

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm Technologies, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner

Case: IPR2025-00363

U.S. Patent No. 10,159,422

**PETITIONER'S RESPONSE TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

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1072	Docket Navigator® Motion Success Statistics for Motions to Stay Pending IPR (Post-Institution), Hon. Maryellen Noreika

Pursuant to the Director's guidance concerning "Interim Processes for PTAB Workload Management" (Mar. 26, 2025) (the "Guidance"), Petitioner iRhythm Technologies, Inc. ("Petitioner") submits this brief opposing Patent Owner Welch Allyn, Inc.'s ("PO") Request for Discretionary Denial ("Brief" or "Br.").

I. Introduction

The operative Guidance provides that "consistent with the discretionary considerations enumerated in existing Board precedent . . . and the Consolidated Trial Practice Guide (Nov. 2019), the parties are permitted to address all relevant considerations" that bear on whether a petition should be discretionarily denied. Guidance at 2. In the Guidance, the Director identified six exemplary factors that parties may address in their discretionary denial briefing: (1) whether the PTAB or another forum has already adjudicated validity/patentability; (2) whether legal changes since issuance bear on patentability; (3) the strength of the unpatentability challenge; (4) the extent of the petition's reliance on expert testimony; (5) settled expectations of the parties; and (6) compelling economic, public health, or national security interests. *Id.*

Previous discretionary denial decisions by the Director indicate that the Director will determine whether to exercise discretion to deny institution "based on a holistic assessment of all of the evidence and arguments presented." *Twitch Interactive, Inc. v. Razdog Holdings LLC*, Case IPR2025-00307, Paper 18 at 3

(PTAB May 16, 2025); *Amazon.com, Inc. v. NL Giken Inc.*, Case IPR2025-00250, Paper 14 at 2 (PTAB May 16, 2025). This approach is consistent with prior precedential Board decisions, including those cited in the Guidance. *Apple Inc. v. Fintiv, Inc.*, Case IPR2020-0019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential) (“holistic view”); *see also Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, Paper 19 at 15-19 (PTAB Sept. 6, 2027) (precedential as to § II.B.4.i) (weighing approach); *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, Case IPR2019-01469, Paper 6 at 9-11 (PTAB Feb. 13, 2020) (precedential) (weighing approach).

Applying this weighing approach, the totality of relevant factors counsels against discretionary denial. Petitioner has mounted a straightforward and meritorious challenge to the patentability of U.S. Patent No. 10,159,422 (the “’422 patent”). Numerous considerations relevant to the strength of the patentability challenge—left unaddressed in PO’s Brief but discussed in detail below—militate against discretionary denial.

Meanwhile, in its request for discretionary denial, PO addresses only a subset of factors: Three of the exemplary factors from the Guidance, the *Fintiv* factors, and a handful of considerations that it purports to have distilled from Board decisions and the trial practice guide that are tangential (at best) to accepted bases for discretionary denial. These arguments largely rest on mischaracterizations of the

petition and supporting Declaration of Dr. Jason Heikenfeld (the “Declaration”) and an attempt to manufacture complexity and confusion where there is none. For example, PO recasts Dr. Heikenfeld’s citation of evidence to support his explanations of a POSA’s general knowledge as a hidden attempt to assert additional invalidity references, infers claim constructions that were never proposed, and reframes the way that the Declaration supports the petition. Dr. Heikenfeld and the petition did none of these things and, in fact, precisely follow the guidance prescribed by the Board and the Federal Circuit, as explained below.

At bottom, PO’s arguments do not address the core of the patentability challenge and, even as set forth in PO’s Brief, the purported problems identified come nowhere close to the fact patterns under which the Board has previously exercised discretion to deny institution.

The considerations of the Guidance and the Board’s precedent demonstrate that there is no basis to exercise the Board’s discretion to deny institution.

II. Factual Background

This petition addressing the ’422 patent is one of five concurrently filed petitions challenging a family of four patents asserted against Petitioner in district court (the “’007 Patent Family”). The patents that comprise the ’007 Patent Family claim nearly identical subject matter—wearable cardiac monitors that include the commonly known features of resistors incorporated into electrical traces and/or

components specifically identified as reusable or disposable—and share similar/overlapping claim language.

Petitioner filed its IPR petitions on December 23, 2024,¹ and across the five petitions, Petitioner seeks IPR of 72 claims. Although each petition presents specific arguments about each challenged patent, for efficiency and because of the substantial similarity of the five patents, Petitioner has selected grounds with much in common: they rely on one of the same three base references (Jensen, Matsumura, or Ozguz), a total of four secondary references (Kroll, DeLuca, Harland, and Thompson), and the state of the art at the time of invention to show that the challenged claims are obvious. Given the strong overlap of issues and art across petitions, these proceedings are excellent candidates for post-institution consolidation, which would lessen the burden on the Board.

Based on the commonalities across the challenges, the Petitioner submitted one consolidated Declaration from Dr. Heikenfeld with all five petitions. Ex. 1009. PO has focused most of its discretionary denial briefing on this consolidated

¹ On February 14, 2025, after the first set of five IPR petitions was filed, PO asserted against Petitioner two additional patents from the '007 Patent Family, U.S. Patent Nos. 8,630,699 and 8,750,974. Petitioner intends to submit IPR petitions challenging these recently asserted patents soon as well.

Declaration. The Declaration, consistent with the Board's requirements and Federal Circuit precedent, contains Dr. Heikenfeld's opinions concerning the invalidity of each of the four challenged patents. It also contains background material supporting Dr. Heikenfeld's assertions about the state of the relevant art, a POSA's knowledge during the relevant time period, and how a POSA would have read and interpreted the references that are cited as grounds of invalidity. Dr. Heikenfeld's opinions, consistent with the procedures in the Board's trial practice guide, proceed from his conclusion that the claim terms can be interpreted according to their ordinary and customary meaning, and that no explicit constructions are required.

The accused product in the district court action, Petitioner's Zio[®] line of products, has been on the market since 2012, when Petitioner's Zio[®] XT was approved by the FDA. That same year, the first member of the '007 Patent Family, the '007 patent, issued. PO then subsequently filed the applications that would issue as the rest of the members of the '007 Patent Family.

