

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MIM SOFTWARE INC.,
Petitioner,

v.

PROGENICS PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00726
U.S. Patent No. 11,894,141

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. ARGUMENT	4
A. The Fintiv factors, as well as the Director’s “Interim Processes for PTAB Workload Management,” recommend denying institution	4
1. The District Court Litigation already involves the same parties, technologies, products, and issues	6
2. The Fintiv factors weigh heavily against institution.....	9
3. The factors that the Director cited in her March 26 Memorandum also weigh heavily against institution	13
B. The Board should deny institution as to all grounds under 35 U.S.C	15
1. The Petition presents the same or substantially the same art that the Examiner already considered.....	16
2. The Petition fails to show that the Examiner materially erred.....	20
C. Institution should be denied as to all Petitioner’s proposed grounds because the Petition fails to meet the particularity requirements of 35 U.S.C.....	23
1. The Petition’s many alternative obviousness combinations are ambiguous and lack particularity	24
2. The Petition’s particularity problems are exacerbated by its overreliance on overlapping grounds and internal cross-references.....	32
3. The Petition improperly incorporates the expert declaration by reference	36
III. CONCLUSION.....	41

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Adaptics Ltd. v. Perfect Co.</i> , IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019)	26
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	<i>passim</i>
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	<i>passim</i>
<i>Apple Inc. v. Gesture Tech. Partners, LLC</i> , 129 F.4th 1367 (Fed. Cir. 2025)	24
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	17
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014).....	25, 33, 41
<i>Cisco Sys., Inc. v. Video Sols. Pte. Ltd.</i> , IPR2024-00695, Paper 10 (PTAB Sept. 5, 2024).....	10
<i>ClearH2O, Inc. v. Ceva Animal Health Inc.</i> , IPR2020-00039, Paper 21 (PTAB Mar. 18, 2020)	21
<i>Corephotonics, Ltd. v. Apple Inc.</i> , 84 F.4th 990 (Fed. Cir. 2023)	28
<i>Ecto World, LLC v. Rai Strategic Holdings</i> , IPR2024-01280, Paper 13 (PTAB May 19, 2025)	19, 20, 23
<i>Eiko Global, LLC v. Blackbird Tech LLC D/B/A Blackbird Techs.</i> , IPR2017-00980, Paper 16 (PTAB Sept. 1, 2017).....	42
<i>Elite Performance Footwear, LLC v. Reebok Int’l Ltd.</i> , IPR2017-01680, Paper 38 (PTAB Jan. 9, 2019)	27

<i>Fidelity Nat'l Info. Serv., Inc. v. Datatransury Corp.,</i> IPR2014-00491, Paper 9 (PTAB Aug. 13, 2014).....	41
<i>Google LLC v. Valtrus Innovations Ltd.,</i> IPR2022-01197, Paper 18 (PTAB June 13, 2023)	19
<i>Harmonic Inc. v. Avid Tech., Inc.,</i> 815 F.3d 1356 (Fed. Cir. 2016)	37
<i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.,</i> 821 F.3d 1359 (Fed. Cir. 2016)	24, 38
<i>Ivantis, Inc. v. Sight Scis., Inc.,</i> IPR2022-01530, Paper 14 (PTAB Mar. 27, 2023)	20
<i>Microsoft Corp. v. FG SRC, LLC,</i> 860 Fed. App'x 708 (Fed. Cir. 2021)	28
<i>Microsoft Corp. v. Koninklijke Philips N.V.,</i> IPR2018-00279, Paper 11 (PTAB June 8, 2018)	19
<i>Nearmap US, Inc. v. Pictometry Int'l Corp.,</i> IPR2024-00729, Paper 9 (PTAB Oct. 10, 2024).....	27
<i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC,</i> IPR2025-00037, Paper 14 (PTAB Apr. 25, 2025)	10, 11, 12
<i>Parus Holdings, Inc. v. Google LLC,</i> 70 F.4th 1365 (Fed. Cir. 2023)	40
<i>Progenics Pharmaceuticals v. MIM Software Inc.,</i> Civil Action No. 1:24-cv-10437-PBS.....	<i>passim</i>
<i>Shenzhen Jimuyida Tech. Co., Ltd, v. Artec Europe S.A.R.L.,</i> IPR2023-01148, Paper 6 (PTAB Jan. 16, 2024)	33
<i>Skechers U.S.A., Inc. v. Nike, Inc.,</i> IPR2025-00141, Paper 20 (PTAB June 3, 2025)	17
<i>Supercell OY v. Gree, Inc.,</i> IPR2021-00500, Paper 7 (PTAB Aug. 16, 2021).....	37

<i>Therabody, Inc. v. Hyperice IP Subco, LLC</i> , PGR2024-00053, Paper 8 (PTAB Apr. 21, 2025).....	10
<i>Valeo N. Am., Inc. v. Magna Elecs., Inc.</i> , IPR2014-01206, Paper 13 (PTAB Dec. 23, 2014)	37
<i>Zetec, Inc. v. Westinghouse Elec. Co., LLC</i> , IPR2014-00384, Paper 10 (PTAB July 23, 2014)	27, 28

Statutes

35 U.S.C. § 101	7, 8
35 U.S.C. § 312(a)	3, 4, 24
35 U.S.C. § 314	5
35 U.S.C. § 315	8
35 U.S.C. § 325(d)	<i>passim</i>

Other Authorities

37 C.F.R. § 42.6(a)(3)	37, 38, 40, 41
37 C.F.R. § 42.104(b)(4)	25
Chief Judge Scott R. Boalick, <i>Guidance on USPTO's rescission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,”</i> PTAB (Mar. 24, 2025)	6, 7, 13
Consolidated Trial Practice Guide, PTAB (Nov. 2019)	25
Director Coke Morgan Stewart, <i>Interim Processes for PTAB Workload Management</i> , PTAB (Mar. 26, 2025)	4, 14, 15, 38
FAQs for Interim Processes for PTAB Workload Management, PTAB.....	38

PATENT OWNER'S EXHIBIT LIST

EXHIBIT	DESCRIPTION
EX2001	Defendant's Memorandum of Law in Support of its Motion to Stay Pending <i>Inter Partes</i> Review, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 89, Apr. 8, 2025.
EX2002	PACER Docket, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS (as of June 11, 2025).
EX2003	Defendant's Motion to Dismiss the Second Amended Complaint, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 43, June 17, 2024.
EX2004	Motion to Dismiss Hearing Transcript (excerpted pp. 1, 4-6), <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Oct. 8, 2024.
EX2005	Order Granting in Part and Denying in Part Defendant's Motion to Dismiss the Second Amended Complaint, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 72, Jan. 14, 2025.
EX2006	Motion to Stay Hearing Transcript (excerpted pp. 1, 5-6), <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, May 12, 2025.
EX2007	Order Granting in Part and Denying in Part Defendant's Motion to Stay Pending <i>Inter Partes</i> Review, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 102, May 13, 2025.
EX2008	MIM's Invalidity and Noninfringement Contentions, Civil Action No. 1:24-cv-10437-PBS.
EX2009	U.S. District Courts, Judicial Caseload Profile 2024 (D. Mass. excerpted).
EX2010	MIM's Responses & Objections to Plaintiffs' First Set of Interrogatories (excerpted pp. 1, 13-14), Civil Action No. 1:24-cv-10437-PBS.
EX2011	<i>Cancer Control Month, 2025 – The White House</i> (Apr. 3, 2025).

EXHIBIT	DESCRIPTION
EX2012	<i>NIH Strategic Plan for Data Science FY 2025-2030</i> , Nat'l Institutes of Health.
EX2013	Rowe, S.P. et al., <i>PET Imaging of Prostate-Specific Membrane Antigen in Prostate Cancer: Current State of the Art and Future Challenges</i> , Prostate Cancer & Prostatic Diseases (2016).

