

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MIM SOFTWARE INC.,
Petitioner,

v.

PROGENICS PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00630
U.S. Patent No. 10,665,346

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ARGUMENT	4
A.	The <i>Fintiv</i> 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.	5
2.	The <i>Fintiv</i> factors weigh heavily against institution.....	8
3.	The factors that the Director cited in her March 26 Memorandum also weigh heavily against institution.	13
B.	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).	15
1.	The Petition’s many alternative obviousness combinations are ambiguous and lack particularity.	17
(i)	The Petition favors quantity of arguments over quality.	18
(ii)	Petitioner cannot make so many arguments and stay within the Petition’s word count limit.....	21
2.	The Petition fails to identify with particularity which portions of the asserted references map to which claim elements.	25
(i)	The independent claims.	26
(ii)	The dependent claims.	29
3.	The Petition improperly incorporates the expert declaration by reference.	32

C.	Grounds C and H should be denied because they impermissibly rely on alleged Applicant Admitted Prior Art (“AAPA”).	37
III.	CONCLUSION.....	37

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Adaptics Ltd. v. Perfect Co.</i> , IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019)	22, 24
<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)	16
<i>Arashi Vision (U.S.) LLC (D/B/A INSTA360) v. GoPro, Inc.</i> , IPR2024-01434, Paper 9 (PTAB Mar. 31, 2025)	25
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014)	17, 31, 35, 36
<i>Cisco Sys., Inc. v. Video Sols. Pte. Ltd.</i> , IPR2024-00695, Paper 10 (PTAB Sept. 5, 2024)	9
<i>Corephotonics, Ltd. v. Apple Inc.</i> , 84 F.4th 990 (Fed. Cir. 2023)	19, 25
<i>Eiko Global, LLC v. Blackbird Tech LLC D/B/A Blackbird Techs.</i> , IPR2017-00980, Paper 16 (PTAB Sept. 1, 2017)	36
<i>Elite Performance Footwear, LLC v. Reebok Int’l Ltd.</i> , IPR2017-01680, Paper 38 (PTAB Jan. 9, 2019)	23
<i>Fidelity Nat’l Info. Servs., Inc. v. Datatransury Corp.</i> , IPR2014- 00491, Paper 9 (PTAB Aug. 13, 2014)	36
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	29
<i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016)	16, 21, 32
<i>Microsoft Corp. v. FG SRC, LLC</i> , 860 Fed. App’x 708 (Fed. Cir. 2021)	24

<i>Nearmap US, Inc. v. Pictometry Int’l Corp.</i> , IPR2024-00729, Paper 9 (PTAB Oct. 10, 2024)	22
<i>Neulion, Inc. v. Filippo Costanzo</i> , IPR2014-00526, Paper 23 (PTAB Sept. 3, 2014)	24
<i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00037, Paper 14 (PTAB Apr. 25, 2025)	9, 10, 11
<i>Parus Holdings, Inc. v. Google LLC</i> , 70 F.4th 1365 (Fed. Cir. 2023)	35
<i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS	<i>passim</i>
<i>Qualcomm Inc. v. Apple Inc.</i> , 134 F.4th 1355 (Fed. Cir. 2025)	3, 37
<i>Shenzhen Jimuyida Tech. Co., Ltd, v. Artec Europe S.A.R.L.</i> , IPR2023-01148, Paper 6 (PTAB Jan. 16, 2024)	31
<i>Smaxtec Inc. v. ST Reproductive Techs., LLC</i> , IPR2024-01067, Paper 7 (PTAB Jan. 21, 2025)	21
<i>Supercell OY v. Gree, Inc.</i> , IPR2021-00500, Paper 7 (PTAB Aug. 16, 2021)	32
<i>Therabody, Inc. v. Hyperice IP Subco, LLC</i> , PGR2024-00053, Paper 8 (PTAB Apr. 21, 2025)	9
<i>Valeo N. Am., Inc. v. Magna Elecs., Inc.</i> , IPR2014-01206, Paper 13 (PTAB Dec. 23, 2014)	32
<i>Zetec, Inc. v. Westinghouse Elec. Co., LLC</i> , IPR2014-00384, Paper 10 (PTAB July 23, 2014)	23, 24
Statutes	
35 U.S.C. § 101	5, 6
35 U.S.C. § 312(a)	2, 15, 21
35 U.S.C. § 314	3

Other Authorities

37 C.F.R. § 42.6(a)(3)	32, 35, 36
37 C.F.R. § 42.22(a)(2)	36
37 C.F.R. § 42.104(b)(4)	17, 19
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)	4, 12
Consolidated Trial Practice Guide, PTAB (Nov. 2019)	17
Director Coke Morgan Stewart, <i>Interim Processes for PTAB Workload Management</i> , PTAB (Mar. 26, 2025)	3
FAQs for Interim Processes for PTAB Workload Management, PTAB	32, 33

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	Scheduling Order, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 85, Mar. 5, 2025.
EX2009	MIM's Invalidity and Noninfringement Contentions, Civil Action No. 1:24-cv-10437-PBS.
EX2010	U.S. District Courts, Judicial Caseload Profile 2024 (D. Mass. excerpted).
EX2011	MIM's Responses & Objections to Plaintiffs' First Set of Interrogatories (excerpted pp. 1, 13-14), Civil Action No. 1:24-cv-10437-PBS.