IPR Number	Challenged Patent	Application Filing Date	Patent Issue Date
IPR2025-00363	10,159,422	01/26/2018	12/25/2018
IPR2025-00374	8,965,492	05/02/2014	02/24/2015
IPR2025-00376	9,155,484	01/13/2015	10/13/2015

IPR Number	Challenged Patent	Application Filing Date	Patent Issue Date
IPR2025-00377 ²	8,214,007	11/01/2006	07/03/2012
IPR2025-00378 ²	8,214,007	11/01/2006	07/03/2012

III. Numerous Factors Counsel Against Discretionary Denial

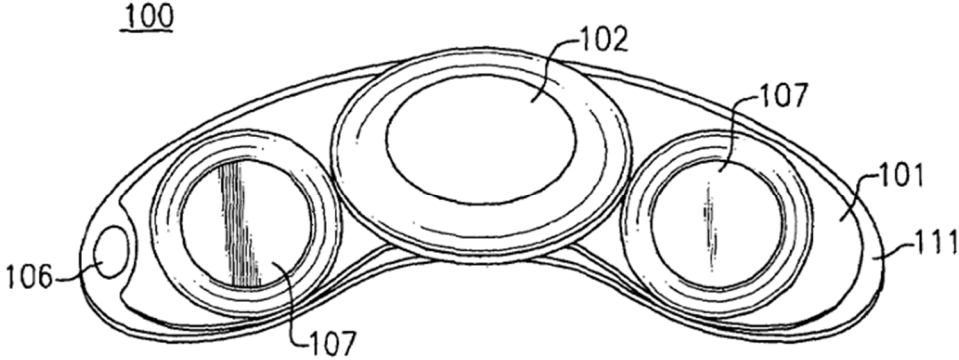
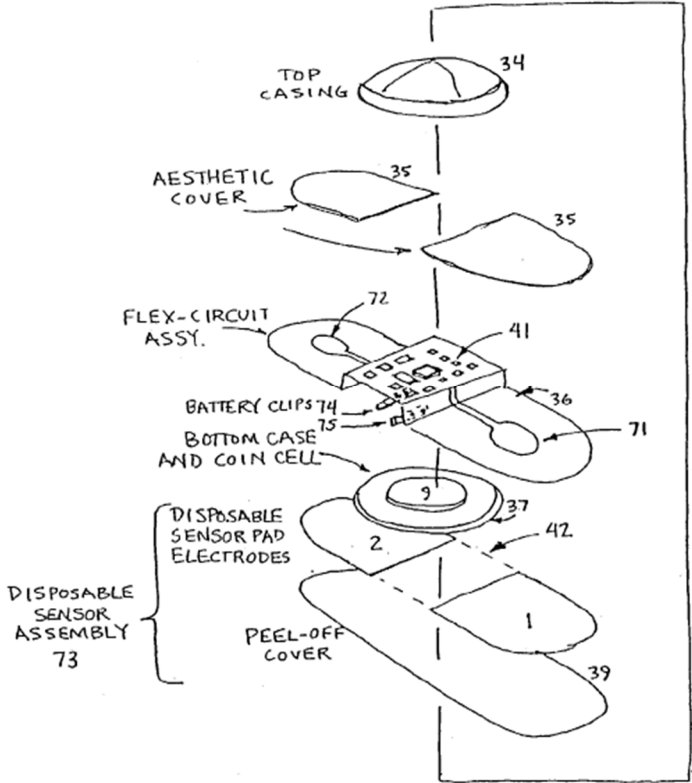
For the factors PO addresses in its Brief—both those explicitly mentioned in the Guidance and otherwise—PO's analysis is flawed for the reasons set forth in Section IV, below. However, PO's treatment of those factors is also incomplete because it fails to consider relevant evidence that weighs heavily *against* discretionary denial.

PO's Brief omits any discussion of at least two relevant factors from the Director's Guidance (prior adjudications and compelling public interests) and ignores evidence constituting "other relevant considerations bearing on the Director's discretion." Guidance at 2. Petitioner submits that the Director and the Board's holistic assessment, should account for the following five considerations, each of which counsels against a discretionary denial.

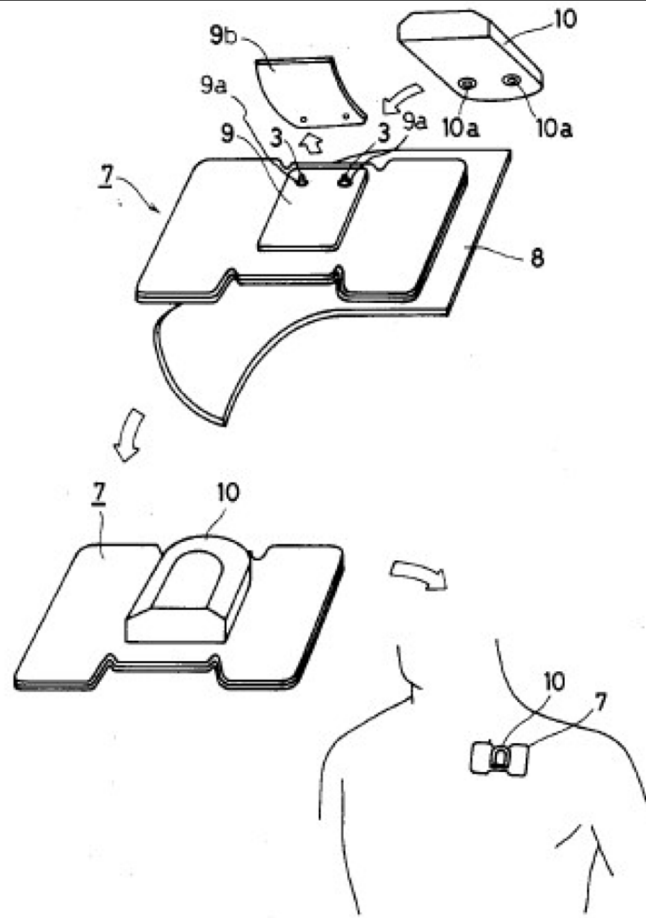
² Petitioner submitted two petitions for IPR of the '007 patent, which differ on the basis of the primary reference asserted. Each petition challenged over 20 claims, necessitating two petitions.

First, PO ignores that neither “the PTAB [n]or another forum has already adjudicated the validity or patentability of the challenged patent claims.” Guidance at 2. None of the family of challenged patents, including the '007 patent, has ever been subject to either an *inter partes* review or an *ex parte* reexamination. They have only been asserted in litigation once by PO, in the pending case against Petitioner in the District of Delaware. No substantive orders have issued in that case, and trial is not scheduled until March 2027, as discussed in further detail below (*see* § IV.F.2). Accordingly, the patentability challenge is neither cumulative nor duplicative, which counsels against granting a discretionary denial.

Second, the “strength of the unpatentability challenge” supports institution, not discretionary denial. Guidance at 2. The grounds in the petition are straightforward. In this petition, Petitioner relies on obviousness combinations based on Matsumura, Jensen, and Ozguz to demonstrate the unpatentability of the claims '422 patent. As the side-by-side figures below illustrate, each of the three base references is highly analogous art—even a cursory evaluation reveals their similarities to the '007 patent family.

