

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.,

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

CASE: IPR2025-01081

U.S. PATENT NO. 8,630,699

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 <i>Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-01355, indicating Petitioner iRhythm's intent to assert additional patents.
2005	Scheduling order in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224
2006	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 26)
2007	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 27)
2008	Notice of Service of Third-Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 41)
2009	Notice of Service of Third-Party Discovery Responses in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 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 <i>Welch Allyn Inc. v. iRhythm Technologies Inc.</i> , 1:24-cv-00224 (ECF 48)

Exhibit No.	Description
2012	[Reserved]
2013	[Reserved]
2014	[Reserved]
2015	[Reserved]
2016	[Reserved]
2017	[Reserved]
2018	iRhythm's Third Amended Counterclaims alleging infringement against PO's related company, Bardy Diagnostics
2019	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 58)
2020	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 61)
2021	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 63)
2022	iRhythm's Notice of Service of Subpoena in <i>Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-01355

The Patent in this proceeding, U.S. Patent No. 8,630,699 (the “’699 Patent”), is a continuation of U.S. Patent No. 8,214,007 (the “’007 Patent”). On June 6, 2025, the Director granted Patent Owner’s request that institution be discretionarily denied in five other proceedings filed by Petitioner, including challenges to the ’007 Patent and three other continuations of the ’007 Patent.¹ See *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, -00374, -00376, -00377, -00378, Paper 10 at 2-3 (P.T.A.B. June 6, 2025). The instant Petition now seeks to challenge the ’699 Patent, yet another continuation of the ’007 Patent, making this the *sixth* challenge to a patent in this same family. The Director has already exercised discretion to deny the previous five challenges because of the settled expectations of the parties and the other reasons of record. *Id.* The Director should similarly deny this Petition, which challenges yet another continuation of the ’007 Patent, for the exact same reasons.

Patent Owner, Welch Allyn, Inc. (“PO”), submits this request for the Director to exercise discretion to deny the Petition in this proceeding pursuant to the Board’s recent guidance on “Interim Processes for PTAB Workload Management,” dated March 26, 2025 (“Guidance”).

¹ The ’007 Patent was challenged in two proceedings, IPR2025-00377 and IPR2025-00378.

I. INTRODUCTION

The '699 Patent issued over eleven years ago, and Petitioner iRhythm was not only monitoring the then-pending prosecution that led to family members of the '699 Patent (*see, e.g.*, Ex. 2010), but made an affirmative decision to not challenge the '699 Patent during the life of the patent, until now. Acting Director Stewart recognized that “Petitioner’s awareness of Patent Owner’s applications and failure to seek early review of the patents favor[ed] denial” of institution of five IPR proceedings involving family members to the '699 Patent. *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, IPR2025-00374, IPR2025-00376, IPR2025-00377, IPR2025-00378, Paper 10 at 2-3 (P.T.A.B. June 6, 2025). The Director need not read further, as this alone is a sufficient basis to deny institution. *See Dabico Airport Sols. Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 (June 18, 2025) (*Sua sponte* denying institution where the challenged patent has been in force for more than 7 years).

To the extent any additional argument is necessary, under both the prior discretionary denial standards (including those set forth in *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (P.T.A.B. Mar. 6, 2019) (informative), *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential), and the requirements under 37 C.F.R. § 42.104(b)(3)) 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 '699 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, a declaration of 277 paragraphs spread over more than 100 pages. Ex. 1003. Examination of this declaration details: (1) significant reliance on non-prior art evidence (*see, e.g.*, Ex. 1008 (dated 2006), Ex. 1010 (dated 2008), Ex. 1011 (dated 2013), 1024 (dated 2022)); (2) lack of opinions on claim construction (Ex. 1003, ¶ 50); and (3) reliance on ancient documents to fabricate "state-of-the-art problems" (Ex. 1009, ¶ 939 (citing 1012 (a paper purportedly from 1979))). All of this unnecessarily and improperly shifts 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 100+ 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 44 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 '699 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 v. Fintiv*, IPR2020-00019, Paper 11, 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) “relevant considerations” now identified in the Guidance; and (b) “discretionary considerations enumerated in existing Board precedent.” *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 the “Relevant Considerations” Identified in the Guidance.