I. INTRODUCTION

Patent Owner Progenics Pharmaceuticals, Inc. respectfully requests that the Board discretionarily deny institution of IPR2025-00726 because instituting the Petition filed by MIM Software Inc. (“Petitioner”) would create inefficient parallel proceedings and because the Petition suffers from significant flaws that warrant denial of institution.

First, the *Fintiv* factors weigh in favor of denying institution. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 6 (PTAB Mar. 20, 2020) (precedential). All of the parties in this IPR proceeding are parties in the parallel district court case, which has been active since February 23, 2024. *Progenics Pharmaceuticals v. MIM Software Inc.*, Civil Action No. 1:24-cv-10437-PBS (“District Court Litigation”). Instituting the Petition will create inefficient parallel proceedings (with the corresponding risk of inconsistent holdings and judgments). By Petitioner’s own admission, the patents currently being litigated in the District Court Litigation present overlapping issues with the patent challenged by the Petition. *Infra*, 7. Despite the overlap, Petitioner has already set the stage for resulting inconsistencies and inefficiencies. For instance, in the Petition, Petitioner failed to offer construction for terms the Petitioner itself has argued are “central” to assessing the validity of the challenged claims in district court. EX2001, 8. Further confusion and inefficiencies would be introduced were an IPR of Patent No. 11,894,141 (“the

'141 Patent") to be instituted. Such a waste of resources can be avoided by denying institution of this proceeding and allowing the dispute to continue in the District Court Litigation, where both parties have already made substantial investments, and will make even more substantial investments in the near future (including before the Board issues an institution decision).

Second, the Petition relies primarily on the same prior art that the Examiner considered during prosecution. The Petition cites three primary art references. But during prosecution, the Examiner cited two of the Petition's three primary references, and the Patent Owner listed the third on an IDS. EX1004, 224; EX1004, 242. The Examiner discussed the prior art of record with the applicant before requesting claim amendments and then allowing the claims. EX1004, 223. The Petition briefly suggests that the Examiner could or should have combined the asserted references to find the '141 Patent obvious, but the Petition fails to explain how the Examiner made any clear and material error. Pet., 3-4. Thus, the Board should deny institution under 35 U.S.C. § 325(d), as the primary references were already considered and overcome during prosecution.

Third, the Petition's conclusory arguments fail to satisfy the particularity requirements of 35 U.S.C. § 312(a). Rather than identify "with particularity each claim challenged, the grounds on which the challenge is based, and the evidence that supports the grounds," the Petition falls back on vague and conclusory explanations

that do not map to the claim elements. *See* 35 U.S.C. § 312(a)(3). Consequently, the Petition impermissibly presents a confounding set of alternative anticipation/obviousness combinations without a clear explanation of how each combination maps to each relevant claim element.

Fourth, the Petition improperly over-relies on incorporation-by-reference to the accompanying expert declaration (EX1002). Entire claim elements are addressed only via citation to the expert declaration. Petitioner's overreliance on expert testimony is an apparent effort to present dozens of arguments while remaining within the petition word limit. As a result, no single argument for unpatentability (or even for institution) is independently compelling. Rather, the Board and Patent Owner are left to search outside of the Petition to understand Petitioner's argument. But Petitioner bears the burden to demonstrate *in its Petition* why the claims allegedly are unpatentable. Petitioner has failed to meet it.

As the Director recently emphasized, the Board has discretion to deny institution of petitions, particularly to achieve efficiency, conservation of limited resources, and fairness. *See, e.g.,* Director Coke Morgan Stewart, *Interim Processes for PTAB Workload Management*, PTAB, 2 (Mar. 26, 2025) ("March 26 Memorandum"); *Fintiv*, IPR2020-00019, Paper 11, 6 ("[T]he Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review."). Additionally, institution is only authorized when the petition

demonstrates “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314. Here, the Petition is procedurally and substantively weak; risks upsetting the settled expectations of the parties; and jeopardizes the presidential administration’s interests in promoting innovation in AI for cancer treatment. As such, the Petition should be denied.

II. ARGUMENT

A. The Fintiv factors, as well as the Director’s “Interim Processes for PTAB Workload Management,” recommend denying institution.

Instituting the Petition would not be a good use of the Board’s limited resources because the parallel District Court Litigation already involves: (a) the same parties, (b) the same technologies, (c) the same accused products, (d) the same technical issues, and even (e) some of the same invalidity references and claim construction issues. Petitioner’s invalidity contentions rely on the ’141 Patent’s specification as a prior art reference.¹ *See* EX2008, 4-6, 8-9. Institution would thus

¹ Petitioner’s invalidity contentions cite U.S. Patent Application Publication 2018/0144828 (“Baker”), which is the pre-grant publication of U.S. Patent Application No. 15/794,220 (the “’220 Application”). *See* EX2008, 4-6, 8-9. The ’141 Patent is a continuation of, and shares a common specification with, the ’220 Application.

guarantee the inefficiencies of duplicative proceedings while posing an acute risk of inconsistent judgments.

Under the Board's precedential guidance in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, the Board considers six factors in determining whether a parallel litigation would create inefficiency and risk of inconsistent judgments. Those factors recommend denying institution of the Petition. So, too, does the Director's recent directive regarding "Interim Processes for PTAB Workload Management." The Director created the new processes "to ensure that the PTAB continues to meet its statutory obligations as to *ex parte* appeals, while continuing its capacity to conduct AIA proceedings[.]" Chief Judge Scott R. Boalick, *Guidance on USPTO's rescission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,"* PTAB, 1 (Mar. 24, 2025). To that end, the Director launched the discretionary denial review stage of IPR, whereby the Director and PTAB judges can decide straightaway whether the PTAB's limited resources and "workload needs" require dedicating resources to each filed IPR petition. *Id.*, 3.

Given the significant overlap between the parallel District Court Litigation and the Petition, institution would create exactly the kind of duplicative and inefficient parallel proceedings that the Board seeks to avoid. The overlap and resulting duplication is especially poignant now, when the Board is so focused on

the efficient performance of its substantial duties and the District Court is already so steeped in the underlying issues. *See id.*

1. The District Court Litigation already involves the same parties, technologies, products, and issues.

A brief synopsis of the District Court Litigation helps clarify the overlap and inefficiency in proceeding in two fora. Patent Owner and its corporate affiliate sued Petitioner over a year ago (Feb. 23, 2024) in the United States District Court for the District of Massachusetts for infringing two patents in the District Court Litigation. EX2002, Dkt. No. 1. Patent Owner and EXINI Diagnostics AB amended the complaint on March 15, 2024, and April 5, 2024, thereby accusing Petitioner of infringing seven patents (adding the '141 Patent on March 15, 2024). *See id.*, Dkt. Nos. 14, 25.

On June 17, 2024, Petitioner moved to dismiss the District Court Litigation in full, seeking dismissal of four patents (including the '141 Patent) on Section 101 invalidity grounds and dismissal of the three remaining patents on procedural grounds. EX2003, 1. The parties submitted about a hundred pages of briefing, delving into the validity of the patents and the technical operation of the accused products. *See* EX2002, Dkt. Nos. 43-44, 48, 57, 61. The district court convened a multi-hour hearing, at which the judge stated that resolving the motion to dismiss would require substantial work for the Court to learn the technology and understand the asserted claims. EX2004, 4-6. Several months later, in a detailed, 35-page

opinion, the Court denied Petitioner’s motion as to six of the seven patents, completely denying the motion to the extent it challenged four patents (including the ’141 Patent) as invalid under 35 U.S.C. § 101. EX2005, 35.