, 007 Patent (Ex. 1001)	
Jensen (Ex. 1011)	

Matsumura (Ex. 1012)



Ozguz (Ex. 1014)

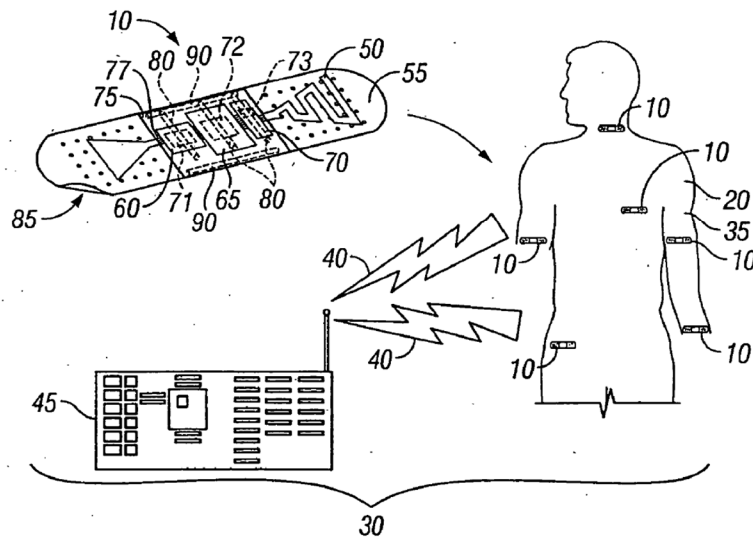


FIG. 2A

Additionally, the claims of the '007 patent largely involve basic, well-known principles in the electrical arts (*e.g.*, resistivity). As such, analysis of the '007 patent and the grounds Petitioner has assembled is unlikely to impose a substantial burden on the Board's specialist judges.

Third, and related to “the strength of the unpatentability challenge,” no factors relevant to 35 U.S.C. § 325(d) counsel in favor of discretionary denial. *See* Paper 1 at 69-70. Six of the seven prior art references (Matsumura, Kroll, Ozguz, DeLuca, Harland, and Thompson) cited across the family of IPR petitions presently before the Board do not qualify as art previously presented to the Office, and arguments based on these references do not overlap with those previously presented to the Office. *See Advanced Bionics*, Paper 6 at 7-9.

Jensen was never cited by the examiner during prosecution, but still qualifies as art previously presented to the Office because it was listed on Information Disclosure Statements supplied by the applicant. *See id.* However, applying the Board's framework in *Becton, Dickinson & Co. v. B Braun Melsungen AG*, Case IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017), Petitioner's arguments related to Jensen are novel, and unlike those previously considered by the examiner.

The “asserted art [in the petition] and the prior art evaluated during examination” are not “cumulative” (Factor B). The Examiner never cited Jensen, let alone substantively addressed any Jensen-based prior art combination or any

combination similar to the Jensen-based combinations that are asserted in the petition, including because the examiner never considered art disclosing different configurations of disposable and reusable components. Indeed, this inclusion in the Jensen-based combination constitutes a “material difference[] between the asserted art and the prior art involved during examination” (Factor A). Jensen was only listed in an IDS; it was not discussed or “evaluated during examination” and was never cited as “the basis for rejection” (Factor C). The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of discretionary denial. *See, e.g., Gene Co. Pty Ltd. v. Trs. of Columbia Univ.*, Case IPR 2024-00313, Paper 13 at 56-57 (PTAB June 24, 2024); *Advanced Energy Indus. v. Reno Techs. Inc.*, Case IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc. v. RideShare Displays, Inc.*, Case IPR2021-01602, Paper 7 at 14-16 (PTAB Apr. 11, 2022).

Petitioner's arguments related to Jensen have never previously been presented to the Office, nor has the obviousness combinations (with Matsumura) forming the grounds of the petitions, thus there is no “overlap between the arguments made during examination and the manner in which petitioner relies on the prior art” (Factor D). The examiner never substantively considered how Jensen may be combined with prior art disclosing resistive traces, which Petitioner submits constitutes an error (Factor E). And finally, “additional evidence and facts presented in the petition”—

specifically the novel prior art combinations set forth therein—warrant the Board’s review in this *inter partes* proceeding (Factor F).

Fourth, a “consideration bearing on the Director’s discretion” that was never addressed by the PO, is the possibility of consolidation across the IPRs. Guidance at 3. This petition is filed alongside four other petitions covering three other patents. The claims of each of these patents are extremely similar—as are the invalidity grounds asserted across each petition. Petitioner believes that this case can be readily consolidated with IPR2025-00374, -00376, -00377, and -00378 to reduce the burden on the parties and the Board.

Fifth, and finally, PO fails to address “public health . . . interests” implicated by this patentability challenge. Guidance at 2. The challenged independent claims, at least in the manner asserted by PO against Petitioner in the district court litigation, are extremely broad and therefore threaten to stifle innovation and preclude the field in an area of technology that bears directly on the public health—the design and development of cardiac monitors.

Each of these factors weighs in favor of instituting the petition and should be considered as part of the Director and the Board’s holistic assessment.

IV. Petitioner’s Rebuttal to PO’s Arguments for Discretionary Denial

PO offers a limited set of arguments in favor of discretionary denial, each of which is flawed. As set forth in the following sections, PO’s assertions misinterpret

the content of the petition and supporting consolidated expert Declaration, misapply the law, and emphasize collateral minutiae that the Board has not used as a basis for discretionary denial. The Director and Board should not accord weight to PO's analysis for the reasons set forth below.

**A. The Petition Satisfies the Particularity Requirement of
35 U.S.C. § 312(a)(3)**

PO's Brief leads with an argument about a statutory IPR requirement (35 U.S.C. § 312(a)(3)), confusingly trying to recast Dr. Heikenfeld's well-researched declaration and its explanation of the general knowledge of a POSA as an issue of particularity. *See* Br. § II.a.1.

Section 312's particularity requirement is straightforward: the petition "must provide an understandable explanation of the element-by-element specifics of the patentability challenges, including the identification of particular portions of prior art on which the petitioner is relying." *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1001 (Fed. Cir. 2023). That is exactly what the petition does: it enumerates four grounds of unpatentability, showing claim-by-claim and element-by-element where in the cited prior art each of the challenged claims is disclosed. Each ground also recites "the general knowledge of a POSA," *i.e.*, how a person of ordinary skill in the art (POSA) would have read or understood a cited reference in view of information that was well-known and conventional at the time of the invention.

In the petition, the POSA's knowledge is ***not asserted prior art*** and it is ***not a gap-filler*** for missing limitations. Rather, it is used to explain a POSA's understanding of the prior art and why certain limitations of the '422 patent would have been obvious in view of the disclosures of the cited art. This is an important distinction. Separate from the "prior art presented as a basis for obviousness," a patent challenger may also refer to background references in the prior art that "legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness" and "as evidence of the background understanding of skilled artisans." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015). Indeed, the Federal Circuit has stated that the obviousness analysis ***requires*** an inquiry into the POSA's general knowledge to explain how prior art would be understood. *See, e.g., Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (citing *Dow Jones & Co. v. Abilene Ltd.*, 606 F.3d 1338, 1349, 1353 (Fed. Cir. 2010)). That is all Petitioner has done here.

