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: IPR2025-00376

U.S. PATENT NO. 9,155,484

PATENT OWNER'S ARGUMENT FOR DISCRETIONARY DENIAL

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TABLE OF PATENT OWNER EXHIBITS

Exhibit No.	Description
2001	Information Disclosure Statement dated May 18, 2015 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the '007 Patent, reference no. 67
2002	Information Disclosure Statement dated August 7, 2013 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the pre-grant publication that issued as the '007 Patent, reference no. 101
2003	iRhythm's Amended Answer alleging infringement against PO's related company, Bardy Diagnostics
2004	26(f) Report from *Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.*, 1:24-cv-01355, indicating Petitioner iRhythm's intent to assert additional patents.
2005	Scheduling order in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224
2006	Notice of Service of Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 26)
2007	Notice of Service of Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 27)
2008	Notice of Service of Third-Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 41)
2009	Notice of Service of Third-Party Discovery Responses in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 47)
2010	Excerpt from Zenious et al., BIODESIGN; THE PROCESS OF INNOVATING MEDICAL TECHNOLOGIES
2011	Notice of Service of Third-Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 48)

Exhibit No.	Description
2012	Statutory Disclaimer filed in U.S. Patent No. 9,155,484

Patent Owner, Welch Allyn, Inc. ("Welch Allyn" or "PO"), submits this paper regarding discretionary denial pursuant to the Board's recent guidance on "Interim Processes for PTAB Workload Management," dated March 26, 2025 ("Guidance").

I. INTRODUCTION

U.S. Patent No. 9,155,484 (the "'484 Patent") issued almost ten years ago, and Petitioner iRhythm was not only monitoring the then-pending prosecution that led to the '484 Patent, but made an affirmative decision to not challenge the '484 Patent during the life of the patent, until now. Under both the prior discretionary denial standards (including that set forth in *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (P.T.A.B. Mar. 6, 2019) (informative)) and pursuant to the new factors set forth in the Guidance, the Petition is a poster-child for exercising discretion to better allocate resources elsewhere. The heavy burden that the Petition's challenge to the '484 Patent will place on the Patent Office warrants the Director exercising discretion to deny the challenge.

The Petition's challenge is "supported" by the declaration of Dr. Jason Heikenfeld, an omnibus declaration of over 1700 paragraphs spread over more than 500 pages. Ex. 1009. Examination of this declaration details: (1) significant reliance on non-prior art evidence (*see, e.g.*, Ex. 1035, Ex. 1020, Ex. 1021); (2) lack of opinions on claim construction (Ex. 1009, ¶ 51); (3) reliance on ancient documents

to fabricate "state-of-the-art problems" (Ex. 1009, ¶ 1049 (citing Ex. 1060 (a paper purportedly from 1917))); and (4) cross-citing or incorporating by reference opinions across proceedings (Ex. 1009, ¶ 1052 (which cites to Section XIX.A.2, a section that either does not exist, or is referring to a different proceeding)). All of which unnecessarily and improperly shift the burden to the Board and PO to sift through Petitioner's declaration to exhume Dr. Heikenfeld's actual opinions from the morass of irrelevant and inapplicable information muddled together in his 500+ pages. This improper reliance infects ***all*** claims that are challenged in the Petition.

Moreover, the Petition inordinately relies on this "general knowledge of a person of skill in the art," failing to provide a motivation to combine the ***55*** references it submits with the Petition, many of which are not actually prior art, and others which are from almost half-a-century before the '484 Patent and are used to allegedly indicate "problems facing the state of the art." This strategy by Petitioner improperly shifts the burden to unpack the Petition's challenge to the Board and PO and is itself an independent basis to deny the Petition.

Lastly, as detailed below, the precedential decision of *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential) further favors utilizing the discretionary power of the Director to deny institution.

PO respectfully submits that the Petition is not a good use of the Board's time and resources. To maintain the other statutory deadlines in existing proceedings, and the workload needs of the PTAB, the Petition should be denied so resources can be properly allocated to Petitions that better adhere to the framework set forth in the Trial Practice Guide.

II. THE PETITION SHOULD BE DISCRETIONARILY DENIED

The Board's recent Guidance provides that "to facilitate [the new] bifurcated approach, the USPTO will permit parties to file separate briefing on requests for discretionary denial of institution." Guidance, 2. The Guidance allows Patent Owners to address grounds for discretionary denial including: (a) "discretionary considerations enumerated in existing Board precedent;" and (b) other "relevant considerations" now identified in the Guidance. *Id.* PO respectfully submits that discretionary denial is appropriate under both sets of considerations and addresses each in turn. Last, as addressed in Section (c) below, the *Fintiv* factors also favor discretionary denial of the Petition.

a. Discretionary Denial Is Appropriate Under Existing Board Precedent and the Trial Practice Guide.

PO respectfully requests that the Board discretionarily deny the Petition because it fails to meet the particularity requirements of 35 U.S.C. § 312(a)(e) in identifying the grounds and evidence on which the challenge is based and,

separately, attempts to shift the burden of claim construction to the Board and PO in violation of 37 C.F.R. § 42.104(b)(3).

