the FAC.

54. iRhythm denies the allegations of paragraph 54 of the FAC.

RELIEF REQUESTED

iRhythm denies that Bardy is entitled to any of the relief requested in the FAC or any relief whatsoever. iRhythm denies all allegations in the FAC that have not been specifically admitted in paragraphs 1-54 above.

III. DEFENSES, AFFIRMATIVE OR OTHERWISE

iRhythm asserts the following additional defenses to the FAC. In doing so, iRhythm does not assume any burden of proof on any issue that is Bardy's burden as a matter of law. iRhythm also reserves the right to amend or supplement these defenses as additional facts become known.

FIRST DEFENSE: FAILURE TO STATE A CLAIM

The FAC fails to allege facts sufficient to state a cause of action upon which relief may be granted.

SECOND DEFENSE: NON-INFRINGEMENT ('473 PATENT)

iRhythm has not infringed, and currently does not infringe, any valid claim of the '473 patent either literally or under the doctrine of equivalents.

THIRD DEFENSE: NON-INFRINGEMENT ('562 PATENT)

iRhythm has not infringed, and currently does not infringe, any valid claim of the '562 patent either literally or under the doctrine of equivalents.

FOURTH DEFENSE: INVALIDITY ('473 PATENT)

The claims of the '473 patent are each invalid for failure to comply with one or more conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable statutory provisions of Title 35 of the United States Code.

FIFTH DEFENSE: INVALIDITY ('562 PATENT)

The claims of the '562 patent are each invalid for failure to comply with one or more conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or any other applicable statutory provisions of Title 35 of the United States Code.

SIXTH DEFENSE: [RESERVED]

SEVENTH DEFENSE: UNENFORCEABILITY

Bardy's claims of infringement against iRhythm regarding the Asserted Patents are barred, and the Asserted Patents are unenforceable against iRhythm, due to equitable doctrines, including the doctrines of waiver, acquiescence, equitable estoppel, unclean hands, and/or patent misuse.

Upon information and belief, iRhythm further contends, as set forth herein, that the Asserted Patents are unenforceable as a result of inequitable conduct before the United States Patent and Trademark Office ("PTO"). Specifically, Bardy and its patent attorneys failed to comply with the duty of good faith and candor owed to the PTO by knowingly and deliberately failing to disclose information material to the patentability of the claims of the Asserted Patents during prosecution. Upon information and belief, but for such failures, the Asserted Patents would not have been allowed.

In particular, Bardy and its patent attorneys failed to disclose to the PTO during prosecution of the Asserted Patents that Bardy terminally disclaimed claims 1-10 of U.S. Patent No. 11,051,743 (the "'743 patent"). *See* Exhibits 8, 9, *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 6, Exhibit 2003 (P.T.A.B. Apr. 24, 2023).

Bardy is the assignee of the '743 patent. The '743 patent is a parent patent to which the Asserted Patents claim priority.

On December 21, 2022, Vital Connect, Inc. filed a Petition for *Inter Partes* Review ("IPR") of the '743 patent. Exhibit 10, *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 1 (P.T.A.B. Dec. 21, 2022).

On April 21, 2023, Bardy submitted to the PTO a statutory disclaimer of claims 1-10 of the '743 patent under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a). *See* '743 patent file wrapper,

"Statutory disclaimers per Manual of Patent Examining Procedure (MPEP) 1490," accessible at https://patentcenter.uspto.gov/applications/17119945/ifw/docs?application=.

On April 24, 2023, Bardy filed a Statutory Disclaimer with the Patent Trial and Appeal Board disclaiming claims 1-10 of the '743 patent under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a). Exhibits 8, 9.

Bardy subsequently filed the patent applications that issued as the '473 patent and the '562 patent on August 12, 2024 and August 30, 2024, respectively—more than one year after the filing of the Statutory Disclaimer of the '743 patent claims.

The same law firm, and named attorneys, are listed in the file wrapper of the '743 patent and the Asserted Patents. *See, e.g.*, '743 patent "Address & Attorney/Agent Information," accessible at https://patentcenter.uspto.gov/applications/17119945/attorney?application=; *see also* '473 patent, "Address & Attorney/Agent Information," accessible at https://patent-center.uspto.gov/applications/18800675/attorney?application=; *see also* '562 patent, "Address & Attorney/Agent Information," accessible at https://patentcenter.uspto.gov/applications/18821409/attorney?application=.

In particular, Kevin T. McCormick signed all filings and submissions on behalf of Bardy during prosecution of the applications that became the '473 and '562 patents. Mr. McCormick is also listed as one of the attorneys representing Bardy before the USPTO in the file wrapper of the '743 patent.