PO's Brief disregards this critical distinction: it treats Dr. Heikenfeld's assertions about how a POSA would have read the cited prior art as if those assertions were prior art themselves (and part of the grounds). *E.g.*, Br. at 10 ("documents that make up this 'General Knowledge'"). They are not.

Dr. Heikenfeld does not treat them as such, nor does the petition. And as a result, each of PO's arguments—predicated upon this fundamental error—is flawed.

1. The References to which PO Objects Are Not Part of the Grounds

Both the Board and the Federal Circuit have rejected arguments identical to PO's. A "[p]etitioner's reliance on evidence to show the understanding of a skilled artisan is appropriate because 'the obviousness analysis *requires* an assessment of the background knowledge possessed by a person having ordinary skill in the art.'" *Samsung Elecs. Co. Ltd. v. Link Laby's, Inc.*, Case IPR2022-00100, Paper 30 at 34 (PTAB June 7, 2023) (citing *Koninklijke Philips*, 948 F.3d at 1337); *see also Yeda Rsch. & Dev. Co. v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018) (Board may consider non-prior art evidence in assessing knowledge, motivations, what certain terms would mean, and expectations of a POSA regarding prior art).³

Without acknowledging this controlling law, PO argues that the POSA's knowledge "incorporates 55 references," and that Dr. Heikenfeld "reli[ed] on non-prior art references as 'support' for his opinions." Br. at 6. But the art PO objects

³ PO does not explicitly dispute that an expert may testify as to the background knowledge of a POSA. To the extent that PO's Brief is understood to make this argument, it is untenable in view of this cited caselaw.

to is either (1) “evidence of the background understanding of skilled artisans” or (2) cited to corroborate Dr. Heikenfeld’s assessment of “the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness,” which both the Board and the Federal Circuit have repeatedly endorsed. *E.g.*, *Ariosa*, 805 F.3d at 1365.

For example, one of PO’s objections is that

Petitioner’s expert alleges that “Wearable ECG Monitors Were Well Known Prior to the Priority Date” in Section IV.C of his Declaration. However, this section of Dr. Heikenfeld’s declaration sets forth the non-prior art that he relies on for this conclusion.

Br. at 9 (citations omitted). The referenced section is a ***background*** section of the Declaration, not a ground. It provides a historical overview of the field of the purported invention. *E.g.*, Ex. 1009, ¶ 26 (citing patents and publications prior to November 1, 2006 that teach “wearable devices with disposable sensors”). Dr. Heikenfeld cites these sources to corroborate his historical overview of ECG technology as it relates to the state of the art in 2006 and what had been long known: specifically, that wearable ECG monitors for long-term monitoring would have been known to a POSA at the time of the alleged invention. He does not “rely” on these sources as prior art for his opinion about whether the challenged claims are obvious.

He has taken the *required* approach to provide the background on how a POSA would have interpreted the references. *Koninklijke Philips*, 948 F.3d at 1337.

Other references that PO takes issue with all have the same character: they explain the history of the field, provide published corroboration of Dr. Heikenfeld’s explanations of natural laws and scientific principles (rather than asking the Board to “take his word for it”), or provide information about the state of the art as it would have existed in 2006. *See* Br. at 7-8, 11. They *do not*, as PO contends, supply “missing limitations” for the invalidity grounds. The following table—which addresses all eight references that PO discusses in detail in its Brief—illustrates the propositions for which Dr. Heikenfeld cited these sources, colored according to their character:

 Historical Proposition	 Law of Nature / Scientific Principle	 State of the Art
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Exhibit No.	Exemplary Proposition from Declaration
1020	- “Physicians have analyzed their patients’ heart rhythms for centuries—even before they had a way to reliably track and interpret the meaning of the rhythm” (Ex. 1009, ¶ 17)
1021	- “Electrocardiograms . . . were captured for the first time in the late 1880s using a mercury capillary electrometer.” (Ex. 1009, ¶ 17) - “Dr. Dilliam Einthoven won a Nobel Prize in Medicine in 1924 for his development of the first practical ECG monitor.” (<i>Id.</i>)
1024	- “ECGs work by measuring the electrical activity which controls the heartbeat.” (Ex. 1009, ¶ 19)

Exhibit No.	Exemplary Proposition from Declaration
1025	- “Over a half-century before the invention date, 12-electrode ECG was standardized.” (Ex. 1009, ¶ 20)
1027	- “A typical ECG readout includes several distinct waves: The P-wave, Q-wave, R-wave, S-wave, and the T-wave” (Ex. 1009, ¶ 21) - “The P-wave represents the atrial electrical activity, while the Q, R, S, and T waves all represent ventricular activity” (<i>Id.</i>)
1030	- “By 1969, Holter <i>minimonitors</i> (the size of a cigarette package) were being commercially produced” (Ex. 1009, ¶ 23)
1035	- Screen printing technique used to print circuit boards as early as World War II (Ex. 1009, ¶ 30) - POSA would understand conductor to be synonymous with traces (Ex. 1009, ¶ 44)
1043	- Resistivity of a conductor depends on the properties of the conductor (Ex. 1009, ¶ 47) - Current always flows in the direction of decreasing electric potential or voltage (<i>Id.</i>)

The same is true for the rest of the “55 references” with which PO takes issue (but does not address). *Id.* at 6. They are not cited as grounds for unpatentability. There is nothing complex or confusing about what these references say or how they are being used. Because the petition does not rely on them as prior art, there is no need to discuss their prior art status. *Cf. id.* at 8-9. However, it is worth noting that many of the non-prior art sources that PO cites are historical reviews, which are cited because they describe what was historically known in the art before the priority date. *See, e.g.*, Exs. 1020, 1021, 1025, 1030.

PO also takes issue with Dr. Heikenfeld's cross-references to other portions of his Declaration—specifically, his discussion of prior art in the context of a different challenged patent. PO ignores, however that Dr. Heikenfeld is merely discussing the prior art, and his discussion of prior art in the context of one patent applies equally to another because he is discussing *the same art*. For example, PO's criticism of Dr. Heikenfeld's "motivation to combine argument," that it comes from "a completely different patent . . . from an entirely separate proceeding," Br. at 11–12 & n.3, is unpersuasive. Motivation to combine two references is not contingent on the patent being challenged.