1. The Petition Fails to Meet the Particularity Requirements of 35 U.S.C. § 312(a)(e).

Petitioners are required to "identif[y], in writing and ***with particularity***, each claim challenged, ***the grounds on which the challenge to each claim is based***, and ***the evidence that supports the grounds for the challenge to each claim***." 35 U.S.C. § 312(a)(3). The framework set forth in *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (P.T.A.B. Mar. 6, 2019) (informative) is highly instructive to the treatment that should be afforded the Petition in this proceeding. As set forth in *Adaptics*, when a Petitioner relies on an unreasonable number of references that are unsubstantiated "prior art" in the Petition, the Board should find that Petitioner fails to clearly set forth the basis for its prior art challenges and deny the Petition. *Adaptics* further confirms the impropriety of reliance on conclusory expert testimony to gap-fill elements.

In *Adaptics*, the Petitioner and its expert relied on extraneous non-prior art documents not part of the grounds of the Petition with an "and/or" conjunction in its grounds, and by doing so transformed "the Petition into an empty invitation for the Board and Patent Owner to search the record for evidence that might support the full breadth of Petitioner's contentions." *Adaptics*, IPR2018-01596, Paper 20 at 22-23.

The Board found the "Petition fails to meet the particularity requirement of 35 U.S.C. § 312(a)(3) and that the lack of particularity results in voluminous and excessive grounds." *Id.* at 24. The Board should do so here as well.

a. The Petition's Structure in this Proceeding is More Convoluted than the Petition in *Adaptics*.

In *Adaptics*, the Petitioner provided "catch-all" grounds (i.e., citations to references with "and/or" conjunctions), which the Board found would improperly "require Patent Owner to address whether each and every limitation is taught not only by each [of the primary references in the grounds], but by each of these references in combination with one or more of the other references." *Adaptics*, IPR2018-01596, Paper 20 at 20-21. The Board found that this was "not reasonably bounded in scope and unduly burdensome for both Patent Owner and the Board to address." *Id.* at 21. The Petition in *Adaptics*, however, at least articulated the supplemental references in its recitation of grounds. *Id.* at 9. The Petitioner here does not.

Instead, the Petition foregoes the "and/or" conjunction of *Adaptics* and amorphously relies on the "General Knowledge of a POSA," for all four grounds, (*see* Petition, 3), requiring the Board and PO to sift through thousands of pages of information and over 50 references to guess the Petition's theories and underlying evidence:

Proposed Grounds of Unpatentability	
Ground 1	Claims 1-5 and 15-20 are obvious under pre-AIA § 103 over Matsumura and General Knowledge of a Person of Ordinary Skill in the Art
Ground 2	Claims 1-5, 15, 17, 18, and 20 are obvious under pre-AIA § 103 over Jensen and General Knowledge of a Person of Ordinary Skill in the Art
Ground 3	Claims 1-8, 15, 19, and 20 are obvious under pre-AIA § 103 over Ozguz and General Knowledge of a Person of Ordinary Skill in the Art
Ground 4	Claims 6-8, 11, and 12 are obvious under pre-AIA § 103 over Matsumura, Ozguz, and General Knowledge of a Person of Ordinary Skill in the Art

Petition, 1-2 (annotated).

This "General Knowledge" incorporates 55 references, several that themselves are not even prior art on their face (e.g., Ex. 1053, allegedly from 2007), and others that the Petition fails to even argue are prior art (Ex. 1035, a "textbook" allegedly from some time in 2006). Indeed, this "General Knowledge," the foundation of which is in Sections IV.A through IV.F of Dr. Heikenfeld's declaration, is facially replete with reliance on non-prior art references as "support" for his opinions, as shown in the table below.

Section of Heikenfeld	Exemplary Reliance On Non-Prior Art Documents
Section IV.A	• Ex. 1009, ¶ 17 (citing Ex. 1020 allegedly dated in 2008) • Ex. 1009, ¶ 17 (citing Ex. 1021 allegedly dated in 2013) • Ex. 1009, ¶ 19 (citing Ex. 1024, a website allegedly dated in 2025) • Ex. 1009, ¶ 20 (citing Ex. 1025 allegedly dated in 2012) • Ex. 1009, ¶ 21 (citing Ex. 1027 a website allegedly dated in 2025)
Section IV.B	• Ex. 1009, ¶ 23 (citing Ex. 1021 allegedly dated in 2013) • Ex. 1009, ¶ 23 (citing Ex. 1030 allegedly dated in 2022)
Section IV.C	• Ex. 1009, ¶ 30 (citing Ex. 1035 allegedly dated in 2006)
Section IV.E	• Ex. 1009, ¶ 36 (incorporating by reference Ex. 1009, Sections IV.C-D (citing Ex. 1035 allegedly dated in 2006))
Section IV.F	• Ex. 1009, ¶¶ 44-45 (citing Ex. 1035 allegedly dated in 2006) • Ex. 1009, ¶ 47 (citing Ex. 1043 allegedly dated in 2019)