The remainder of the case continued. 364 days after Patent Owner filed the District Court Litigation—*one day before Petitioner’s one-year deadline* to file under 35 U.S.C. § 315—Petitioner filed this Petition (“Pet.”). See EX2002, Dkt. No. 1; Pet. (Paper 1). In the Petition, Petitioner stated it planned to move to stay the District Court Litigation only “if the petitions are granted.” Pet., 75. Notwithstanding that (untrue) representation to the Board, however, Petitioner moved on April 8, 2025, to stay the District Court Litigation in full (EX2001), even though the Board had not even accorded a filing date to this Petition, let alone decided whether to grant institution. See Paper 5, 1. The district court received briefing on the motion to stay and held another hearing. EX2002, Dkt. Nos. 88-93, 97, 101, 103. At the hearing, Petitioner emphasized the “*significant overlap in the claims across all six patents,*” stating that, “*across all six patents, the issues relating to claim construction, and to a large extent infringement, are going to overlap.*” EX2006, 6 (emphasis added). The district court partially stayed the District Court Litigation, but continued the Litigation’s steady progress as to two of the asserted patents that involve the “significant[ly] overlap[ping] issues” as the patent challenged by the Petition. *Id.*; see also EX2007, 2-3. The district court ordered

Patent Owner and Petitioner to “file a joint status report within fourteen days of the PTAB’s issuance of final determinations as to any of the IPRs.” EX2007, 3.

The District Court Litigation proceeds apace. The parties have exchanged over six hundred pages of claim charts covering the parties’ contentions of infringement, non-infringement, validity, and invalidity. *See* EX1028. Petitioner’s invalidity contentions even rely on the specification of the ’141 Patent as a prior art reference. *See* EX2008, 4-6, 8-9; *supra*, n.1.

Meanwhile, the parties have produced thousands of pages of documents, exchanged claim construction proposals, conferred about those proposals in preparation for briefing, served written discovery requests, responded and objected to those requests, exchanged lengthy deficiency letters, conferred about those letters to try to resolve the disputes, negotiated search terms designed to find relevant documents, and have begun collecting, reviewing and producing documents per those search terms. Pursuant to the district court’s scheduling order, the parties will continue investing substantially in the District Court Litigation before the Board’s deadline to even decide institution. *See* EX1028, 2-3.

In light of the striking overlap between the District Court Litigation and the Petition, institution would guarantee the substantial inefficiencies of duplicative proceedings while running an acute risk of inconsistent judgments. It is no surprise,

then, that the *Fintiv* factors and the Director’s recent memorandum recommend against institution.

2. The Fintiv factors weigh heavily against institution.

The third, fourth, and fifth *Fintiv* factors—which, respectively, concern the resources already invested in the District Court Litigation (3rd), as well as the substantive overlap (4th) and the party overlap (5th) between the parallel proceedings—weigh especially heavily against institution.

As discussed above, both parties have made substantial investments in the District Court Litigation, including filing and resolving a complex motion to dismiss, exchanging initial disclosures, negotiating an entered protective order, exchanging interrogatory responses, responding and objecting to dozens of document requests, exchanging voluminous infringement and invalidity contentions, preparing and exchanging claim construction positions, and so forth. The Board has found that completing these tasks in the district court cuts against institution. *See, e.g., Therabody, Inc. v. Hyperice IP Subco, LLC*, PGR2024-00053, Paper 8, 13 (PTAB Apr. 21, 2025); *Cisco Sys., Inc. v. Video Sols. Pte. Ltd.*, IPR2024-00695, Paper 10, 12-13 (PTAB Sept. 5, 2024); *Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC*, IPR2025-00037, Paper 14, 10-12 (PTAB Apr. 25, 2025). Petitioner would now have the Board duplicate the district court’s effort, while the district court continues working on related patents.

The overlapping parties also cuts strongly in favor of denying institution. Petitioner is the defendant in the parallel District Court Litigation, and Patent Owner is one of two plaintiffs. Thus, the same parties are litigating the validity of the same patent in two fora. *See Fintiv*, IPR2020-00019, Paper 11, 6 (factor 5 concerns “whether the petitioner and the defendant in the parallel proceeding are the same party”). That strongly favors denial. *See Nokia of Am. Corp.*, IPR2025-00037, Paper 14, 13-14.

The “significant overlap” in the substantive issues across both proceedings also weighs strongly in favor of denial. EX2006, 6. As Petitioner’s quoted statements reflect, the parallel District Court litigation already involves: (a) the same parties, (b) the same technologies, (c) the same accused products (SurePlan MRT, Contour ProtégéAI, LesionID, and LesionID Pro), (d) the same technical issues, and even (e) some of the same invalidity references and claim construction issues.

Especially given the substantial progress of the District Court Litigation and the potential for overlapping expert issues and technical discovery, institution would thus risk all sorts of inefficiencies and inconsistencies. For example, Petitioner failed to provide claim constructions in the Petition that Petitioner itself told the district court case are “central.” *See* EX2001, 8. In its Memorandum in Support of its Motion to Stay the District Court Litigation, Petitioner stated that the terms “hot spot,” “machine learning,” “anatomical image,” “nuclear medicine (‘functional’)

image,” “risk index,” risk map,” and “[radiopharmaceutical] uptake,” are “central to the claims of the four challenged patents as well as the claims of the remaining two patents,” and that “[t]he parties are likely to seek construction of these terms during the *Markman* hearing.” *Id.* The terms “machine learning,” “risk index,” and “nuclear medicine image” appear in each of the independent claims (1, 24, 27, 31-35), and the term “hotspot” appears in several dependent claims (19-21), yet the Petition only proposes claim construction for one of those terms, “risk index.” Pet., 9-12. By failing to provide claim constructions in its Petition of terms the Petitioner itself considers to be “central,” ambiguity and inefficiency would be further injected into the parallel proceedings, were an IPR of the ’141 Patent to be instituted. These dynamics weigh strongly against institution, before even considering the prospect for other inconsistent judgments relating to validity and claim construction. Petitioner’s *Sotera* stipulation does not come close to eliminating this substantial overlap, nor does it neutralize the inefficiencies of concurrent proceedings or the risk of inconsistent judgments.

Other *Fintiv* factors weigh against institution, or are at least neutral. The district court’s only-partial stay means that fact and expert discovery, claim construction, and motion practice are continuing in the district court. Therefore, the partial stay does not materially “allay concerns about inefficiency and duplication of efforts.” *Fintiv*, IPR2020-00019, Paper 11, 6.

Nor does the timing of the district court trial date and the Board’s Final Written Decision (“FWD”) substantially move the needle. Although the district court has not yet set a trial date, based on the current schedule, the trial may occur around the same time as the Board’s FWD. The District Court Litigation’s schedule has pretrial *Daubert* briefing concluding in early December 2026. EX1028, 3. Thus, the trial may occur at the end of 2026 or the beginning of 2027.² Because the filing date was accorded to the Petition on April 14, 2025, any FWD may not arrive until Q4 2026. Even if the FWD were to precede the district court trials, both proceedings will be moving deep into their respective schedules, increasing the chances of

² Based on the median time to trial for a District of Massachusetts civil litigation (33.5 months as of Dec. 2024), the trial in the District Court Litigation would occur in Q4 2026. *See* EX2009. Thus, using the median time to trial, the FWD and trial would likely occur at the same time. *See* Chief Judge Scott R. Boalick, *Guidance on USPTO’s rescission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,”* USPTO, 3 (Mar. 24, 2025) (“[I]n applying *Fintiv*, the Board may consider any evidence that the parties make of record that bears on the proximity of the district court’s trial date . . . including median time-to-trial statistics for civil actions in the district court in which the parallel litigation resides.”).

conflicting decisions and wasted resources. That risk of inconsistent judgments and duplicative trial proceedings weighs especially strongly against institution in this context.