2. The Board's *Adaptics* Decision Is Not on Point

PO's particularity argument attempts to forge an analogy between iRhythm's petition and the petition in *Adaptics Ltd. v. Perfect Co.*, Case IPR2018-01596. In doing so, the PO repeats its fundamental error of choosing not to distinguish between references cited as background (that explain how one with ordinary skill in the art would have understood the prior art disclosures that form the grounds of unpatentability) and the prior art disclosures forming the grounds themselves. *See, Dominion Dealer Sols., LLC v. AutoAlert, Inc.*, Case IPR2014-00684, Paper 9 at 8 (PTAB Oct. 6, 2014); *Samsung*, Paper 30 at 34; *Koninklijke Philips*, 948 F.3d at 1337; *Yeda Rsch. & Dev.*, 906 F.3d at 1031; *Ariosa*, 805 F.3d at 1365. When the

background references to which PO objects are understood properly, PO's analogy to *Adaptics* fails for at least the following three reasons.

First, PO cannot analogize the background references cited in the Declaration to the distinct “catch-all ground” submitted by petitioner in *Adaptics*. The *Adaptics* petitioner included a large set of potential obviousness grounds based on various combinations, set forth as follows:

[I]f [reference 1] and [reference 2] are not anticipatory, the challenged claims are obvious over these references in combination with each other, [references 3-9] and/or [reference 10].

Adaptics, Paper 20 at 18 (PTAB Mar. 6, 2019). This bears no resemblance to the stated grounds of iRhythm's petition.

Indeed, the Board's decision in *Adaptics* explains the dramatic contrast between improper “kitchen-sink” petitions and iRhythm's petition. *Cf.* Br. at 22. The *Adaptics* Board rejected the catch-all ground recited above, noting that even for two-reference combinations, it would amount to 17 combinations. *Adaptics*, Paper 20 at 19. Thus, the ground was unreasonable as it “require[d] patent owner to address whether each and every claim limitation is taught not only by each of [reference 1] and [reference 2], but by each of these references in combination with

one or more of the other references *asserted in the proceeding.*” *Id.* at 20-21 (emphasis added).

That reasoning is inapplicable here. The general knowledge of a POSA is *not* a “reference” “asserted in the proceeding.” Nor are the background references cited in the Declaration “asserted in the proceeding” as grounds of unpatentability. Rather, they are cited to evidence Dr. Heikenfeld’s opinions on what the general knowledge of a POSA would comprise. For this reason, PO’s argument that Petitioner’s grounds reduce to an impermissible use of “or” also misses the point. *Cf.* Br. at 21-22. Nowhere, for example, does Dr. Heikenfeld or the petition argue that they “teach” a claim element. *Cf. Adaptics*, Paper 20 at 21. Rather, the prior art and publications that are *asserted* to constitute the Grounds of Unpatentability are in the Petition, including in the table that PO copied into its brief: Matsumura, Jensen, and Ozguz. *See* Br. at 6.

The fact that Dr. Heikenfeld cited material confirming his opinions as to how a POSA would understand/implement the inventions disclosed by these asserted references does not somehow transform the petition into a “kitchen-sink,” as PO argues. This is the only way for Dr. Heikenfeld to adduce “additional supporting evidence or provide any technical reasoning to support his statement[s],” as the Board *requires*. *Xerox Corp. v. Bytemark, Inc.*, Case IPR2022-00624, Paper 9 at 15

(PTAB Aug. 24, 2022) (citing, *inter alia*, 37 C.F.R. § 42.65(a); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000)).

Second, the petition and Declaration do not repeat the error of the *Adaptics* expert declaration by relying on “additional” documents (not cited as grounds) to teach limitations. The *Adaptics* Board rejected an expert declaration’s reliance on “*additional* documents relating to” the asserted prior art in the grounds—additional documents like “[reference 2] operating manual, patents, and product brochure[s].” *Adaptics*, Paper 20 at 22. There, the petitioner’s expert opined that some of these additional documents taught specific limitations. *Id.* Here, contrary to PO’s arguments, Dr. Heikenfeld makes no such assertions. He does not “rely” on the additional documents to teach limitations. Nor are the additional documents further, related disclosures of the Matsumura, Jensen, or Ozguz art. *Cf. id.* The documents merely confirm Dr. Heikenfeld’s assertions of what a POSA’s “general knowledge” is and how it bears on a reading of the prior art.

Third, contrary to PO’s argument, the “public availability” of the background references is immaterial. In *Adaptics*, the Board was confronted with dubious testimony seeking to establish that the asserted prior art was indeed relevant, and qualified prior art. *Id.* at 22-23. PO has not contested whether the asserted prior art in the Petition—Matsumura, Jensen, and Ozguz—is prior art to the ’422 patent. Nor

could it. The references are all printed patents and publications, and their prior art status is facially apparent. Exs. 1011; 1013; 1015-1017.

Predicated on its flawed *Adaptics* analogy, Petitioner's contention that the petition "shifts" a burden to PO and the Board misses the mark. The petition explains, for each ground, how the combination of references renders obvious each limitation of every challenged claim. Consistent with Federal Circuit law, the petition and Declaration elaborate how a POSA would understand the cited disclosures. Neither PO nor the Board needs to review the other references that Dr. Heikenfeld cited in his Declaration as if they were part of the invalidity grounds. *Cf.* Br. at 12-13. But should either question the certainty of his conclusions, he has provided objective corroboration for his opinions. No burden has been shifted. Rather, iRhythm and Dr. Heikenfeld have carried their burden of supplying supporting evidence and technical reasoning to support their conclusions.

3. The Recent Federal Circuit *Qualcomm* Decision Confirms That Petitioner May Appropriately Rely Upon the General Knowledge of a POSA

Finally, the recent Federal Circuit decision in *Qualcomm Inc. v. Apple Inc.* only confirms the conclusion above. *Qualcomm* is not directly on point as it involved the question of whether Applicant-Admitted Prior Art [AAPA] may be included as part of the grounds of a petition, which Petitioner did not do here. 134 F.4th 1355 (Fed. Cir. 2025). However, after first reaffirming "that the plain meaning

of § 311(b) does not permit the basis [of the petition] to include AAPA,” the Federal Circuit explicitly recognized that there are “instances in which a petition may rely in part on AAPA, *such as to indicate the general knowledge of a person of ordinary skill in the art*, without contravening § 311(b).”⁴ *Id.* at 1365 (Fed. Cir. 2025) (emphasis added) (citing *Koninklijke Philips*, 948 F.3d at 1339). In other words, the Federal Circuit (once again) confirmed the propriety of a petitioner furnishing evidence of a POSA’s General Knowledge, which is exactly what the petition and Dr. Heikenfeld’s declaration did.