Just like in *Adaptics* where "the Petition present[ed] virtually no analysis of how or why the references [from the declaration] were publicly accessible," neither Dr. Heikenfeld nor the Petition make any argument as to why the underlying support (in the right-most column) informs a POSA's "General Knowledge." *Adaptics*, IPR2018-01596, Paper 20 at 23. For example, Petitioner and its expert make no showing that Exhibits 1020, 1021, or 1035, are actually prior art (despite relying on

Ex. 1035 for the bulk of the analysis of, for example, Claim 2[1]). *See* Ex. 1009, ¶ 1048), which in turn relies on Ex. 1035). The Petition completely fails to even allege that Ex. 1035 is prior art, and Dr. Heikenfeld provides no further testimony on the matter.

b. The Petition's Reliance On "General Knowledge" Matters in this Proceeding because it Shifts the Burden to PO and the Board to Identify the Actual Challenge Grounds and Evidence.

The Petition, through its reliance on this amorphous "General Knowledge of a POSA," improperly shifts the burden to the Board and PO to excavate the actual grounds of the challenge. For example, beginning with the background sections of Petitioner's expert declaration, Petitioner's expert alleges that "Wearable ECG Monitors Were Well Known Prior to the Priority Date" in Section IV.C of his Declaration. Ex. 1009, ¶ 25. However, this section of Dr. Heikenfeld's declaration sets forth the non-prior art that he relies on for this conclusion. *See* Ex. 1009, ¶ 30 (citing Ex. 1035, dated in 2006). Dr. Heikenfeld's reliance on non-prior art in the background sections, Sections IV.A-IV.F, of his Declaration matters because this forms the foundation of his "General Knowledge" and analysis.

[1] Independent Claim 1 and dependent Claims 4 and 5 have been disclaimed. Ex. 2012.

The documents that make up this "General Knowledge" fail to make an appearance in the Petition, remaining behind the scenes in the expert declaration. For example, despite characterizing "Wearable ECG Monitors [as] Well Known Prior to the Priority Date," in Section IV.C of his declaration, Dr. Heikenfeld relies heavily on Exhibit 1035 in this section. *See* Ex. 1009, ¶ 30 (citing Ex. 1035). Neither Petitioner nor Dr. Heikenfeld provides any evidence that this publication is prior art to the '484 Patent. This infects Dr. Heikenfeld's opinions as they relate to the entirety of his analysis. This is just one of many instances of Dr. Heikenfeld's reliance on such non-prior art documents to support a "long-known" and "well-understood" opinion.

Notably, Section IV.C of Dr. Heikenfeld's declaration spans paragraphs 43-48, and setting aside its further reference to even more sections, relies on five additional references. Section IV.B is even worse, relying on, among other things, references from 2022 (Ex. 1030, cited in paragraph 23), and Section IV.A relies on, among other things, a document dated in 2008 (Ex. 1020), a document dated in 2013 (Ex. 1021), websites printed in 2024 (Exs. 1024 and 1027), and a document dated 2012 (Ex. 1025).

Dr. Heikenfeld expressly relies on this non-prior art analysis with regard to, for example, Claim 2, where he uses Ex. 1035 to support his opinion regarding the

interpretation of *Matsumura* (Ex. 1009, ¶ 1048) as well as the foundational predicate for his entire presentation of evidence (Ex. 1009, ¶ 14 ("In preparation of this declaration, I relied on my knowledge of electrical and biomedical engineering, my professional experience, ***and the exhibits filed herewith***.")). This is then relied on by the Petition at page 22.

Unpacking Dr. Heikenfeld's masterclass of incorporation by reference and reliance on cross-cited information is exactly why *Adaptics* was decided in the manner it was: failure by the Petitioner to clearly, and with particularity, commit to a theory warrants discretionary denial because it places an undue burden on the Board and PO to sort through and identify theories that are Petitioner's burden to establish.

2. The Petition Improperly Attempts to Shift the Burden of Claim Construction to the Board and PO in Violation of 37 C.F.R. § 42.104(b)(3).

37 C.F.R. § 42.104(b)(3) mandates the Petition must include a statement that identifies "[h]ow the challenged claim is to be construed." Where the Petitioner sets forth arguments or observations of what a claim term means, but does not provide an explicit construction for the claim term, "the Petitioner improperly attempts to shift the burden of construing the claim term . . . to the Board[,]" and institution should be denied. *See ams AG v. 511 Innovations, Inc.*, No. IPR2016-01792, Paper

15 at 13 (P.T.A.B. Mar. 16, 2017) (denying institution) ("[U]nder the circumstances discussed above, including that the parties disagree over whether the prior art discloses or suggests the claimed 'minimal height,' Petitioner fails to meet its burden under 37 C.F.R. § 42.104(b)(3) of providing a claim construction for the term 'minimal height.' Therefore, we decline to institute an *inter partes* review of the challenged claims.").