3. The factors that the Director cited in her March 26 Memorandum also weigh heavily against institution.

Finally, several additional factors weigh against institution, including three factors listed in the Director’s March 26 Memorandum, such as “[t]he strength of the unpatentability challenge,” “[s]ettled expectations of the parties, such as the length of time the claims have been in force,” and “[c]ompelling economic, public health, or national security interests.” March 26 Memorandum, 2.

The Petition should be denied because it is particularly weak in its arguments for unpatentability. *See id.* As discussed further below, the Petition is rife with conclusory assertions, fails to argue with particularity, and over-relies on the expert declaration and internal cross-referencing. Section II(C), *infra*. The Petition is decidedly not the kind of strong unpatentability challenge that supports institution. *See* March 26 Memorandum, 2.

A compelling public health interest also counsels for denying institution. *See* March 26 Memorandum, 2. The ’141 Patent claims novel systems and methods that save lives and improve cancer care. The claims of the ’141 Patent encompass tools that assist radiologists and oncologists in assessing lesions on PET/CT scans using machine learning. Several dependent claims are tailored to prostate cancer, which

is a key target for public health initiatives. These tools enable more reproducible, accurate, and scalable interpretations of complex scans, and they reduce inter-reader variability, optimize treatment selection, and facilitate earlier intervention—all of which improve clinical outcomes.

The claimed technology also aligns closely with other presidential public health priorities, like Cancer Control Month’s focus on “emerging technologies like artificial intelligence to support cutting edge research . . . that will improve the lives of cancer patients.” *See* EX2011, 2. Similarly, the National Institutes of Health have prioritized AI-enabled diagnostics and decision-support systems for cancer in recent grant solicitations and strategic plans. *See* EX2012, 16-17.

Against such presidential concerns, instituting the Petition risks chilling innovation in a field that is both capital-intensive and lifesaving. Patent certainty is especially important in areas subject to FDA regulation, where innovators must make long-term investments in software validation, compliance, and clinical integration. Patent Owner respectfully submits that the Board should not disrupt patent rights that support such important public health tools, particularly where the Petition presents no compelling new rationale for doing so. Thus, the presence of compelling public health interests further supports discretionary denial. *See* March 26 Memorandum, 2.

B. The Board should deny institution as to all grounds under 35 U.S.C. § 325(d).

The Board should deny institution under 35 U.S.C. § 325(d) because (a) every ground of the Petition is based on the same prior art that was presented to the Office, considered, and overcome during prosecution, and (b) the Petition fails to show that the Examiner made any material error.

Section 325(d) provides that the Board may reject a petition if, as is the case in this Petition, “the same or substantially the same prior art or arguments previously were presented to the Office.” Per *Advanced Bionics*, the Board applies a two-step test when deciding whether to deny institution pursuant to Section 325(d): First, the Board determines whether the Petition presents the same or substantially the same art (or arguments) previously presented to the Office. If so, the Board then asks whether the Petition demonstrates that the Office materially erred in its consideration of that same art. If the Petition fails to show a material error, the Board defers to the earlier examination and denies institution. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8-9 (PTAB Feb. 13, 2020) (precedential). As the Board emphasizes, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred.” *Id.*, 9. Section 325(d) reflects a strong “commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* When applying the two-part *Advanced Bionics* test, the Board also

considers the non-exclusive *Becton, Dickinson* factors, which assist in the evaluation of whether the same or substantially the same prior art or arguments were previously presented to the Office. *Advanced Bionics*, IPR2019-01469, Paper 6, 7; *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (PTAB Dec. 15, 2017).

1. **The Petition presents the same or substantially the same art that the Examiner already considered.**

The Examiner undisputedly cited the Petition’s primary references (Maier and Huang) during prosecution of the ’141 Patent. EX1004, 224. Patent Owner also undisputedly cited the Petition’s third main reference (Armor) in an IDS submitted to the Office. *See* EX1004, 179. Petitioner acknowledges these gating facts as true. Pet., 3-4.

In particular, Patent Owner listed Armor on the IDS filed on January 10, 2023. *See* EX1004, 179. On September 19, 2023, the Examiner also signed the IDS, noting at the bottom that “ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.H.A./.” The Examiner did not line through the Armor reference. EX1004, 242. *See Skechers U.S.A., Inc. v. Nike, Inc.*, IPR2025-00141, Paper 20, 13 (PTAB June 3, 2025) (holding first step of *Advanced Bionics* test satisfied where the reference “was cited on an IDS by the applicant, and the Examiner indicated that all references were considered”). The Examiner himself identified Maier and Huang and included them in his list of six references on his “Notice of References Cited.”

EX1004, 224. On September 18, 2023, per the Examiner’s interview summary, the Examiner conducted “a telephone interview, which was initiated by the examiner with applicant’s representative,” and “Examiner suggested ways to clarify the independent claim or amend the claim that may overcome **the prior art of record** and requested a Terminal Disclaimer, and agreement was reached.” EX1004, 223 (emphasis added). In granting the claim, the Examiner stated: “Based on telephone on September 18, 2023, with respect to cancellation of claims 3-10, 15, 17-18, 22-39, 43-44, 46-49, 52, and amended claims 1, 19, 40, 45, 55, 59, 67 and new claims 68-71, also **review of prior art of record**, all have been fully considered and are persuasive.” EX1004, 286 (emphasis added). The Examiner thus allowed the claims after considering Maier, Huang, and Armor, and requesting amendments to the independent claims to overcome the art. Therefore, the Petition runs afoul of the first prong of the *Advanced Bionics* framework because the Petition presents “the same or substantially the same prior art” previously presented to the Office.

Petitioner tries to evade this inevitable conclusion by suggesting that the Examiner did not “properly consider” Maier, Huang, or Armor because he did not expressly write about them during prosecution. *See* Pet., 3-4. First, Petitioner is incorrect. The Examiner did indeed write about them during prosecution. Maier and Huang (which form the core of the Petition’s challenges) were identified and cited by the Examiner himself and appear on the short list of *six* references cited by

the Examiner (PTO-892) and, moreover, the Examiner’s interview summary states, that he had discussed the “prior art of record” with Patent Owner’s counsel. *See* EX1004, 224; EX1004, 223. That the Examiner did not indulge in a lengthy written discussion about those references does not change the fact that the art was indisputably “presented to the Office” (and indeed, presented *by* the Office) per the plain language of Section 325(d).

But even if the Examiner did not write about the references at all, Petitioner’s argument fails. The statute and the Board are clear that art simply provided to the Office and listed in an applicant’s IDS is art “previously presented” to the Office, and is a proper basis for a Section 325(d) rejection. *See, e.g., Advanced Bionics*, IPR2019-01469, Paper 6, 7-8 (“Previously presented art includes art . . . provided to the Office by the applicant such as on an [IDS]”); *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18, 15 (PTAB June 13, 2023) (“providing a document to the Office in an [IDS] is sufficient to satisfy prong one of the *Advanced Bionics* analysis”); *Microsoft Corp. v. Koninklijke Philips N.V.*, IPR2018-00279, Paper 11, 7 (PTAB June 8, 2018) (denying institution under 325(d) where Examiner reported in the prosecution history that he had discussed with applicant “art available in the parent prosecution history”).

For example, in the Board’s recent precedential opinion in *Ecto World*, the patent applicant submitted an IDS that contained over 1,000 prior art references.

Ecto World, LLC v. Rai Strategic Holdings, IPR2024-01280, Paper 13, 4 (PTAB May 19, 2025) (precedential). Furthermore, the Examiner had requested that the applicant identify references “to which the examiner should pay particular attention,” but the applicant never responded to that request. *Id.*, 2. Here, in contrast, there is neither an overwhelming volume of references, nor a failure of the patent applicant to respond to the examiner’s inquiry about the prior art. *See id.* The facts presented in this Petition therefore provide compelling grounds for Section 325(d) denial, when compared to *Ecto World*.