The Guidance sets forth factors for evaluation as part of the discretionary denial stage. The considerations particularly supportive to a denial here include the: (1) settled expectations of the parties, such as the length of time the claims have been in force and Petitioner's long-standing awareness of the '699 Patent; (2) extent of the Petition's reliance on expert testimony; and (3) strength of the unpatentability challenge.

1. The Parties' Expectations for the Eleven-Year Old '699 Patent.

The parent patent to the '699 Patent, the '007 Patent, issued in 2014 and claims priority to 2006. Ex. 1001, Cover. The '007 Patent has been in force for thirteen years and the '699 Patent for over eleven years. *Id.*; see also *Dabico*, IPR2025-00408, Paper 21 (*Sua sponte* denying institution where the challenged patent has been in force for more than 7 years).

Petitioner, in its infancy when the '007 Patent published and was issued, was particularly focused on patent searches and monitoring its competitors patent portfolios. 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.

However, not only was Petitioner actively monitoring competitor patents, but it was particularly focused on Patent Owner’s patents, including the family of the ’699 Patent. 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, the ultimate parent patent to the ’699 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 then 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). This type of specific awareness sets this case apart from the *sua sponte* decision in *Dabico*, IPR2025-00408, Paper 21, where the mere age of the patent was sufficient to deny institution. Here, there is direct documentary evidence that not only was the Petitioner aware of the parent ’007 Patent, but its monitoring was specific enough to allow for the modification of its IDS submission to indicate that the ’007 Patent had issued from its previously cited pre-grant publication.

By delaying at least ten years from the date it first became aware of the ’007 Patent (not to mention the eleven years subsequent the issuance of the ’699 Patent), Petitioner has created an implicit expectation between the parties, an acquiescence as to the patentability of the claims of the patent family, including the ’699 Patent.

This awareness led to a long period of awareness and not challenging the ’007 Patent and its progeny including the ’699 Patent. 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.

2. The Petition is Over-Reliant on Expert Testimony,
Favoring Discretionary Denial.

The Petition's over-reliance on expert testimony, and implicitly on a number of non-prior art references, further 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 expressly bases all 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 statements, making it unclear what is actually being relied upon and, therefore, 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	
<u>Ground 1</u>	Claims 1-4 are obvious under pre-AIA § 103 over Jensen, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 2</u>	Claim 8 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and <u>General Knowledge of a POSA</u>
<u>Ground 3</u>	Claims 1, 2, 4 are obvious under pre-AIA § 103 over Matsumura, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 4</u>	Claim 3 is obvious under pre-AIA § 103 over Matsumura, Kroll, Khandpur, <u>and of a POSA</u>
<u>Ground 5</u>	Claim 8 is obvious under pre-AIA § 103 over Matsumura, Kroll, Thompson, and <u>General Knowledge of a POSA</u>

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, at least as essential as the other expressly identified references. However, to the extent that Petitioner responds by arguing the “General Knowledge” is not actually essential to each ground, 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 that 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 over half

of the limitations in independent Claim 1, and more in the dependent claims. As outlined above, in independent Claim 1 alone, the Petition identifies elements 1(a), 1(b), 1(d), 1(e), 1(f), 1(g) as elements that are only rendered obvious to the extent Dr. Heikenfeld's opinions regarding how a POSA would have understood certain terms (which themselves are based on evidence that is not contemporaneous and often not even prior art) are correct. In doing so, all but one of the elements of sole independent Claim 1 are based on analysis that is itself not rooted in the cited references. *See* 35 U.S.C. § 311; *see also Qualcomm Inc. v. Apple Inc.*, 134 F.4th 1355 (Fed. Cir. 2025) (holding that Applicant Admitted Prior Art **cannot** be the basis for an IPR challenge).

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”)).²

² Unlike in *Shockwave Medical, Inc. v. Cardiovascular Systems, Inc.*, Nos. 2023-1864, 2023-1940, 2025 WL 1922023 (Fed. Cir. July 14, 2025), here the “general knowledge” that the Petition relies on is unclearly allocated across all of the different elements of the Petition and the Declaration. Specifically, the alleged

This, however, is not the normal application of the law or the standard practice for the Board.