The Petition violates this rule, and should be discretionarily denied, because: (a) a facial examination of Petitioner's expert declaration shows that Petitioner is attempting to implicitly construe claims without providing any actual claim construction analysis; and (b) because there is no claim construction analysis, Petitioner shifts the burden to PO and the Board to identify and construe relevant claim terms.

a. A Facial Examination of Petitioner's Expert Declaration Shows that Petitioner Is Attempting to Implicitly Construe Claims Without Providing Any Actual Claim Construction Analysis.

The Petition's entire discussion of claim construction is: "Claims are interpreted with their ordinary and customary meaning as understood from the perspective of a person of ordinary skill in the art ("POSA")." Petition, 2. The Declaration provides no further analysis: "For purposes of these Petitions, the Challenged Claims are interpreted according to their plain and ordinary meaning."

Ex. 1009, ¶ 51. However, throughout the Petition, there are multiple elements that are implicitly construed through a reliance on Petitioner's expert declaration in an effort to force the Petition's "art" to meet the claims.

For example, at least three separate terms, found in ***all*** claims (either directly or indirectly) of the '484 Patent (see table below), appear to be implicitly construed in Petitioner's expert declaration and incorporated by reference into the Petition:

Claim Element + Term	**Petition**	**Expert Decl.**
Claim 2/7(d): "trace"	Pet., 21-22, 61-62	Ex. 1009 ¶¶ 1048-1050
Claim 15(b): "flexible printed circuit layer"	Pet. 25-27	Ex. 1009 ¶¶ 1069-1074
Claims 1(a) and 15(a)/7(f): "housing retaining a processor"/ "housing containing a processor"	Pet. 15-16; 25-26; 63-64	Ex. 1009 ¶¶ 1022-1026; 1066-1067; 1270-1273

Petitioner purports to apply the ordinary and customary meaning of the terms (*see* Petition, 2); however, the Petition is filled with implicit claim constructions that lack support or explanation. *See ams AG*, IPR2016-01792, Paper 15 at 8, 13 (denying institution where "Petitioner improperly attempts to shift the burden of construing the claim term 'minimal height' to the Board. *See* 37 C.F.R. §

42.104(b)(3).”). This failure renders the Petition fundamentally defective, as it leaves the Board without a clear and reasoned basis to evaluate claim scope thereby shifting the burden of claim clarification to the Patent Owner and the Board.

b. Because There Is No Claim Construction Analysis, Petitioner Shifts the Burden to PO and the Board to Identify and Construe Relevant Claim Terms.

As noted above, under 37 C.F.R. § 42.104(b)(3), Petitioner has an affirmative burden to set forth how the challenged claims should be construed. *See Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 at 10 (P.T.A.B. Mar. 1, 2019). A petition for *inter partes* review must clearly articulate a rationale for “[h]ow the challenged claim is to be construed.” 37 CFR § 42.104(b)(3). If the petitioner construes a claim term, but “does not establish that such interpretations are appropriate[,]” it is fatal to the petitioner's ground. *Vicor Corp. v. Delta Elecs., Inc.*, IPR2024-00704, Paper 11 at 8 (P.T.A.B. Oct. 2, 2024). Controlling law mandates that claim terms in an IPR be construed using the same standard as in a civil action under 35 U.S.C. § 282(b), including “construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also* 37 C.F.R. § 42.100(b) (2021). To determine the meaning of a disputed claim term, one must “look principally to the intrinsic evidence of record, examining the

claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc)).

Like the petition in *Vicor Corp.*, the Petition does not even purport to apply the controlling law of *DePuy Spine, Inc.* and *Phillips*. The singular reference to claim construction states "Claims are interpreted with their ordinary and customary meaning as understood from the perspective of a person of ordinary skill in the art ("POSA")." Petition, 2 (citing *Phillips*, 415 F.3d at 1303).

Despite this, the Petition repeatedly engages in improper claim construction through reliance on Dr. Heikenfeld's "definitional" opinions. Ex. 1009, ¶ 1047 (treating Ex. 1035 as if it were a dictionary in offering an opinion about how a POSA would understand certain terms). Exhibit 1035 is neither a dictionary, nor evidence of how a POSA would have understood any term at the time of the '484 Patent's filing. Instead, the Petition, through the "shield" of its expert, deviates significantly from the "ordinary and customary meaning" of the terms without providing any rationale for doing so, often treating an amalgamation of non-contemporaneous, unhelpful, irrelevant documents as if they were helpful to the *Phillips* inquiry.

As an example of the Petition's failings, dependent Claim 2 (from which dependent Claim 3 depends) and independent Claim 7 both require "traces" and the Petition relies on this non-prior art Exhibit 1035 to interpret a printed trace as any "conductors on a printed circuit board," by alleging through Dr. Heikenfeld that "trace" and "conductor" are ***interchangeable***. Ex. 1009, ¶ 1048 (cited in the Petition at Petition pages 21-22). Similarly, the Petition does nothing to explain how it interprets the "flexible printed circuit layer" of Claim 15 (Petition at 25-27), and instead simply relies on the analysis of the claimed "flexible circuit layer" of Claim 1, completely ignoring the added limitation regarding the printed traces of Claim 15.