Although the Petition’s four secondary references (Neumaier, Cardinale, Giesel, and Weineisen) were not presented to the Examiner, their absence does not change the step 1 analysis for at least two reasons. First, the Petition does not contend that any claim is invalid exclusively based on the secondary references; every claim depends on at least some combination of Maier, Huang, and/or Armor (all of which the Examiner considered). The Petition does not even contend that the secondary references add anything to Maier, Huang, and/or Armor that the Examiner did not consider during prosecution. Pet., 3-4. Second, the secondary references only add generic discussions of various PSMA radiopharmaceuticals, the use of which is cumulative of the disclosures in Armor and in other art cited in the IDS. *See, e.g.*, EX1004, 248 (citing EX2013); *Ivantis, Inc. v. Sight Scis., Inc.*, IPR2022-01530, Paper 14, 29 (PTAB Mar. 27, 2023) (denying institution under § 325(d)

where “[t]he asserted art is either the same as, or **cumulative** to, the prior art that Examiner has already considered during prosecution”) (emphasis added). The Petition does not plough any new ground with the secondary references. Regarding the independent claims, the secondary references do not add anything beyond the disclosure of Armor, which was cited and considered during prosecution. EX1004, 242. The Petition merely grafts the secondary references to Maier/Huang/Armor for certain dependent claims involving specific radiopharmaceuticals. Therefore, the secondary references make no difference to the ultimate analysis under Section 325(d). The Board recognizes that, “[a]lthough the examiner did not consider [these] secondary references . . . during prosecution, because Petitioner’s primary references . . . were also the primary references involved during the original examination, this factor weighs in favor of denying institution.” *ClearH2O, Inc. v. Ceva Animal Health Inc.*, IPR2020-00039, Paper 21, 25 (PTAB Mar. 18, 2020).

The Petition thus satisfies the first step of the *Advanced Bionics* framework.

2. The Petition fails to show that the Examiner materially erred.

Because the Petition relies on the same prior art that the Examiner already considered, the burden shifts to the Petitioner to demonstrate that the Examiner materially erred when it considered the art during prosecution. *Advanced Bionics*, IPR2019-01469, Paper 6, 8. Material error is a high bar. The Petition must identify specific errors by the Examiner, such as “misapprehending or overlooking specific

teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.*, 8 n.9. The Petition cannot simply identify room for reasonable disagreement with the Examiner’s reasoning. Absent clear and material error, the Board will not second-guess the Examiner. *See id.*, 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability . . . this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.”).

The Petition fails to carry its heavy burden. The Petition argues that the Examiner erred because he could or should have cobbled together the teachings of Wu and Zhao³ (i.e., the primary references cited in the Notice of Allowance but which are not asserted by the Petition) with Maier, Huang, and Armor to arrive at the claimed invention because, according to the Petitioner, those three references are “closer prior art in more (albeit not all) respects” than Wu and Zhao. Pet., 3-4. But the mere assertion that the Examiner could or should have made an obviousness rejection is insufficient to demonstrate clear material error, especially when, as here,

³ The Petition criticizes the Examiner for failing to “properly consider” the details of “Zhang.” Pet., 3-4. But Petitioner gets the reference’s name wrong. It is Zhao, not “Zhang.”

it is paired with only three sentences of cursory explanation about what Petitioner believes the Examiner should have done and without any explanation of how what the Examiner did was materially wrong. Pet., 4; *see Ecto World*, IPR2024-01280, Paper 13, 5 (holding that “a petitioner must provide an analysis” specific to step two of the *Advanced Bionics* test). Section 325(d) requires more than just mere disagreement with the Examiner’s decision. *Advanced Bionics*, IPR2019-01469, Paper 6, 10-11. The Petition thus fails to show clear error.

What is clear is that the Examiner did not find any combination of Wu and Zhao with Maier, Huang, or Armor (nor other prior art) compelling enough to reject the claims, even though the Examiner discussed and reviewed the “prior art of record” with the applicant during the course of prosecution. *See* EX1004, 223; EX1004, 286. The Examiner also closely reviewed the claims. After all, he and the applicant discussed amendments to overcome the prior art, and the Examiner ultimately required amendments to the independent claims to allow the case. EX1004, 223. Petitioner’s hindsight-driven disagreement with the Examiner’s judgment is insufficient.⁴

Therefore, the Board should deny institution under Section 325(d).

⁴ The secondary references do not change the analysis for the reasons discussed above. *Supra*, 19-20.

C. Institution should be denied as to all Petitioner’s proposed grounds because the Petition fails to meet the particularity requirements of 35 U.S.C. § 312(a)(3).

Under 35 U.S.C. § 312(a)(3), a petition must identify “with particularity each claim challenged, the grounds on which the challenge is based, and the evidence that supports the grounds.” This standard ensures that the Patent Owner and the Board have a clear, complete, and specific understanding of the Petitioner’s unpatentability theories at the institution stage. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’”) (quoting 35 U.S.C. § 312(a)(3)); *Apple Inc. v. Gesture Tech. Partners, LLC*, 129 F.4th 1367, 1375 (Fed. Cir. 2025) (“‘Ultimately, it is the petitioner’s burden to present a clear argument.’”) (citation omitted).

The Petition fails to meet the particularity standard in several ways. To start, it presents a confounding set of obviousness combinations without explaining with particularity how each of those combinations maps to the specific limitations of the challenged claims. Furthermore, to the extent the Petition addresses the proposed combinations, those explanations fail to provide a particularized explanation of how the asserted references allegedly map to the claim elements. Additionally, the Petition improperly over-relies on incorporation by reference of both the expert

declaration and internal cross-references. These defects prevent the Board from making a threshold determination of patentability under Section 314(a), and thus require denial of institution.

1. The Petition’s many alternative obviousness combinations are ambiguous and lack particularity.

The Board’s regulations require that the Petition “(1) specify sufficiently where each element of the claims is found in the applied references, and (2) include a detailed explanation of the significance of the quotations and citations from the applied references.” *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12, 11 (PTAB Aug. 29, 2014); 37 C.F.R. § 42.104(b)(4) (requiring that every petition explain with particularity “where each element of the claim is found in the prior art patents or printed publications relied upon”). Echoing these requirements, the PTAB’s Consolidated Trial Practice Guide cautions that Petitioners should “avoid submitting a repository of all the information that a judge could possibly consider, and instead focus on concise, well-organized, easy-to-follow arguments supported by readily identifiable evidence of record.” Consolidated Trial Practice Guide, PTAB, 39 (Nov. 2019), <https://www.uspto.gov/TrialPracticeGuideConsolidated> (last visited June 13, 2025).

