UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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iRhythm, Inc.,

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

CASE: IPR2025-00377

U.S. PATENT NO. 8,214,007

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST

"[T]he agency's decision to deny a petition [in an *inter partes* review] is a matter committed to the Patent Office's ***discretion***." *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (citing 35 U.S.C. § 314(a)) (all emphasis added unless otherwise indicated); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("the PTO is permitted, but never compelled, to institute an IPR"). Petitioner's Request (Paper 11) does not identify an abuse of discretion, an erroneous finding of material fact, or an erroneous conclusion of law warranting reconsideration of the Director's Discretionary Denial. *See* USPTO Director Review Process, available at https://www.uspto.gov/patents/ptab/decisions/director-review-process. The Request simply asks the Director to reevaluate a single argument that Petitioner previously presented (Paper 9)—this time with newly alleged, unsupported "facts"—and reach the opposite conclusion.

The Request fails because: (I) the Director's Discretionary Denial was based on a "holistic assessment of all the arguments and evidence presented," not "solely on 'settled expectations;'" (II) the Request relies on new, unsubstantiated "facts;" and (III) the Request's claim of an APA violation in this proceeding lacks merit.

I. THE DIRECTOR'S DENIAL WAS BASED ON A "HOLISTIC ASSESSMENT" OF THE ARGUMENTS AND EVIDENCE

The Request argues that "the Acting Director denie[d] iRhythm's petitions based ***solely*** on 'settled expectations.'" Paper 11 at 7. Not true. While the Director held that "Petitioner's awareness of Patent Owner's applications and failure to seek

early review of the patents favors denial and outweighs the above-discussed considerations," the very next sentence states: "[a]lthough ***certain arguments*** are highlighted above, the determination to exercise discretion to deny institution is based on a ***holistic assessment of all of the evidence and arguments presented***." Paper 10 at 3. The Director analyzed numerous arguments as part of a "holistic" review, including Patent Owner's arguments that the Petition: (1) failed to meet the particularity requirement; (2) improperly burden shifted; (3) failed to state necessary claim constructions; (4) over-relied on expert testimony; (5) relied on non-prior art documents; (5) relied on ancient documents evidencing "current" problems; (6) contravened settled expectations between the parties; and (7) failed the traditional *Fintiv*-factors. *See* Paper 7. Each of these arguments independently supports discretionary denial and the Director, exercising authorized discretion, holistically balanced the issues and record presented in the papers to deny institution. The Request fails to properly address any of these legitimate bases for denial.

II. THE REQUEST RELIES ON NEW, UNSUBSTANTIATED "FACTS"

Patent Owner, in addressing "settled expectations of the parties," presented three exhibits in support of its argument in the Discretionary Denial Request. *See* Paper 7 at 29-31 (citing Exs. 2001, 2002, 2010). In response, Petitioner presented ***no*** evidence and barely more than a page of attorney argument. *See* Paper 9 at 32-33. But "attorney argument is not evidence and cannot rebut other admitted evidence."

Elbit Sys. of Am., LLC v. Thales Visionix, Inc., 881 F.3d 1354, 1359 (Fed. Cir. 2018). The Request now contends that Petitioner's citation to Patent Owner's pending patent applications is insufficient to show knowledge of the patent that later issued (*id.*), yet Petitioner failed to raise this argument in its discretionary briefing and ignores that Exhibit 2010 (cited in Paper 7 at 29) is a public textbook containing iRhythm's public admission that it monitored competitor's patent portfolios. The Denial appears to have fully considered and accorded the appropriate weight to Petitioner's attorney argument on the "settled expectations of the parties."

The Request now raises new arguments and asks the Director to infer additional factual information, without any evidentiary basis in the record. Paper 11 at 3-5, 8-10. For example, the Request contends the Director failed to consider that "iRhythm, an American innovator spun out of Stanford University, launched its first life-saving cardiac monitor in 2012." *Id*. at 1. Neither Petitioner's discretionary briefing, nor the Request, provides any support for this statement. Stanford is not even mentioned in Petitioner's discretionary briefing. *See* Paper 9. Nor is there any evidence regarding when Petitioner launched any of its products or what features those products contained. Papers 9 at 11. Petitioner advances numerous other new, unsupported factual assertions, including: Patent Owner never commercialized its invention; Patent Owner seeks to "tax the commercial market"; Petitioner built its market through "millions of dollars of investment"; and the formation of Petitioner.

Paper 11 at 1-3. Notably absent throughout the Request's allegations is a single citation to any evidence. Petitioner had the opportunity to support its arguments with evidence (it submitted five new exhibits with its discretionary paper), but chose to give the "settled expectations" factor short shrift, citing no evidence. Paper 9 at 32-33. Petitioner cannot cure evidentiary shortcomings with more attorney argument.

III. PETITIONER IDENTIFIES NO APA, DUE PROCESS, OR OTHER VIOLATIONS FOR ITS REQUEST

A number of bases raised and argued in Patent Owner's Discretionary Denial paper and considered in the Director's "holistic assessment" pre-date the Director's March 2025 Memorandum. Paper 7 at 4-11 (argument regarding the Petition's lack of particularity under *Adaptics*), 11-19 (argument regarding burden shifting). There are many bases for discretionary denial not rooted in the March 2025 Memorandum's articulation of factors that are available for evaluation by the Director that are independent bases for the denial, all unaddressed by the Request. Thus, it is not readily apparent where Petitioner's claimed APA violation would arise in this matter. Moreover, Petitioner was on fair notice of the factors articulated in the March 2025 Memorandum that the Director intended to use in the discretionary denial process. Both parties had the opportunity to present evidence and develop a record of all of their arguments, and were afforded up to 14,000 words to do so. *See TQ Delta, LLC v. DISH Network LLC*, 929 F.3d 1350, 1356 (Fed. Cir. 2019) (no APA violation where "the party asserting the APA violation 'had notice…and an

opportunity to be heard'"). Similarly, it is not readily apparent where a Due Process violation would occur since Petitioner has also not been deprived of any ***rights*** by the denial of institution. 35 U.S.C. § 314(a); *Cuozzo*, 579 U.S. at 273 (institution is always up to the director's discretion). Petitioner simply disagrees with the outcome, which is not a basis for a Constitutional challenge.

The Request contends that the PTAB's precedential-designated decision in *NHK* "is dispositive" yet it is not clear that *NHK* is binding on the Director. Paper 11 at 9-10. Rather, ***panel*** decisions such as *NHK* are subject to review by the Director, like here where the Director has already weighed in on the decision to deny institution. *United States v. Arthrex, Inc.*, 594 U.S. 1, 24 (2021). Moreover, *NHK Spring v. Intri-Plex Techs.*, cannot be precedential for a holding that it did not make—*i.e.,* that a lack of articulated "tactical advantage" necessitates institution—as it was a ***denial*** of institution. No. IPR2018-00752 (P.T.A.B. Sept. 12, 2018).[1]

The Request, therefore, identifies no basis for the Director to review the Director's decision to exercise discretion to deny the Petition and should be denied.

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[1] The Request also raises a number of apparent policy arguments. Paper 11 at 10-13. Patent Owner does not address these arguments here, and for this matter defers to the judgment of the Director and the USPTO regarding patent policy and resource allocation decisions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2025, I caused a true and correct copy of the foregoing to be served on the following counsel of record for Petitioner by electronic mail to the following addresses:

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