The Petition improperly construes these claim terms because it provides no evidence, support, or argument that "show[] a reasonable likelihood that it would prevail in its challenge asserted as Ground[s] [1-4]." *See Vicor Corp.*, IPR2024-00704, Paper 11 at 9.

The Petition also cites no supporting evidence from the '484 Patent itself in support of its theories, rather it simply points do Dr. Heikenfeld's conclusory statements. When reviewing Dr. Heikenfeld's declaration, it simply parrots the Petition, which is not "persuasive or helpful as it repeats the Petitioner's arguments and offers little or no elaboration as to how one of ordinary skill in the art would

understand the term[.]" *InfoBionic, Inc. v. Braemer Manuf., LLC*, IPR2015-01704, Paper 11 at 6 (P.T.A.B. Feb. 16, 2016) (denying institution).

Dr. Heikenfeld does not "disclose the underlying facts or data on which the opinion is based." 37 C.F.R. § 42.65(a). Rather, it is simply a conclusion, and his opinion is therefore "entitled to little or no weight." *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022) (precedential) (citing 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.")); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) ("Lack of factual support for expert opinion to factual determinations, however, may render the testimony of little probative value in a validity determination." (quoting *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985)). This leaves it to the reader to decipher the actual scope of claims that the Petition is challenging.

b. Discretionary Denial Is Appropriate Under Other "Relevant Considerations" Identified in the Guidance.

The Guidance sets forth further factors for evaluation as part of the discretionary denial stage. Particularly relevant here are: (1) extent of the Petition's reliance on expert testimony; (2) strength of the unpatentability challenge; and (3)

settled expectations of the parties, such as the length of time the claims have been in force.

1. The Petition Is Over-Reliant on Expert Testimony, Favoring Discretionary Denial.

In addition to supporting denial under the older *Adaptics* line of thinking (as outlined above), the same over-reliance on expert testimony, and implicitly on a number of non-prior art references, warrants denial.

The Guidance states that one relevant factor within the Board's "discretionary considerations" is "[t]he extent of the petition's reliance on expert testimony." Guidance, 2. The Petition in this proceeding far surpasses reasonable reliance on expert testimony because: (1) the Petition bases its alleged Grounds of unpatentability on expert testimony (i.e., General Knowledge of a POSA); and (2) the Petition's alleged "General Knowledge" is typically presented as a conclusory statement with citations to nested sections of a single 500+ page (1700 paragraph) expert declaration, that contains opinions for several PTAB proceedings (and an internal web of cross-references that themselves cross proceedings), which is overly burdensome on Patent Owner and the Board to attempt to unpack the Petition's actual theories.

A facial examination of the Petition demonstrates the magnitude to which this expert testimony and its reliance on non-prior art plays a part in the Petition—**each and every Ground in the Petition is based on "General Knowledge of a POSA"**:

Proposed Grounds of Unpatentability	
Ground 1	Claims 1-5 and 15-20 are obvious under pre-AIA § 103 over Matsumura and General Knowledge of a Person of Ordinary Skill in the Art
Ground 2	Claims 1-5, 15, 17, 18, and 20 are obvious under pre-AIA § 103 over Jensen and General Knowledge of a Person of Ordinary Skill in the Art
Ground 3	Claims 1-8, 15, 19, and 20 are obvious under pre-AIA § 103 over Ozguz and General Knowledge of a Person of Ordinary Skill in the Art
Ground 4	Claims 6-8, 11, and 12 are obvious under pre-AIA § 103 over Matsumura, Ozguz, and General Knowledge of a Person of Ordinary Skill in the Art

Petition, 1-2 (annotated). Absent this reliance on the "General Knowledge of a POSA"—i.e., removing this improper expert testimony— each Ground ***fails in its entirety***. As reflected in the Petition's own table, this "General Knowledge" is ***essential*** for each ground. However, to the extent that Petitioner responds by arguing the "General Knowledge" is not actually essential, then this case is even more akin to *Adaptics* since the Petition would require replacing the conjunction "and" with an "or" or an "and/or"—opening the door to multiple interpretations for each ground, rendering each ground unbounded and more complicated than in *Adaptics*.

This "General Knowledge" in the Petition's Grounds is not a one-off citation for a single element in a dependent claim or an attempt to support a combination. Rather, the Petition's "General Knowledge" appears to be relied upon for many limitations in independent claims and even more in the dependent claims. As outlined above, in dependent Claim 2 alone, the entire analysis is based on how Dr. Heikenfeld alleges a POSA would have understood certain terms. Similar conclusions are drawn in 15(b) (Ex. 1009, ¶¶ 1068-1072), 15(d) (Ex. 1009, ¶ 1080), 15(e) (Ex. 1009, ¶ 1085), and elements "a," "b," "d," "e," and "g" of Claim 7. All told, every claim, either directly or indirectly, are allegedly disclosed by what a "POSA would understand" (i.e., expert testimony), not the prior art itself.