The Petition is not “concise, well-organized,” or “easy-to-follow,” especially (but not only) for the independent claims. By presenting too many grounds, the Petition cannot—and does not—provide a sufficiently particularized explanation to

support each ground. The Board strongly disfavors petitions, like the instant Petition, that combine many references or alternative theories without clearly delineating how each one applies to each relevant element. *See, e.g., Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20, 16-18 (PTAB Mar. 6, 2019). “The statutory requirement for particularity in a petition for IPR takes on heightened importance when considered in conjunction with [the Board’s] ‘all-or-nothing’ approach” to institution, whereby “the Board is required to make ‘a binary choice—either institute review or don’t.” *Id.*, 16-17 (citing *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018)). “Because the Board’s practice . . . is to institute on all grounds asserted in a petition, the Board may consider whether a lack of particularity as to one or more of the asserted grounds justifies denial of an entire petition.” *Id.*, 17. The Board is thus especially reluctant to institute “a petition [that] contains voluminous or excessive grounds” because such petitions contain grounds unsupported by a sufficiently particularized explanation. *Id.*

This Petition is just the kind of petition that the Board disfavors. Petitioner tries to cover too much ground within its word count limit.⁵ In doing so, Petitioner

⁵ While the Petition certifies that the word count is 2 words under the limit, the Petition reaches that count by impermissible reliance on conclusory arguments and extensive incorporation-by-reference to the expert declaration (as well as extensive

provides only high-level assertions about how the prior art relates to many critical claim elements, relying on generic statements instead of detailed mapping for each limitation. Thus, “the Petition places a significant and unfair burden on the Patent Owner to respond adequately to underdeveloped arguments for numerous asserted grounds.” *Zetec, Inc. v. Westinghouse Elec. Co., LLC*, IPR2014-00384, Paper 10, 14 (PTAB July 23, 2014) (denying institution). “[U]nder these circumstances, attempting to evaluate fully the numerous grounds and underdeveloped assertions in the Petition to determine whether Petitioner has shown that it would be likely to

internal cross-referencing). *See Nearmap US, Inc. v. Pictometry Int’l Corp.*, IPR2024-00729, Paper 9, 20-21 (PTAB Oct. 10, 2024) (denying institution for failure to plead with particularity and improper incorporation by reference where “the only way to potentially understand Petitioner’s proposed unpatentability challenges is to wade through the 85,000+ words of [the expert’s] Declaration, which dwarfs the 14,000 words granted to petitioners”); *Elite Performance Footwear, LLC v. Reebok Int’l Ltd.*, IPR2017-01680, Paper 38, 33 (PTAB Jan. 9, 2019) (“[T]he Office has imposed word limits on the length of a petition requesting an IPR. To avoid self-help attempts to increase the length of the petition, our rules prohibit incorporation by reference of arguments in one document into another[.]”) (citations omitted).

prevail in any unpatentability challenge would place a significant burden on the Board and contravene the efficient administration of the Office.” *Id.*, 15; *see also Microsoft Corp. v. FG SRC, LLC*, 860 Fed. App’x 708, 713 (Fed. Cir. 2021) (“It is not the Board’s job to cobble together assertions from different sections of a petition or citations of various exhibits in order to infer every possible permutation of a petitioner’s arguments. Arguments in a petition must be made with particularity, not opacity[.]”).

The Petition repeatedly cites references and figures from the cited prior art, without specifying which portions of those references and figures render anticipated or obvious which specific elements of the challenged claims. This impermissibly leaves the Board and Patent Owner to guess at Petitioner’s case. *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1001-02 (Fed. Cir. 2023) (“The IPR petition, thus, 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.”) (citation omitted).

(i) The independent claims.

The Petition’s particularity failings are evident in the independent claims. For example, limitation (c) of claim 1 requires “**access[ing]** one or more of the medical images associated with a particular patient **from the database . . .**” (emphasis added). The Petition never identifies how the asserted references teach “access[ing]

. . . from a database.” Instead, the Petition conclusorily asserts that “Maier discloses these limitations,” and cites to Maier and an internal cross-reference without quoting either, before asserting that “[a] POSITA would recognize that Maier must access such medical images from a database,” citing to the expert declaration. Pet., 20. This conclusory explanation is insufficiently particularized.

Similar shortcomings arise for limitation (f) of claim 1. That limitation claims: “wherein the one or more medical images comprise . . . a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan.” Pet., 23. The Petition acknowledges that “Maier does not disclose this limitation,” but then asserts that Huang does. *Id.* Nowhere in its discussion of Huang, though, does the Petition expressly tie all the claimed elements in this limitation to Huang. For instance, the Petition contains no discussion of how Huang teaches “a CT scan **overlaid** with a nuclear medicine image.” *Id.*, 24 (emphasis added). Nor does the Petition link “the one or more medical images” discussed in limitation (f) to the corresponding element in limitation (d) (“automatically analyze **the one or more medical images** using a machine learning algorithm”) (emphasis added). Petitioner’s omission is critical, especially since the combination of the particular type of analysis (using a machine learning algorithm) and a particular type of image (a CT scan overlaid with a nuclear medicine image) was an element that the Examiner expressly pointed to in his reasons for allowance. EX1004, 297-98

(allowing patent claims in part because the prior art does not “teach or suggest, among other things, ‘automatically analyze the one or more medical images using a machine learning algorithm . . . wherein the one or more medical images comprise a composite image of the particular patient, the composite image comprising a CT scan ‘**overlaid**’ with a nuclear medicine image’”) (emphasis added).

Other deficiencies relate to limitation (h) of claim 1. Limitation (h) includes the element of “geographically identify[ing] a 3D boundary for each of one or more regions.” Pet., 31. The Petition says that Huang discloses creating “3D bounding boxes,” but never explains why a “3D bounding box” is a “3D boundary for each of one or more” specific tissue “regions.” Pet., 31-34. The Petition never even attempts to bridge that inferential gap.

Similar issues plague the Petition’s treatment of limitation (i) of claim 1. Limitation (i) covers “computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s), a value of each of one or more risk indices, each risk index value indicative of cancer state or progression in the patient.” EX1001, 37:36-40; Pet., 35. The Petition asserts that Maier “calculates . . . metrics related to . . . lung cancer” and that Huang “enable[s] the computer to understand which organs . . . each hot-spot is located [in].” Pet., 35-38. But the Petition does not explain with particularity how these general disclosures equate to “computing” a “risk index value indicative of cancer state or progression,” especially

where the Petition admits that Maier does not analyze composite images. Pet., 37. At most, the Petition asserts that “Huang teaches multi-modal composite imaging, including PET/CT and SPECT/CT.” *Id.* But that attenuated connection does not even begin to address the elements of the claim limitation relating to computations “using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s),” and “a value of each of one or more risk indices” where “each risk index value” is “indicative of cancer.” EX1001, 37:36-40; Pet., 35.

The Petition also fails to map the “processor” element across all limitations of claim 1. Claim 1 requires that the various steps be performed by “a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to” do various things disclosed in the ensuing limitations. EX1001, 37:9-12. For limitations (b) and onwards, the Petition never explains how a processor performs the recited steps. The Petition does not even specifically define what a processor is. Instead, the Petition provides multiple options without any explanation of how the various elements are processor(s) performing the requisite functions. Pet., 18 (“Maier discloses these limitations, which are generic recitations of structures present in any computer-implemented system like Maier’s,” and then citing Maier’s mention of a processor as “one or more processing resources such as a central processing unit (CPU)...”). Yet when the Petition cursorily walks through the remaining limitations of claim 1, the Petition

never explains how “the processor” is performing these steps, let alone which of the various processors are performing the individual steps, setting up another failure of particularity.

For independent claim 27 (“A method for tracking prostate cancer progression and treatment efficacy over time”), the Petition cites Huang’s discussion of change quantification and Armor’s general discussion of imaging prostate cancer, but does not explain how either reference (individually or in combination) satisfies the full scope of tracking progression *and* treatment efficacy *over time* in prostate cancer patients. *Id.*, 63-64. The Petition never identifies a specific disclosure that links image-derived metrics to treatment efficacy tracking, nor any specific disclosure merging Huang’s general image processing system with prostate cancer analysis.

(ii) The dependent claims.

The Petition’s particularity shortcomings also extend to the dependent claims. For example, for claim 12 (“wherein the imaging agent comprises 18F-PSMA-1007”), the Petition conclusorily references Cardinale and Giesel, with no discussion in the Petition about how the PSMA-binding agent fits with the claimed imaging and risk index computation pipeline. *Pet.*, 62-63. The Petition leaves the Board and Patent Owner to parse citations to exhibits and internal cross-references in order to try to divine the proposed claim-mapping and motivation to combine.