B. The Petition’s Approach to Claim Construction is Proper

1. PO’s Attempt to Litigate Factual Claim Construction Issues at the Discretionary Denial Stage Should Be Rejected

As the petition repeatedly emphasized, the ’422 patent and its claims recite conventional, well-known elements in an obvious configuration. Petitioner and Dr. Heikenfeld, consistent with the standard for claim construction in IPR proceedings, reasoned that the terms of the ’422 patent’s claims did not require an express construction. Instead, they can be interpreted in terms of their “ordinary and customary meaning”—“the meaning that the term would have to a person of ordinary

⁴ In *Qualcomm*, the Federal Circuit assessed the appropriate scope of the grounds—the issue PO raises here—under 35 U.S.C. § 311(b).

skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application” in view of “the context of the entire patent, including the specification.” *Philips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The Petition’s approach comports with the Board’s Trial Practice Guide: “[A] petitioner may include a statement that claim terms require no express construction.” USPTO, Pat. Trial & Appeal Bd. Consol. Trial Prac. Guide 44 (Nov. 2019) (“TPG”).

PO, disregarding the Board’s explicit guidance to the contrary, argues that iRhythm’s petition is deficient for failure to announce implicit claim constructions. But PO’s arguments about deficiencies are substantive disputes about whether, and if so how, claim terms in the ’422 patent should be construed. There is a protocol for addressing arguments like PO’s: “The [PO] may then respond to these positions and/or propose additional terms for construction The petitioner may respond to any such new claim construction issues raised by the patent owner” TPG at 44-45. Discretionary denial briefing is not the appropriate forum to resolve such disputes, and PO’s arguments should be rejected.

2. Regardless, iRhythm’s Petition Does Not “Implicitly Construe” Claims

PO conjectures that “at least three separate terms, found in all independent claims of the ’422 Patent . . . *appear to be* implicitly construed in Petitioner’s expert declaration and incorporated by reference into the Petition.” Br. at 14 (emphasis

added). However, PO fails to define “implicit construction,” distinguish it from the “ordinary and customary meaning of a claim term,” or explain any way in which Petitioner has misidentified the ordinary and customary meaning. *Philips*, 415 F.3d at 1313.

The Federal Circuit has used the phrase “implicit claim construction” where an invalidity (or infringement) analysis turns on a **limiting** construction—one that would **exclude** things from the claim’s scope—that was not explicitly sought during the claim construction process. *See, e.g., Voice Tech. Corp. v. Unified Pats.*, 110 F.4th 1331, 1343 (Fed. Cir. 2024) (“Voice Tech’s arguments appear to rely on an implicit claim construction of ‘decodes’ that would exclude ‘parsing,’ ‘speech-to-text translation,’ or ‘matching,’ but Voice Tech never sought construction of the claim term ‘decodes.’”); *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049, 1056 (Fed. Cir. 2024) (Board engaged in “implicit claim construction” where it construed claim term reciting “determining . . . based at least in part on [five inputs]” to mean “no input can be based in part on another input and that each input must be distinct”); *Samsung Elecs. Co. v. UUSI, LLC*, 775 F. App’x 692, 696 (Fed. Cir. 2019) (rejecting Board’s “implicit claim construction of “selectively comprising comprises the microcontroller selective providing a signal output frequency to each row” to require “providing different frequencies to different rows of touch pads”).

For none of the four terms identified in PO’s Brief does Petitioner seek a limiting construction; nor does Dr. Heikenfeld opine that the term should be construed to limit the scope of the invention. To the contrary, and as shown below, in each example the petition and Declaration merely indicate that the disclosures are entirely consistent with the “plain and ordinary meaning.”

Claim Term	Passage from Declaration
“trace”	“[A] POSA would have understood that the Ag/AgCl coating taught by Matsumura would have been screen printed onto the conductive material 2 to form traces” Ex. 1009 ¶ 1387 (cited in Ex. 1009 ¶ 1398).
“housing”	“Matsumura teaches that ‘reusable signal processor 10’ is enclosed in a housing 10c which can be ‘easily attached and detached’ to bioelectrode pad 7.” Ex. 1009 ¶ 1408.
“disposed in the housing”	“[Matsumura’s] processing circuit (the claimed processor) is disposed within the housing 10c of the signal processor 10.” Ex. 1009 ¶ 1412.

Petitioner has not sought “implicit constructions” of the claim terms. Its approach is consistent with the TPG and Federal Circuit Precedent, and therefore entirely appropriate.

Regarding the terms “a housing” and “a processor disposed in a housing,” PO’s arguments illustrate the error of its position. Br. at 17. PO maintains that Petitioner “construes ‘disposed in the housing’ so broadly that it includes anything that merely touches, rests atop, or is in physical contact with another component.”

Id. In other words, PO is seeking an (undisclosed), limiting construction of “housing” and “disposed in the housing.” The TPG provides clear guidance on how PO can do this: identify these claim terms together with its claim construction proposals in its preliminary response. The discretionary denial brief is not an appropriate place for that determination.

PO's cited Board decisions are not only distinguishable; in many cases, they confirm that Petitioner's approach in the petition is entirely appropriate.

For example, in *ams*, the Board observed that an explicit construction is ***not*** necessary: “Petitioner does not provide an explicit claim construction and ***does not show (or assert) that claim 1 in light of the '096 patent Specification provides a plain and ordinary or implicit meaning*** for ‘minimal height.’” *ams AG v. 511 Innovations, Inc.*, Case IPR2016-01792, Paper 15 at 13 (PTAB Mar. 16, 2017) (emphasis added). Dr. Heikenfeld's declaration does exactly what the Board in *ams* asked; it ***shows*** how each of those terms has a plain and ordinary meaning ***in view of the claims and specification***. Nothing more is needed.

In *Vicor*, the Petitioner relied on an explicit construction advanced by the Patent Owner in district court litigation. The Petitioner conceded that the claim construction was not correct, and offered no evidence to suggest why this interpretation was appropriate. The Board rightfully declined to institute an IPR

predicated on a known, incorrect construction. *Vicor Corp. v. Delta Elecs., Inc.*, Case IPR2024-00704, Paper 11 at 8-9 (PTAB Oct. 2, 2024).

InfoBionic is especially inapposite because, in that case, Petitioner sought an ***express construction*** of the term “subset” based on a general dictionary definition. *See InfoBionic, Inc. v. Braemer Mfg., LLC*, Case IPR2015-01704, Paper 11 at 5 (PTAB Feb. 16, 2016). The PTAB found unpersuasive expert testimony that parroted extrinsic evidence in support of this express construction. *Id.* at 6. Petitioner did not seek explicit constructions for the terms of the '422 patent. And Dr. Heikenfeld's expert testimony does not “parrot” extrinsic evidence; it cites passages from the specification that demonstrate that the patent itself provides a plain and ordinary meaning for the claim terms.

Unaided by the case law it cites, and unmoored from well-settled principles of claim construction, PO's claim construction-based arguments should also be rejected.

C. The Petition's Reliance on Expert Testimony Is Not a Sound Basis for Discretionary Denial

In addressing the Guidance's fourth factor, “[t]he extent of the petition's reliance on expert testimony,” PO for the most part rehashes its arguments about the Board's precedent and the TPG, arguing that this forms an independent basis for

denial. Br. at 19-26. In doing so, PO's argument conflates the ***volume*** of expert testimony with the ***extent of reliance***.