Patent Owner acknowledges that general knowledge of a person of ordinary skill in the art may, under certain limited circumstances, be relied upon to supply a missing claim limitation (*see, e.g.*, *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020) (a narrow holding limited to "obvious to try")). This, however, is not the normal application of the law or the standard practice for the Board. The TPG, and the Federal Circuit, traditionally reject the use of expert testimony to take the place of teachings of the actual references that make up the ground of the challenge in the Petition. TPG at 36; *K/S Himpp v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1365 (Fed. Cir. 2014). Indeed, the traditional, and governing,

rule is to reject testimony such as Dr. Heikenfeld's because it is nothing more than "conclusory statements and unspecific expert testimony." *Koninklijke Philips N.V.*, 948 F.3d at 1338 (quoting *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366 (Fed. Cir. 2016)); *In re Ethicon, Inc.*, 844 F.3d 1344, 1348, 1352 (Fed. Cir. 2017) (concluding that the Board properly gave "little weight" to conclusory expert testimony).

One could conceivably excuse this reliance on "General Knowledge" if the Petition explained developed theories rooted in prior art that were based on an expert's opinions that also set forth the underlying facts and data that supported the expert's conclusions, as required under FRE 702. Here, such detail is woefully lacking.

Through its web of incorporation, the Petition effectively relies on all of Dr. Heikenfeld's analysis regarding the alleged prior art. For example, the Petition begins by citing the entirety of Dr. Heikenfeld's "background" Sections IV.A through IV.D. Petition at 3-6 (citing Ex. 1009, ¶¶ 17-36). Through this, the Petition improperly sets the table of "background" relying on evidence that is itself not "background."

The pervasiveness of this conduct further underscores the propriety of discretionary denial. Each actual ground in the Petition is bookended with "General

Knowledge of a POSA." Petition, 14 (Ground 1), 33 (Ground 2), 47 (Ground 3), and 69 (Ground 4). Further, the Petition goes on to rely on Dr. Heikenfeld's declaration for ***each and every*** claim element. The Guidance confirms that Petitioner's attempts to circumvent the Trial Practice Guide's directions regarding experts is now a basis to decline institution. Guidance at 2; TPG at 36 ("Expert testimony may be presented to establish the scope and content of the prior art for determining obviousness and anticipation" but it "cannot take the place of a disclosure in a prior art reference."). The Petition relies on Dr. Heikenfeld, not just to provide testimony regarding the prior art references and alleged motivation to combine, but to pack the record with over fifty-five different references under the guise of "General Knowledge."

This factor favors exercising discretion and denying this Petition.

2. The Petition's Over-Reliance on Non-Prior Art Documents.

In addition to the issues outlined above, the Petition improperly relies extensively on non-prior art, outdated, and irrelevant references.

The Petition seemingly agrees that no combination of the actual prior art references identified in the specific Grounds of alleged unpatentability actually teaches the independent claims of the '484 Patent. Instead, it resorts to reliance on amorphous "General Knowledge" for ***each*** ground, leaving the reader to guess

which limitations this "General Knowledge" purportedly teaches, how to interpret this "General Knowledge," or how a POSA would have applied this "General Knowledge" in the prior art period.

The Petition's reliance on non-prior art, outdated, and irrelevant references is an aggravating factor that undermines its obviousness theories. Specifically, the Petition claims to establish the "state of the art" through the use of 55 references. However, many of these references are not actually prior art, and the Petition fails to distinguish which references qualify as valid art for the state-of-the-art determination.

As described above, of the 66 exhibits submitted with the Petition, the Petitioner relies on 55 references (Exs. 1011 through 1065) as supporting its unpatentability theories. Of these 55 references, eight are decidedly not prior art, being from ***after*** the November 2006 priority date of the '484 Patent. For example, Exhibits 1020 (dated in 2008); 1021 (dated in 2013); 1024 (dated in 2023); 1025 (dated in 2012); 1027 (dated in 2025), 1030 (dated in 2022), 1043 (dated in 2019), and 1035 (dated in 2006), are all dated anywhere from months to ***19 years after*** the priority date of the '484 Patent (November 1, 2006). Dr. Heikenfeld's reliance on these non-prior art documents is extensive: he cites Ex. 1035 approximately 62 times in his declaration and Exhibit 1043 approximately ten times in his declaration,

not including any internal cross references that incorporate these references. He further relies on Exhibits 1020, 1021, 1024, 1025, 1027, and 1030 in his "background sections" which are cross-referenced repeatedly throughout his declaration including his actual analysis of claim elements and explanations for why the alleged combinations would be made.

That the Petition relies on references from after the priority date of the '484 Patent as alleged evidence of the "state of the art" at the time of the invention–2006–creates confusion, undermines the foundation of the obviousness challenge, and distorts the obviousness inquiry making it difficult for both the Patent Owner and the Board to decipher the proper state of the art at the time of the claimed invention. It weakens the Petition's challenge.