Therefore, as discussed above, the Petition fails to adequately map the references to the claim elements with particularity. As the Board has repeatedly held, this failure warrants denying institution. *See C-Cation Techs., LLC*, IPR2014-00454, Paper 12, 10; *Shenzhen Jimuyida Tech. Co., Ltd, v. Artec Europe S.A.R.L.*, IPR2023-01148, Paper 6, 18 (PTAB Jan. 16, 2024) (denying institution because, “[i]nstead of a meaningful element-by-element analysis with a substantive discussion and explanation of how the prior art teaches or suggests each element,” Petitioner offered claim charts “paired with conclusory statements that the reference teaches the element, followed by block quotes and/or string cites from each prior art reference”).

2. The Petition’s particularity problems are exacerbated by its overreliance on overlapping grounds and internal cross-references.

The Petition also overindulges in internal cross-referencing. Petitioner chose to assert multiple grounds that cover overlapping sets of claims with different combinations of references. Petitioner’s approach might have been fine had the Petition explained with particularity how each asserted combination covers each claim element. But that is not what the Petition does. Instead, in an effort to cram as many arguments into the Petition as possible, the Petition resorts to incorporating broad swaths of argument by internal cross-reference, even when those incorporated arguments relate to different claim limitations or even different claims.

For example, in Ground A (Maier, Huang, and Armor), Petitioner addresses claims 1-3, 6-9, 13-26, and 32-35, while in Ground B (adding Neumaier), Petitioner addresses claims 6-11. Pet., 9. The claims covered by Ground B thus overlap with the claims covered by Ground A (i.e., dependent claims 6-9, which depend from claim 1). But Petitioner’s Ground B analysis for claims 6-9 does not fully explain how Maier, Huang, and Armor meet the limitations of those claims as incorporated from claim 1. *See* Pet., 56-59. Instead, the Petition presumably expects the reader to import that explanation from Ground A based exclusively on internal cross-reference. *Id.*

This overreliance on incorporation by reference (and cross-reference) is a systemic issue throughout the Petition. Many dependent claims (e.g., claims 6-9, Pet., 42-44; claim 15, Pet., 47; claim 18, Pet., 49; claim 19, Pet., 50) receive only terse treatment with references to the expert declaration or via incorporation by reference of earlier arguments. For dependent claims 24-25 and 32-35 (Pet., 52-53; 54-56), as well as independent claim 31 (Pet., 69-70), the Petition cites internal cross-references and the expert declaration *exclusively* for the basis of the argument.

The Petition’s improper reliance on internal cross-referencing crescendos with its vague and cursory treatment of “Claims 32-35.” Pet., 54-55. This section begins with the subheading “Claims 32-35.” *Id.*, 54. It then includes a short discussion that *includes* claim 31 (which is not between “Claims 32-35”) but

excludes claim 33 (which is between “Claims 32-35”). *Id.* It is then followed by a table that excludes claim 31 and includes claim 33:

Limitation	Reasoning {referenced limitation}
[32(pre)]	<i>See</i> Section VIII.B.1.a) {[1(pre)]}
[32(a)]	<i>See</i> Section VIII.B.1.b) {[1(a)]}
[32(b)]	<i>See</i> Section VIII.B.1.c) {[1(b)]}
[32(c)]	<i>See</i> Section VIII.B.1.d) {[1(c)]}
[32(d)]	<i>See</i> Section VIII.B.1.e) {[1(d)]}
[32(e)]	<i>See</i> Section VIII.B.1.f) {[1(e)]}
[32(f)]	<i>See</i> Section VIII.B.1.g) {[1(f)]}
[32(g)]	<i>See</i> Section VIII.B.1.h) {[1(g)]}
[32(h)]	<i>See</i> Section VIII.B.1.i) {[1(h)]}
[32(i)]	<i>See</i> Section VIII.B.1.j) {[1(i)]}
[32(j)]	<i>See</i> Section VIII.B.2 {[2]}
[33(pre)]	<i>See</i> Section VIII.B.1.a) {[1(pre)]}
[33(a)]	<i>See</i> Section VIII.B.1.b) {[1(a)]}
[33(b)]	<i>See</i> Section VIII.B.1.c) {[1(b)]}
[33(c)]	<i>See</i> Section VIII.B.1.d) {[1(c)]}
[33(d)]	<i>See</i> Section VIII.B.1.e) {[1(d)]}
[33(e)]	<i>See</i> Section VIII.B.1.f) {[1(e)]}
[33(f)]	<i>See</i> Section VIII.B.1.g) {[1(f)]}
[33(g)]	<i>See</i> Section VIII.B.1.h) {[1(g)]}
[33(h)]	<i>See</i> Section VIII.B.1.i) {[1(h)]}
[33(i)]	<i>See</i> Section VIII.B.1.j) {[1(i)]}
[33(j)]	<i>See</i> Section VIII.B.8 {[13]}
[34(pre)]	<i>See</i> Sections VIII.B.1.a), VIII.B.1.b) {[1(pre)]-[1(a)]}
[34(a)]	<i>See</i> Section VIII.B.1.c) {[1(b)]}
[34(b)]	<i>See</i> Section VIII.B.1.d) {[1(c)]}
[34(c)]	<i>See</i> Section VIII.B.1.e) {[1(d)]}
[34(d)]	<i>See</i> Section VIII.B.1.f) {[1(e)]}
[34(e)]	<i>See</i> Section VIII.B.1.g) {[1(f)]}
[34(f)]	<i>See</i> Section VIII.B.1.h) {[1(g)]}
[34(g)]	<i>See</i> Section VIII.B.1.i) {[1(h)]}

[34(h)]	See Section VIII.B.1.j) {[1(i)]}
[34(i)]	See Section VIII.B.2 {[2]}
[35(pre)]	See Sections VIII.B.1.a), VIII.B.1.b) {[1(pre)]-[1(a)]}
[35(a)]	See Section VIII.B.1.c) {[1(b)]}
[35(b)]	See Section VIII.B.1.d) {[1(c)]}
[35(c)]	See Section VIII.B.1.e) {[1(d)]}
[35(d)]	See Section VIII.B.1.f) {[1(e)]}
[35(e)]	See Section VIII.B.1.g) {[1(f)]}
[35(f)]	See Section VIII.B.1.h) {[1(g)]}
[35(g)]	See Section VIII.B.1.i) {[1(h)]}
[35(h)]	See Section VIII.B.1.j) {[1(i)]}
[35(i)]	See Section VIII.B.8 {[13]}

Id., 54-55. This *forty-two* row chart, consisting exclusively of internal cross-references, is all that the Petition has to say about claims 32-35 (and perhaps claim 31, but Patent Owner is genuinely uncertain). This gambit—presumably aimed at skirting the word-limit—is improper and insufficiently particularized. Section II(C), *supra*. It also hides underlying analytical errors. When introducing the chart, the Petition asserts that “[i]ndependent claims 31-32 are system claims that are substantially identical to claim 1 except for (1) the omission of limitation [1(j)] and (2) the inclusion of the limitation of claim 2 (claim 31) or claim 13 (claim 32). Ex1002, ¶¶280, 282.” Pet., 54. But claim 31 does not include the “tracking determined values ... over time” limitation from claim 2. EX1001, 37:42-48, 40:53-41:26. And claim 32 does not include the limitation of claim 13. EX1001, 38:5-14, 41:27-67.