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

“background knowledge,” or “state” of ECG sensor devices (Sections IV.A-IV.F of the Declaration), is vaguely applied throughout the Petition, and the Declaration itself, and unnecessarily shifts the burden to the PO and the Board to sift through the Petition and Declaration to identify what arguments are prior art driven and what is background art driven. *See, e.g.*, Petition, 21-23 (discussing motivation to combine *Jensen* and *Kroll*), 26 (discussing claim limitation 1(d)), 31 (discussing claim limitation 1(g)), 37-38 (discussing dependent claim 4), 40 (discussing motivation to combine *Jensen*, *Kroll*, and *Thompson*), 44 (discussing motivation to combine *Matsumura* and *Kroll*), 48 (discussing claim limitation 1(c)), 50 (discussing claim limitation 1(d)), 53 (discussing claim limitation 1(g)), 62 (discussing motivation to combine *Matsumura*, *Kroll*, and *Thompson*); Ex. 1003, ¶¶ 110-114, 116, 138, 143, 161, 180, 185, 201, 220, 226, 241, 266.

expert's conclusions, as required under FRE 702. Here, such detail is woefully lacking.

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, 21 (Ground 1), 39 (Ground 2), 42 (Ground 3), 58 (Ground 4), and 61 (Ground 5). 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 different references under the guise of "General Knowledge."

This factor is an independent basis for exercising discretion and denying this Petition.

3. The Petition's Over-Reliance On Non-Prior Art Documents.

In addition to the issues outlined above, the Petition also relies extensively on non-prior art, outdates, and irrelevant documents. 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 claim of the '699 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 44 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 56 exhibits submitted with the Petition, the Petitioner relies on 44 references (Exs. 1005 through 1045) as supporting its unpatentability theories. Of these 44 references, at least nine are decidedly not prior art, being from *after* the November 2006 priority date of the '699 Patent. For example, Exhibits 1008 (dated in 2006); 1010 (dated in 2008); 1011 (dated in 2013); 1017 (dated in 2012); 1018 (dated in 2023); 1021 (dated in 2025), 1024 (dated in 2022), and 1039 (dated in 2019), were all dated anywhere from months to **19 years**

after the priority date of the '699 Patent (November 1, 2006). Dr. Heikenfeld's reliance on these non-prior art documents is extensive—collectively citing these references approximately 27 times in his declaration, not including any internal cross references that further incorporate these references. He further relies on Exhibits 1010, 1011, 1017, 1018, 1021, and 1024 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 '699 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 '699 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 1012 (dated in 1979); 1020 (dated in 1960); 1025 (dated in 1985); and 1026 (dated in 1984). Nothing about these references from decades before the priority date of the '699 Patent 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.

As another example, because the Petition hides behind the "ordinary and customary meaning" for all claim terms, the Board is left to guess the Petition's actual position on "current-limiting defibrillation protection resistor."³ *See* Petition, 2. Rather than articulate a construction for "current-limiting defibrillation protection resistor," the Petition seemingly construes "current-limiting defibrillation protection

³ This term appears in Grounds 1 and 3 and is discussed in an exemplary way with regard to Ground 1 here.

resistor” to include any type of resistor, without requiring the current-limiting defibrillation protection resistor to protect from defibrillation.

For example, the Petition identifies *Kroll's* lead strips and argues that “Kroll teaches a current-limiting defibrillation protection resistor in the form ‘of a flexible conductive ink compound . . . of a preselected conductivity to provide a certain total lead strip resistance so that each strip [] serves as a current limiter to protect a patient from shock due to malfunction of the device [] or of a complementary medical device.’” Petition, 26. That *Kroll's* lead strips serve to protect the patient does not somehow mean that the lead strips are also “current-limiting defibrillation protection resistors” that protect the device from defibrillation, as required by Claim 1.

A proper claim construction analysis considers the intrinsic evidence of the '699 Patent, which the Petition ignores. The '699 Patent explains that the “resistive traces should survive multiple defibrillation cycles such that body worn monitor 100 remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor.” Ex. 1001, 7:48-54. The '699 Patent is clear that the use of circuit protection including the current-limiting defibrillation protection resistors, which “are typically in the

form of resistive traces 412,” allow “a body worn device [to] survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 15:19-24.

The only way to reconcile the '699 Patents express disclosure (explaining that current-limiting defibrillation protection resistors must *protect the device* from defibrillation) and the Petition's argument (the current-limiting defibrillation protection resistors *protect the patient* from defibrillation) is to broadly construe “current-limiting defibrillation protection resistors” to capture any resistor that provides any resistance for any purpose. The Petition's application of this broad construction without actually construing “current-limiting defibrillation protection resistors,” is improper and should be ignored.