Moreover, many of the other cited references are significantly outdated, lack contextual explanations, and are presented without sufficient clarity as to their relevance to the technology at issue. For example, the Petition does not explain why some very old references (some 50+ years prior to the priority of the '484 Patent) are relevant to the problems facing the ***state of the art*** in 2006 or provide any insight into how they would contribute to a POSA's understanding of the technology at the time of the claimed invention. For example, the Petition relies on numerous ancient references, including: Exhibits 1022 (dated in 1979); 1026 (dated in 1960); 1031

(dated in 1985); 1032 (dated in 1984); 1037 (dated in 1969); 1038 (dated in 1989); 1048 (dated in 1956); 1049 (dated in 1985); 1050 (dated in 1985); 1051 (dated in 1980); 1052 (dated in 1977); 1059 (dated in 1986); 1060 (dated in 1917); and 1061 (dated in 1978). For example, Dr. Heikenfeld uses Exhibit 1038, from 1989, as alleged evidence that in 2006, a POSA would have had problems properly cleaning medical devices. Ex. 1009, ¶ 32. Nothing about these references from decades before the priority of the '484 Patent was filed suggests how a POSA would understand the problems facing the industry in 2006.

In light of the Petition's failure to establish the relevancy of these ancient references, one can only assume they are irrelevant, unreliable, and inapplicable to the field of the invention as of 2006. As such, there is no rational basis for relying on the references, as they lack the modern technological relevance necessary for a POSA to reasonably combine them.

3. The Parties' Expectations for the Nearly Ten-Year Old '484 Patent.

The ultimate parent patent to the '484 Patent, the '007 Patent, issued in 2012 and claims priority to 2006. Ex. 1001, Cover. The '007 Patent has been in force for thirteen years and the '484 Patent for almost ten years. *Id.* In an era where heartrate monitors were often large, in-patient procedure type medical devices, the '007 Patent

represented a novel approach to construction, demarking certain reusable components from other disposable components in a wearable and portable device.

Petitioner, in its infancy, was particularly focused on patent searches. As early as 2010, former iRhythm engineer and founder Uday Kumar was quoted when describing his early approach to competitor patents for his fledgling idea as needing "to figure out if people had done this before so we conducted IP searches. Our focus was on patents that had already been issued as well as pending patent applications." Ex. 2010, 232. As the company progressed, he took that early search and analysis, and in preparation for a meeting with an attorney "revisited the team's early IP assessment and initiated a more detailed review of the prior art…. [He] did more searching, brushed up on what else was out there, and dived much more deeply in the analysis of specific claims." Ex. 2010, 233. Petitioner has an established and public track-record of monitoring existing patents. This awareness led to a long period of awareness and not challenging the '007 Patent and its progeny.

Moreover, due to the early priority date of the '007 Patent, it served as prior art to many other patent applications in the industry, including Petitioner's own filings. Despite knowing of the '007 Patent and its related family members for over a decade, Petitioner did nothing, creating an expectation between the parties.

On August 7, 2013, Petitioner submitted an information disclosure statement ("IDS") in its then-pending application 13/890,144 that indicates it was aware of the application that would ultimately issue as the '007 Patent. Ex. 2001 at 4 (Information Disclosure Statement dated May 18, 2013 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the pre-grant publication that issued as the '007 Patent, reference no. 101).

On May 18, 2015, Petitioner submitted an information disclosure statement ("IDS") in its then-pending application 13/890,144 that specifically identified the '007 Patent, confirming that not only was Petitioner aware of the scope and content of the '007 Patent (as evidenced by the submission of the pre-grant publication), but it was aware that the '007 Patent had issued and was in force. Ex. 2002 at 3 (Information Disclosure Statement dated May 18, 2015 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the '007 Patent, reference no. 67).

By delaying over ten years from the date it first became aware of the '007 Patent (and then the subsequent to issue '484 Patent), Petitioner has created an implicit expectation between the parties, an acquiescence as to the patentability of the claims of the '484 Patent.

The decades-long delay of addressing the validity of this patent family further favors exercising discretion and denying this Petition.

c. The Fintiv Factors Also Favor Discretionary Denial.

The *Fintiv* analysis further provides an independent basis to deny institution of the Petition.

1. Petitioner Has Not Sought a Stay, Favoring Denial.

This factor, unaddressed in the Petition, is either neutral (as the PTAB will have to speculate whether a stay would be granted to the extent asked for) or favors using discretion to deny the Petition (as there has been no stay sought). The underlying district court litigation was filed in February of 2024 and has been pending for over a year.

Regardless, should the Board require background on court-issued stays in Delaware, courts in Delaware have denied stays even when *inter partes* reviews have been instituted, where the parties are competitors, in an effort to maintain parity across proceedings. *See, e.g.*, *Siemens Indus., Inc. v. Westinghouse Air Brake Techs. Corp.*, No. CV 16-284-LPS, 2018 WL 3046511, at *2 (D. Del. June 20, 2018) (denying a stay pending IPR after Petitioner had previously moved for a stay and been asked to re-raise the request post-institution because, in part, "a stay would result in prejudice" to the plaintiff and "an unfair tactical advantage to" defendant).

iRhythm has alleged infringement of its own patents in a separate case against PO's related company, Bardy Diagnostics. Ex. 2003 (iRhythm's Amended Answer alleging infringement against Bardy Diagnostics).