Petitioner’s approach of internal cross-referencing impermissibly forces the Board and Patent Owner to piece together scattered portions of the Petition (and

exhibits). Therefore, as discussed above, the Petition fails to adequately map the references to the claim elements with particularity. As the Board has repeatedly held, this warrants denying institution. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363-64 (Fed. Cir. 2016) (holding that “[s]imply stating” that prior art discloses a limitation without explanation or elaboration “does not satisfy [petitioner’s] burden”); *Valeo N. Am., Inc. v. Magna Elecs., Inc.*, IPR2014-01206, Paper 13, 15 (PTAB Dec. 23, 2014) (denying institution where Petitioner “fails to state explicitly the differences between the [prior art] and the claimed subject matter, does not explain persuasively the relevance of the evidence, and presents conclusory assertions regarding how the references are combined”); *Supercell OY v. Gree, Inc.*, IPR2021-00500, Paper 7, 12 (PTAB Aug. 16, 2021) (“Merely identifying where limitations may be found in several prior art references is not sufficient to demonstrate a reasonable likelihood of success in showing the obviousness of the claims, without articulating how and why specific teachings of the references would have been combined.”). Institution should thus be denied.

3. The Petition improperly incorporates the expert declaration by reference.

The Petition violates 37 C.F.R. § 42.6(a)(3) by incorporating by reference the expert’s arguments instead of presenting those arguments fully in the Petition. The Board could not be clearer: “Arguments must not be incorporated by reference from one document into another.” 37 C.F.R. § 42.6(a)(3); *see also Intelligent Bio-*

Systems, Inc., 821 F.3d, 1366 (petition “ran afoul of § 42.6(a)(3) by improperly incorporating by reference arguments and evidence from the expert declaration”).

The USPTO recently addressed the issue of Petitioners’ over-reliance on expert testimony, posting instructions on the USPTO website on “whether to institute inter partes reviews (IPR).” The USPTO emphasized that, “[w]hile the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony . . . may suggest that the questions are better resolved in an Article III court.” FAQs for Interim Processes for PTAB Workload Management, PTAB, Question 21, <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management> (last visited June 13, 2025); *see also* March 26 Memorandum, 3 (“the extent of the petition’s reliance on expert testimony” is a basis for denying IPR institution). In short, the Petition must be a self-contained submission of the Petitioner’s arguments and evidence, within the word limit. Petitioner cannot circumvent word limits, or avoid stating its case with particularity in the Petition, by referencing the expert declaration for a given claim element.

The Petition, however, repeatedly outsources key arguments to the expert declaration. It impermissibly incorporates by reference large portions of the expert’s analysis instead of spelling out those points in the Petition. For several claim limitations, the Petition simply cites to paragraphs of the expert’s 213-page declaration as sole support for key arguments (rather than explaining those points in

the Petition itself, as required). For example, for limitation (d) of claim 1, the Petition cites certain paragraphs of Maier and then exclusively cites paragraphs of the expert declaration for the conclusion that the cited paragraphs from Maier “constitute[] automatic analysis of the image(s) by a machine learning algorithm.” Pet., 20. The Petition does not explain why those cited portions of Maier meet the claim—it just offloads that explanation to the expert declaration.

By way of another example, for claims 6 and 12 in Ground C, the Petition asserts that the “Maier-Huang-Armor combination of claim 1, further in view of Cardinale and/or Giesel, renders obvious this claim limitation.” *Id.*, 60. But the Petition does not walk through the claim language and pinpoint in each reference the corresponding teachings—it simply assumes the reader will refer back to claim 1’s analysis for the base combination and then read the expert declaration for the rest of the explanation.

Claim 13 is another example. For the preamble, the Petition states that “the Maier-Huang-Armor combination of claim 1 renders obvious this claim limitation” and then cites the references and multiple paragraphs of the expert declaration, without any further elaboration. Pet., 44. For limitation (b), the Petition states conclusorily that “a POSITA would have recognized that risk indices such as volume fraction[], SUV peak or volume[], or T/B ratio or Gleason score are calculated based on ‘determined cancerous tissue levels,’” but then never explains why that is true

beyond a reference to the expert declaration. *Id.*, 45. Thus, Petitioner effectively outsources the actual (and required) claim mapping to the expert’s 213-page declaration.

Petitioner’s incorporation of expert argument is impermissible and warrants denial of institution.⁶ The Board generally disregards any arguments that are not made in the Petition or are not explained clearly in the relevant subsection of the Petition. Indeed, the Federal Circuit has affirmed the Board’s refusal to consider arguments incorporated by reference in a Petition, underscoring that (pursuant to 37 C.F.R. § 42.6(a)(3)) the Board need not “review evidence and issues introduced by a party in violation of its rules or not introduced at all” in the Petition. *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1372 (Fed. Cir. 2023). Incorporating arguments by reference is considered a “self-help increase in the length of the” Petition and a “pointless imposition on the [Board’s] time.” *Id.*

⁶ As noted above (*supra*, 31-32), many dependent claims (e.g., claims 6-9, Pet., 42-44; claim 15, Pet., 47; claim 18, Pet., 49; claim 19, Pet., 50) receive only cursory treatment by reference to the expert declaration or via internal cross-reference. For dependent claims 24-25 and 32-35 (Pet., 52-53; 54-56), as well as independent claim 31 (Pet., 69-70), the Petition cites internal cross-references and the expert declaration *exclusively*.

(citation omitted). The Patent Owner and the Board should not need to hunt through a 213-page, 380-paragraph expert declaration at Exhibit 1002 to understand the Petition's contentions, nor should a Petitioner be allowed to skirt page limits by shunting substantive arguments to an exhibit. *See id.*

The Petition here thus closely parallels the Petition in *Cisco Sys., Inc. v. C-Cation Techs.*, where the PTAB denied institution because the petitioner's extensive references to its expert declaration amounted to improper incorporation by reference. IPR2014-00454, Paper 12, 10-11. The Board explained that such practices "circumvent the page limits imposed on petitions" and impose an unfair burden on the Board and Patent Owner to "sift through over 250 pages of [the expert's declaration] to locate specific arguments" that should have been in the Petition. *Id.*, 10; *see also* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another."). The *C-Cation Techs.* Board refused to consider arguments that were not actually made in the Petition, and denied institution because the petition thus lacked sufficient explanation of unpatentability. *C-Cation Techs.*, IPR2014-00454, Paper 12, 13.

Similar logic led the PTAB to deny institution in *Fidelity Nat'l Info. Serv., Inc. v. Datatresury Corp.*, where the petition outsourced much analysis to the expert declaration and thus failed to contain a "full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence" as

required under 37 C.F.R. § 42.22(a)(2). IPR2014-00491, Paper 9, 8 (PTAB Aug. 13, 2014); *see also Eiko Global, LLC v. Blackbird Tech LLC D/B/A Blackbird Techs.*, IPR2017-00980, Paper 16, 23 (PTAB Sept. 1, 2017) (“Arguments that are not presented and developed in the Petition, and instead are incorporated by reference to [the expert] declaration, are not entitled to consideration.”).

Incorporating extra-Petition argument is highly prejudicial to Patent Owner, and inconsistent with the Board’s rules and due process. Patent Owner is entitled to respond to, and the Board is entitled to weigh arguments set forth in an organized and particularized manner in the Petition, not hunt for arguments buried in hundreds of pages of expert declaration. Institution should thus be denied for this reason alone.

III. CONCLUSION

For the foregoing reasons, institution should be denied.

Date: June 13, 2025

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 9,041 words based on the word count indicated by the word-processing system used to prepare the paper, excluding the table of contents, table of authorities, mandatory notices under 37 C.F.R. § 42.8, certificate of service, certificate of word count, appendix of exhibits, signature block, and claim listing.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **PATENT OWNER'S DISCRETIONARY DENIAL REQUEST** was served electronically in its entirety on June 13, 2025 via electronic mail to the following attorneys of record:

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