The Petition, recognizing the limits of the art it elected for its challenge, disregards the teachings of the '699 Patent in an effort to render its claims obvious. But this attempt should be denied because it fails to both (1) present a cognizable claim construction theory, and (2) if proper would vitiate the actual claim language, rendering the claim element moot, which cannot be correct.

Therefore, the Petition's implicit and improperly broad construction of “current-limiting defibrillation protection resistors” fails.

b. 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
Convolved 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 five 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	
<u>Ground 1</u>	Claims 1-4 are obvious under pre-AIA § 103 over Jensen, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 2</u>	Claim 8 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and <u>General Knowledge of a POSA</u>
<u>Ground 3</u>	Claims 1, 2, 4 are obvious under pre-AIA § 103 over Matsumura, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 4</u>	Claim 3 is obvious under pre-AIA § 103 over Matsumura, Kroll, Khandpur, <u>and of a POSA</u>
<u>Ground 5</u>	Claim 8 is obvious under pre-AIA § 103 over Matsumura, Kroll, Thompson, and <u>General Knowledge of a POSA</u>

Petition, 1-2 (annotated).

This “General Knowledge” incorporates 44 references, some of which are over 50 years old (e.g., Ex. 1020, allegedly from 1950), some that themselves are not even prior art on their face (e.g., Ex. 1011, allegedly from 2013), and others that the Petition fails to establish are prior art (Ex. 1008, a “textbook” from some time in 2006). This “General Knowledge,” found 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 with relation to independent Claim 1:

Section of Heikenfeld	Reliance In Heikenfeld's Declaration	Exemplary Reliance On Non-Prior Art Documents
Section IV.A		• Ex. 1003, ¶ 17 (citing Ex. 1010 allegedly dated in 2008) • Ex. 1003, ¶ 17 (citing Ex. 1011 allegedly dated in 2013) • Ex. 1003, ¶ 19 (citing Ex. 1024, a website allegedly dated in 2025) • Ex. 1003, ¶ 20 (citing Ex. 1017 allegedly dated in 2012) • Ex. 1003, ¶ 21 (citing Ex. 1021 a website allegedly dated in 2025)
Section IV.B	• Motivation to combine (Ex. 1003, ¶¶ 114, 185)	• Ex. 1003, ¶ 23 (citing Ex. 1011 allegedly dated in 2013) • Ex. 1003, ¶ 23 (citing Ex. 1024 allegedly dated in 2022)
Section IV.C	• Motivation to combine (Ex. 1003, ¶¶ 112, 116, 201) • Claim 1(d) (Ex. 1003, ¶ 143) • Claim 1(c) (Ex. 1003, ¶ 220) • Claim 1(e) (Ex. 1003, ¶ 226) • Claim 1(g) (Ex. 1003, ¶ 241) • Motivation to combine (Ex. 1003, ¶ 266)	• Ex. 1003, ¶ 30 (citing Ex. 1008 allegedly dated in 2006)
Section IV.D	• Motivation to combine (Ex. 1003, ¶¶ 110, 266)	• Ex. 1003, ¶ 37 (incorporating by reference Ex. 1003, Sections

Section of Heikenfeld	Reliance In Heikenfeld's Declaration	Exemplary Reliance On Non-Prior Art Documents
	• Claim 1(d) (Ex. 1003, ¶ 138) • Claim 1(g) (Ex. 1003, ¶ 161)	IV.C-D (citing Ex. 1008 allegedly dated in 2006))
Section IV.E	• Motivation to combine (Ex. 1003, ¶¶ 110, 111, 112) • Claim 1(d) (Ex. 1003, ¶ 143) • Claim 1(g) (Ex. 1003, ¶ 161)	• Ex. 1003, ¶ 43 (citing Ex. 1008 allegedly dated in 2006) • Ex. 1003, ¶ 46 (citing Ex. 1039 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 1010, 1011, or 1008, are actually prior art (despite relying on Ex. 1008 for the Petition’s analysis of, for example, Claim 1(a)). *See* Petition, 23 (citing Ex. 1003, ¶ 124, which in turn relies on Ex. 1008). The Petition fails to establish that Ex. 1008 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 asserts that "Using electrical resistance for protection of both the device and the patient was also widely known before November 1, 2006" in Section IV.E of his Declaration. Ex. 1003, ¶ 42. However, the remainder of this section of Dr. Heikenfeld's declaration sets forth the non-prior art that he relies on for this conclusion. *See* Ex. 1003, ¶¶ 42-47 (citing Ex. 1008, dated in 2006, and Ex. 1039, dated in 2019, both after the 2006 priority date of the '699 Patent.). Dr. Heikenfeld's reliance on non-prior art in Section IV.A of his Declaration matters because it forms the foundation of his "General Knowledge" and analysis in this case for, among other things, claim limitations 1(d) (Ex. 1003, ¶ 143) and 1(g) (Ex. 1003, ¶ 161). As independent Claim 1 is the sole independent claim and is present in Grounds 1 and 3, the impact is not trivial.