To the extent the Director is unpersuaded regarding whether a stay would or would not be granted where no stay has been sought by Petitioner, any evidence on this factor is at best neutral. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (P.T.A.B. May 13, 2020) (precedential), cautions against speculating whether the district court would grant a stay if one were requested.

2. Proximity of the Court's Trial Date Is Neutral.

Trial is scheduled for March 22, 2027. Ex. 2005 (scheduling order). However, as *Fintiv* outlines, "if the court's trial date is at or around the same time as the projected statutory deadline…or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors." *Fintiv*, IPR2020-00019, Paper 15 at 9. Therefore, this factor is neutral.

3. The Parties and Court Are Far Into Litigation in the Parallel Proceeding, Favoring Denial.

Even at this pre-institution decision stage, both parties have served and pursued discovery in earnest. Ex. 2006 (PO's Notice of Service of Party Discovery); Ex. 2007 (Petitioner's Notice of Service of Party Discovery). Based on Petitioner's decision to escalate the discovery efforts in the case, the parties have further begun

the process of conducting third-party discovery. Ex. 2008; Ex. 2009; Ex. 2011. Moreover, by the time the institution decision is due, substantial completion of fact discovery will be less than three-months away. Ex. 2005.

The district court has become Petitioner's preferred venue for this dispute, and the parties have expended significant time and resources already, favoring discretionary denial.

4. Petitioner's Failure to File a *Sotera*-type Stipulation with the Petition Favors Denial.

Petitioner has not filed a *Sotera*-type stipulation. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-0109, Paper 12 (P.T.A.B. Dec. 1, 2020). It could have done so with its Petition and instead made the strategic decision not to, thereby waiving the opportunity to commit to adjudicating validity of the '484 Patent before the Board. Petitioner's failure to provide such a stipulation with its Petition should be fatal to this factor as allowing a late-filed *Sotera* stipulation would improperly give a tactical advantage to the Petitioner on this issue. Given the recent guidance rescinding the USPTO Director's June 21, 2022, memorandum, Petitioner had ample opportunity to prepare and serve such a stipulation with its Petition or in the period of time before this paper was due.

Given the more compressed discretionary denial timelines outlined in the Guidance, there is not adequate time for PO to address any delinquent *Sotera*

stipulation filed after PO's paper. Under the prior guidance, protracted *Fintiv*-type briefing allowed for each party to have post-Patent Owner Preliminary Response papers to address discretionary denial, including *Fintiv* factors, unusual 325(d) arguments, and other discretionary factors. *See, e.g. BMW of N. Am. LLC v. Northstar Sys. LLC*, IPR2023-01017, Paper 12 at 10 n.11 (P.T.A.B. June 9, 2023) (outlining that "As a practical matter, of course, a petitioner would need to submit a *Sotera* stipulation well in advance of the Board's deadline for entering its institution decision, in order to ensure that the Board has the opportunity to consider it." But declining to discretionarily deny because each party had a supplemental paper post POPR). Under the new Guidance and timing, there is no such opportunity.

Accordingly, because the parallel district court action remains a viable option for Petitioner to address the validity of the '484 Patent, and because it failed to include a timely *Sotera* stipulation, this factor favors discretionary denial.

5. The Same Parties Are in the Parallel District Court Proceeding, Favoring Denial.

Petitioner here is the defendant in the parallel district court litigation, this factor favors denial of institution under § 314(a). *See Sotera Wireless, Inc.*, IPR2020-01019, Paper 12 at 19. The co-pending district court action exists before a judge who has extensive experience with patent disputes, and there is no basis to take away PO's constitutional right to a trial on the merits of its claims. Moreover,

"proceeding in parallel with the district court litigation is an inefficient use of our time and resources." *NHK Spring Co., LTD., v. Intri-plex Techs., Inc.*, IPR2018-00752, Paper 8 at 11 (P.T.A.B. Sept. 12, 2018) (precedential).

6. The Additional Factors Outlined Herein Further Favor Denial.

Fintiv further provides for the analysis of "other factors," which include those outlined in greater detail above. Given these other factors outlined in this paper favor discretionary denial, so too does this factor of the *Fintiv* analysis. As Factor 3, 4, 5, and 6 favor denial, Factor 2 is neutral, and Factor 1 either favors denial or is neutral, the *Fintiv* analysis favors discretionary denial. Even if Factors 2 and/or 3 are found to favor not exercising the Director's discretion to deny the Petition, the balance of the factors still favor denial.

III. CONCLUSION

Under the factors set forth in the Guidance, including those articulated in *Fintiv* and *NHK*, Patent Owner respectfully requests that the Petition be denied as an inefficient use of the Board's time and resources.

Dated: April 22, 2025

Respectfully submitted,

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Certification of Word Count Under 37 C.F.R. § 42.24(d)

The undersigned hereby certifies that the foregoing contains 6,571 words according to the word count of the word-processing software used to prepare the foregoing and accounting for the words in the figures as required by the Trial Practice Guide.

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 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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