As explained above, the portion of the Declaration pertinent to this IPR is 557 paragraphs and 166 pages in length. Ex. 1009. It is that long by necessity; it challenges 18 claims (two of which are independent claims, each with over seven limitations) across three grounds. The figures that PO cites in its brief are hyperbolic: they refer to the totality of the Declaration, which supports ***five IPR petitions***, challenging ***four patents***, and ***72 claims***.

Separating substantive reliance from volume illustrates the folly of PO's argument: as explained above, each ground recites the "General Knowledge of a POSA" to explain further how a POSA would understand the disclosure of the prior art in relation to a handful of limitations in independent claims. PO is correct that the general knowledge of a POSA is essential to each of the grounds in the petition—as it is for ***every obviousness analysis***. Compare *Koninklijke Philips*, 948 F.3d at 1337, with Br. at 20-21. However, PO's vague intimation that the POSA's general knowledge is supplying limitations—or else being used improperly in the Petition—is wrong for all of the reasons discussed in Section IV.A. Cf. Br. at 26 (complaining that PO cannot discern "limitations [the] General Knowledge purportedly teaches").

PO's self-inflicted confusion about the grounds is incoherent in view of the explicit wording of the Petition. For example, with respect to Ground 1, claim 1,

Petitioner identifies two claim limitations that are *obvious in view of Matsumura*. Paper 1 at 16 (“Matsumura renders obvious . . .”) (limitation 1b), 18 (“Matsumura renders this limitation obvious . . .”) (limitation 1d). Limitations that are explicitly taught by Matsumura are prefaced with the phrase “Matsumura discloses.” *E.g., id.* at 15, 17, 19. Other references to a POSA’s understanding merely provide background knowledge or else confirm that a cited reference discloses what Petitioner argues it does. Thus, PO’s claim that “seven of the eight elements in Claim 1 . . . are allegedly disclosed by what a ‘POSA would understand’” is demonstrably false. *Cf. Br.* at 23. So are its other hyperbolic assertions about “reliance” on the POSA’s knowledge.

PO also maintains that the Declaration is nothing more than “conclusory statements and unspecific expert testimony.” *Id.* As explained in Sections II and IV.A-B, above, the Declaration does exactly what the Board requires: it shows Dr. Heikenfeld’s work, rather than relying on vague recitations. *See Xerox*, Paper 9 at 15. Dr. Heikenfeld’s expert testimony complies with the Board’s precedents, PTO regulations, and the TPG. It is, as such, permissible.

Once again, PO deems incorporation by reference “overly burdensome,” *Br.* at 20, and raises the specter of improper incorporation by explaining that certain incorporated passages come from “completely different patent[s]” or “entirely separate proceeding[s],” *id.* at 25 n.5. PO fails to mention that *all of the material*,

including the incorporated portions, are found in a *single, consolidated Declaration*.

The Declaration does not create an undue burden.

D. PO's Concern with Non-Prior Art and "Ancient" Documents is Misplaced

PO's Brief also reasons that alleged reliance on "non-prior art documents" and "ancient references" is a consideration bearing on the Director's discretion. Br. at 26-29. Once again, these arguments are predicated on misinterpretations of *how* documents are used in the petition and should not be accorded any weight by the Director or the Board. There is also no indication that such considerations have ever been cited as a reason for exercising discretion to deny institution.

As explained above in Section IV.A, the references identified by PO (1) establish useful background by way of the history of a field; (2) corroborate a representation of a law of nature (*e.g.*, a principle of electrical conduction); or (3) corroborate a representation about the state of the art in a particular field of invention. Contrary to PO's argument, there is no need "to distinguish" by date "which references qualify as valid art for the state-of-the-art determination." Br. at 27.

Indeed, "non-prior art evidence of what was known . . . can be relied on for their proper supporting roles, *e.g.*, indicating the level of ordinary skill in the art, what certain terms would mean to one with ordinary skill in the art, and how one

with ordinary skill in the art would have understood a prior art disclosure.” *Dominion Dealer Sols.*, Paper 9 at 8 (instituting petition); *see also Yeda Rsch. & Dev.*, 906 F.3d at 1041-42 (Fed. Cir. 2018) (affirming propriety of reliance on non-prior art to support and explain opinion re POSA’s understanding).

Moreover, PO’s contention that Ex. 1035 (which, again, is *not* a grounds reference) was not publicly available in 2006 is unfounded. *See, e.g.*, Br. at 1-2, 6, 8. This reference, a textbook titled “Printed Circuit Boards: Design, Fabrication, and Assembly” was first published by McGraw-Hill on September 7, 2005, Ex. 1067, and the excerpts provided by Petitioner clearly show a 2006 copyright notice, Ex. 1035 at 1. PO provides no basis for its vague allegations to the contrary.

PO’s argument about reliance on “ancient” documents similarly misses the mark. *See* Br. at 28-29. The purportedly ancient documents are cited to establish laws of nature and perennial issues in the field of invention. PO’s particular concern with the relevance of a claim in an “ancient document”—*e.g.*, that “cleaning medical devices” was a concern—to the state of the art in 2006 is an empirical question. *See id.* That is, it is a ***factual issue*** that PO has not meaningfully disputed, and that the Board cannot resolve at this time.

E. The Settled Expectations of the Parties, If Any, Do Not Warrant Discretionary Denial

Finally, referring back to the Guidance, PO argues that “[d]espite knowing of the ’007 Patent and its related family members for over a decade, Petitioner did nothing, creating an expectation between the parties.” Br. at 30; *see also* Guidance at 2. In other words, PO reasons that, even if the ’422 patent and its family members are invalid, iRhythm has no business challenging it because the family has existed for so long.

PO cites no case law in support of its “expectations” theory. But even without direct precedent, the argument fails as a matter of common sense. After its founding in 2006, Petitioner received FDA clearance for its accused Zio® devices in July 2012 (Zio® XT), June 2017 (Zio® AT), and May 2021 (Zio® Next-Generation), respectively. Yet, PO did not assert any claims of the ’422 patent (or other members of the ’007 Patent Family), or threaten such assertion, until 2024. If anything, the “settled” expectation was that the ’422 patent had nothing to do with petitioner’s products, and Petitioner did not need to expend resources in contesting an invalid patent. Nor could Petitioner have anticipated that PO would repeatedly file continuations to procure invalid patents and expand the ’007 patent’s problematic claims far beyond their original scope. The argument that iRhythm could have—let

alone *did*—tacitly acquiesce to the validity or enforceability of the '007 patent by omission strains credulity and should be rejected.

If PO at one point had any valid claim of infringement (it has not and still does not), it sat on its rights: It is PO's inaction that created a settled expectation that iRhythm would be able to continue to market and sell its devices and that the public would be able to obtain iRhythm's cardiac monitors. Accordingly, this factor is equivocal at best.