The claims of the Asserted Patents are not patentably distinct from the disclaimed claims of the '743 patent.

Bardy obtained the Asserted Patents after and in full knowledge of the Statutory Disclaimer of the '743 patent claims.

Bardy and at least its attorney Mr. McCormick failed to provide notice of the Statutory Disclaimer during prosecution of the Asserted Patents. *See, e.g.*, '473 patent, "Documents & transaction history," accessible at https://patentcenter.uspto.gov/applications/18800675/ifw/docs?application= (no submission of the Statutory Disclaimer); *see also* '562 patent, "Documents & transaction history," accessible at https://patentcenter.uspto.gov/applications/18821409/ifw/docs?application= (no submission of the Statutory Disclaimer).

Additionally, upon information and belief, but for Bardy's and at least Mr. McCormick's failure to comply with their duty of good faith and candor, the PTO would not have issued the Asserted Patents.

For at least the reasons set forth above, the Asserted Patents are unenforceable under the doctrine of inequitable conduct.

iRhythm is investigating the facts relating to the unenforceability of the Asserted Patents and will continue to do so throughout the discovery process. To the extent that this investigation reveals any additional facts or circumstances relevant to unenforceability, iRhythm reserves the right to seek leave to amend to assert such allegations and/or defenses based thereon that may be appropriate.

EIGHTH DEFENSE: PROSECUTION LACHES

Bardy's claims are barred, in whole or in part, by prosecution laches. Under this doctrine, a patentee forfeits the right to enforce a patent based on unreasonable and undue delay in patent prosecution that prejudices the defendant. *See Sonos, Inc. v. Google LLC*, No. C 20-06754 WHA, 2023 WL 6542320, at *17–18 (N.D. Cal. Oct. 6, 2023). That is the case here.

Bardy filed U.S. provisional patent application 61/882,403, to which each of the Asserted Patent claim priority, on September 25, 2013.

The patent applications from which the ’473 patent and the ’562 patent issued were filed on August 12, 2024 and August 30, 2024, respectively.

Accordingly, Bardy waited close to 11 years before filing the continuation applications that led to the ’473 and ’562 patents, without justification.

iRhythm was significantly prejudiced by Bardy’s delay at least because it made a substantial investment in and continued to independently develop the iRhythm Zio devices. *Id.* at *18–19 (defendant suffered “extreme prejudice” due to patentee’s inexcusable delay in filing claims that claim priority through a lengthy priority chain to applications filed over a decade earlier where “unearthing the layers of file histories would have resembled an exercise in archeology”). For at least the reasons set forth above, the Asserted Patents are unenforceable under the doctrine of prosecution laches.

NINTH DEFENSE: COLLATERAL ESTOPPEL

Bardy’s claims of infringement against iRhythm are barred, in whole or in part, under the doctrine of collateral estoppel.

On December 21, 2022, Vital Connect, Inc. filed a Petition for *Inter Partes* Review asserting prior art against the claims of the ’743 patent. Exhibit 10.

In response, on April 24, 2023, Bardy filed a Statutory Disclaimer disclaiming claims 1-10 of the ’743 patent under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a). Exhibits 8, 9.

The Asserted Patents claim priority to the ’743 patent and the claims of the Asserted Patents are patentably indistinct from the disclaimed claims of the ’743 patent.

Accordingly, Bardy is collaterally estopped from asserting the claims of the Asserted Patents against iRhythm.

TENTH DEFENSE: GOOD FAITH

iRhythm has engaged in all relevant activities in good faith, thereby precluding Bardy, even if it prevails, from recovering its reasonable attorneys' fees or costs under 35 U.S.C. § 285.

ELEVENTH DEFENSE: DEDICATION TO THE PUBLIC

The relief sought by Bardy is barred, in whole or in part, because Bardy dedicated to the public all methods, systems, and products disclosed in the asserted patents but not literally claimed therein.

TWELFTH DEFENSE: LIMITATIONS ON DAMAGES AND COSTS

Bardy's claim for damages is barred, in whole or in part, by 35 U.S.C. § 286 or 287. To the extent any claim of the Asserted Patents is invalid, Bardy is barred from recovering costs by 35 U.S.C. § 288.

THIRTEENTH DEFENSE: NO EXCEPTIONAL CASE FOR PLAINTIFF

iRhythm has not engaged in any conduct that would make this an exceptional case that would entitle Bardy to an award of attorneys' fees or enhanced damages.

RESERVATION OF ADDITIONAL DEFENSES

iRhythm reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional defenses are appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Lucinda C. Cucuzzella

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March 24, 2025

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2025, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused to be served copies of the foregoing document on March 24, 2025, upon the following in the manner indicated:

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