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, 2017 WL 1052498 (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 according to 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 this Petition, the Challenged Claims are interpreted according to their plain and ordinary meaning." Ex. 1003, ¶ 50. 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 the sole independent claim of the '699 Patent, have these implicit claim constructions, found only in the declaration. These deficiencies infect the entire Petition.

Claim Element + Term	Petition	Expert Decl.
Claim 1(d), 1(g): "current-limiting defibrillation protection resistor"	Pet., 24-27, 30-32	Ex. 1009, ¶¶ 135-145, 156-162, 222-228, 237-243

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 according to 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. *See, e.g.*, Ex. 1003, ¶ 258 (treating Ex. 1008 as if it were a dictionary in offering an opinion about how a POSA would understand certain terms). Exhibit 1008 is neither a dictionary, nor evidence of how a POSA would have understood any term. 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, independent Claim 1 of the '699 Patent expressly requires “at least one current-limiting defibrillation protection resistor.” Ex. 1001, cl. 1. The Petition improperly construes the claim term “current-limiting defibrillation protection resistor” because it provides no evidence, support, or argument that “show[] a reasonable likelihood that it would prevail in its challenge.” See *Vicor Corp.*, IPR2024-00704 at 9. The Petition, through its reliance on Dr. Heikenfeld, seemingly construes “current-limiting defibrillation protection resistor” to include any resistor that provides resistance for any purpose and pays no heed to the claim's requirement that at least one current-limiting defibrillation protection resistor must protect the device from defibrillation.

In support of this dubious interpretation, the Petition cites no supporting evidence, and Dr. Heikenfeld substantially 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). One possible exception is Dr. Heikenfeld's allegation that "[i]t would be obvious to place Kroll's resistive traces over, or alternatively in place of, the copper wiring traces disclosed by Jensen. Thus, the modified traces would be disposed between at least one of the plurality of electrical connections (i.e., the ECG electrode) and the ECG electronics module." Ex. 1003, ¶ 160. However, Dr. Heikenfeld "does not disclose the underlying facts or data on which the opinion is based" and his opinion is therefore "entitled to little or no weight." *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug 24, 2022) (designated precedential Feb. 10, 2023) (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."). This leaves it to the reader to decipher the actual scope of claims that the Petition is challenging.

As discussed in greater detail below in Section II.b.2, the Petition's approach is not only deficient, but it is incorrect.

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. The '699 Patent is one of six patents asserted in the underlying district court litigation, and the other five patents were recently the subject of IPR2025-00363, -00374, -00376, -00377, and -00378, wherein Acting Director Stewart granted PO's request for discretionary denial and denied Petitioner's institution of IPR. As a result, a stay in the underlying district court litigation is unlikely as there are five remaining patents not subject to IPR.

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); Ex. 2018 (iRhythm’s Third Amended Counterclaims 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 (Patent Owner's Notice of Service of First Set of Requests for Production); Ex. 2007 (Petitioner's Notice of Service of Interrogatories and Requests for Production); Ex. 2019 (Petitioner's Notice of Service of Interrogatories); Ex. 2020 (Patent Owner's Notice of Service of Interrogatories); Ex. 2021 (Petitioner's Notice of Service of Second Sets of Interrogatories and Requests for Production). 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; Ex. 2022. Moreover, by the time the institution decision is due, substantial completion of fact discovery will have passed, and the close of fact discovery will be only one month 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 '699 Patent before the Board. See USPTO, FAQs for Interim Processes for PTAB Workload Management, FAQ No. 15, www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management (last updated July 25, 2025). 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 “[a]s 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 ’699 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). This is particularly

true because there are five additional asserted patents, each of which are a family member to the '699 Patent.

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: August 25, 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 7,314 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 August 25, 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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