F. The *Fintiv* Analysis Does Not Counsel Toward Discretionary Denial

Under the Guidance, the factors enumerated in the Board's precedential *Fintiv* decision are not conclusive, but part of "all relevant considerations" that the Director and Board may weigh in adjudicating a request for discretionary denial. Guidance at 2. PO argues that the *Fintiv* factors weigh in favor of a discretionary denial. As explained below, however, PO's *Fintiv* analysis fails to address all relevant considerations. In particular, taking account of the details of the pending District Court litigation (including the likelihood of a post-institution stay), the progress of discovery, and the "other circumstances" enumerated above (relevant to Factor 6), the *Fintiv* analysis does not favor discretionary denial; it is—at best—neutral.

1. Factor 1: District Court Stay

PO argues that the first *Fintiv* factor is neutral or militates in favor of denial because Petitioner has not sought a stay. Br. at 32; *see also Fintiv*, Paper 11. PO's argument fails to address the stay practices of the district court judge presiding over the parties' dispute.

Judge Noreika has, in previous litigations, issued a stay where IPR has been instituted on the majority of patents in suit. *See, e.g.,* Ex. 1068 (*Nuance Commc 'ns, Inc. v. MModal, LLC*, C.A. No. 17-1484 (MN) (D. Del.), D.I. 226 at 25-30 (granting stay pending IPR of five of six asserted patents)); Ex. 1069 (*MQ Gaming, LLC v. Lego Sys., Inc.*, C.A. No. 19-00905 (MN) (D. Del.), Minute Entry (Mar. 17, 2021) (granting motion to stay following instituted IPR for five of eight patents); 1070 (*MQ Gaming*, D.I. 145 (Motion to Stay)). Docket Navigator® statistics show that Judge Noreika has granted post-institution motions to stay pending IPR in a majority of cases where the issue was presented. The only exceptions included situations where a Final Written Decision issued before she ruled on the motion to stay or where only a subset of the asserted patents were subject to an IPR institution. Thus, and contrary to PO's assertion, evidence shows that a stay is likely to be granted if an IPR proceeding is instituted.

Petitioner will submit a motion for a stay forthwith if its IPR petitions are instituted. It has not yet done so based on the district court judge's policies, but it

has already alerted the district court judge of its intent to file a stay if the petitions are instituted and the district court judge has included this point in the scheduling order for the case.

In view of these considerations, the first *Fintiv* factor does not weigh in favor of denial.

2. Factor 2: Proximity of Trial Date to Board's Statutory Deadline for Final Written Decision

PO contends that Factor 2 is neutral. Petitioner submits that this factor militates *against* a discretionary denial because institution stands to substantially reduce the unnecessary expenditure of resources. Trial is scheduled for March 2027, fully six months after the projected statutory deadline. *See* Ex. 1071. Even in the absence of a stay (*see supra*), the Board's decision would precede the close of expert discovery, case dispositive motions, the preparation of the pretrial order, and trial itself. A Board decision finding some or all claims of the '422 patent unpatentable would lessen the burden on the parties and the court, simplify the litigation, and avoid unnecessary expenditure of resources.

Further, and as emphasized above with respect to Factor 1, a stay is likely if the IPR petitions are instituted. Issuing a stay in the midst of fact discovery would result in even greater burden reduction for the parties and the court.

3. Factor 3: Investment in the Parallel Proceeding by the Court and the Parties

PO argues that this factor favors denial because of Petitioner's purported "decision to escalate the discovery efforts in the case." Br. at 33. Not so—it weighs against discretionary denial. The volume of discovery has been minimal to date and the parties' responses have been largely preliminary—both in terms of document production and in terms of written discovery responses. Instead, pursuant to the Scheduling Order, Petitioner has produced core technical documents and PO has only produced IPR exhibits, prosecution records, limited records of licenses, and photographs of the accused devices. No ESI search terms have been negotiated and PO has produced only a limited set of documents responsive to the first round of discovery requests.

PO specifically asserts that "by the time the institution decision is due, substantial completion of fact discovery will be less than three-months away." *Id.* It is unclear why PO emphasizes the document production deadline, as the ultimate close of fact discovery is not until mid-January 2026, about five months after the institution deadline. And, further, the parties' substantive claim construction briefing will be yet to begin due to Judge Noreika's practice of conducting claim construction between fact and expert discovery. But even on its face, PO's argument

is unpersuasive: if the Petitioner were to obtain a stay following institution, this would halt discovery long before all of these deadlines.

PO also fails to mention that the district court has not “issued substantive orders related to the patent,” such as a preliminary injunction or a claim construction order. *Fintiv*, Paper 20 at 9-10. Nor does PO contest that Petitioner “acted diligently,” preparing five IPR petitions in parallel and submitting them well before the statutory deadline. *Id.* at 11.

For these reasons, the third factor weighs against a discretionary denial.

4. Factor 4: Overlap of Issues Raised in the Petition and the Parallel Proceeding

Petitioner has not filed a *Sotera* stipulation in the pending district court litigation. At the same time, Petitioner understands that estoppel precludes its ability to submit overlapping grounds of invalidity, which is why it intends to, and has told the District Court that it will, seek a stay.

As such “concerns of inefficiency and the possibility of conflicting decisions” are limited in this case by the combination of IPR estoppel and a high likelihood of a stay being issued upon institution. Thus, while this factor favors discretionary denial, Petitioner submits that it should be entitled to only slight weight.

5. Factor 5: Identity of Petitioner and District Court Defendant

Petitioner is the defendant in the pending district court litigation. But as noted above, a district court stay is likely if the co-pending petitions are instituted. *Fintiv*, Paper 20 at 16. Petitioner acknowledges that this factor weighs slightly in favor of discretionary denial.

6. Factor 6: Other Circumstances

As explained above in Section III, several other circumstances favor institution, and Petitioner submits that such considerations also weigh in the Board's *Fintiv* analysis. *See Fintiv*, Paper 20 at 14.

V. Conclusion

For the foregoing reasons, Petitioner respectfully submits that the Board should deny the request for discretionary denial of institution.

* * *

Dated: May 19, 2025

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**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION**

Pursuant to 37 C.F.R. §42.24(b) *et seq*, the undersigned certifies that this **Response To Patent Owner's Request For Discretionary Denial** complies with the 14,000-word type-volume limitation. The Response contains 8,404 words, excluding the parts of the Response exempted from the type-volume limitation.

Dated: May 19, 2025

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CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. § 42.6, the undersigned certifies that on May 12, 2025, I caused a true and correct copy of the foregoing PETITIONER'S RESPONSE TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL and related Exhibits 1067 through 1071 to be served electronically on Petitioner's lead and backup counsel at the following addresses:

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