EXHIBIT	DESCRIPTION
EX2012	<i>Cancer Control Month, 2025 – The White House</i> (Apr. 3, 2025).
EX2013	<i>NIH Strategic Plan for Data Science FY 2025-2030</i> , Nat’l Institutes of Health.

I. INTRODUCTION

Patent Owner Progenics Pharmaceuticals, Inc. respectfully requests that the Board discretionarily deny institution of IPR2025-00630 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*, 6-7. 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.10,665,346 (the

“346 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’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.

Third, 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 over-reliance 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.

Fourth, certain of Petitioner's arguments rely on an incorrect legal standard. Specifically, some of the Petition's grounds rely on alleged Applicant Admitted Prior Art in a way that the Federal Circuit expressly forbade. *Qualcomm Inc. v. Apple Inc.*, 134 F.4th 1355, 1365 (Fed. Cir. 2025). Thus, institution on those grounds is inappropriate.

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*, USPTO, 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 "demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 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. Institution would thus 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 the ’346 Patent (i.e., the patent at issue here) and another patent 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. *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 ’346 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 instant ’346 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 (EX2002, Dkt. No. 88), 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* EX2008. Petitioner’s invalidity contentions rely on two of the same primary references that Petitioner asserts in the Petition (i.e., Renisch and Suehling). *See* EX2009, 4-6, 8-9. Petitioner’s invalidity contentions even rely on the specification of the ’346 Patent as a prior art reference.¹ *See id.*

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* EX2009, 4-6, 8-9. The

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* EX2008, 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

³46 Patent is a continuation of, and shares a common specification with, the '220 Application.

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. *See* EX2002. 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, 5-6. 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. Petitioner’s invalidity contentions rely on two of the same primary references that Petitioner asserts in the Petition (i.e., Renisch and Suehling), as well as the ’346 Patent’s specification as a prior art reference. *See* EX2009, 4-6, 8-9; *supra*, n.1.

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” and “risk map” appear in independent claims 1 and 13 of the ’346 Patent, yet the Petition only proposes claim construction for one of those terms, “risk map.” Pet., 9-11. 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 ’346 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. EX2008, 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 conflicting decisions and wasted resources. That risk of inconsistent judgments and duplicative trial proceedings weighs especially strongly against institution in this context.

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* EX2010. 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.”).

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: “[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. *Infra*, 15-37. The Petition is decidedly not the kind of strong unpatentability challenge that supports institution. *See* March 26 Memorandum, 2.

Additionally, the settled expectations of the parties support denying institution. The ’346 Patent issued in May 2020, and has now been “in force” for over five years. *See* EX1001, 1; March 26 Memorandum, 2. During this time, Patent Owner, its licensees, and commercial partners have invested substantial resources on the assumption that the claims are valid and enforceable. After all, the challenged claims were not granted in haste. As a result, the public (including competitors, collaborators, and the broader clinical imaging community) has known and relied upon the Patent’s scope for *over five years*. *See* March 26 Memorandum, 2.

Notably, Petitioner—a sophisticated commercial actor—waited over five years after issuance, only filing its Petition two months ago in response to an infringement suit. Petitioner’s choice to delay its challenge—including waiting until nearly the final day of the one-year statutory deadline to file the Petition—undermines any suggestion that the patent created market uncertainty. Indeed, Petitioner admits that it operated in the relevant market with full knowledge of the ’346 Patent at least as early as October 2022. *See* EX2011, 14. Yet Petitioner now seeks to disrupt settled expectations long after the patent was granted. This disruption therefore weighs against institution.

A compelling public health interest also counsels for denying institution. *See* March 26 Memorandum, 2. The ’346 Patent claims novel systems and methods that save lives and improve cancer care. The claims of the ’346 Patent encompass a system and method for generating cancer risk maps using machine learning applied to radiopharmaceutical imaging—a domain with far-reaching implications for early cancer detection, clinical decision support, and precision medicine. 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* EX2012, 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* EX2013, 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. 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 still 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.” Notably, the Petition does not present a single coherent two- or three-reference combination paired with a sustained and thorough explanation for why that ground renders the claim(s) obvious (as is more typical for petitions worthy of institution). Instead, the Petition presents a convoluted and conclusory menu of obviousness combinations involving an amalgam of references:

Ground	Prior Art	Basis	Claims Challenged
A	Renisch	§102(a)(1)/(2)	1-7, 9-10, 13
B	Renisch in view of Wu	§103	1-7, 9-10
C	Renisch, or Renisch in view of Wu, each in view of the Applicant's Admitted Prior Art ("AAPA") or D'Souza	§103	5
D	Renisch, or Renisch in view of Wu, each in view of Sprencz	§103	8
E	Renisch, or Renisch in view of Wu, each in view of Maier	§103	9-11
F	Renisch, or Renisch in view of Wu, each in view of Menon	§103	12
G	Sprencz	§102(a)(1)/(2)	1-10, 13
H	Sprencz in view of AAPA or D'Souza	§103	5
I	Sprencz in view of Maier	§103	11
J	Suehling	§102(a)(1)/(2)	1-10, 13
K	Suehling in view of Maier	§103	11
L	Suehling in view of Menon	§103	12

Pet., 8.³ By presenting so many alternative combinations in a single petition, the Petition fails to meet its burden for at least three reasons.

(i) The Petition favors quantity of arguments over quality.

First, the Petition's anticipation and obviousness arguments are so sprawling that it is impossible to understand which precise sub-combinations apply to which precise elements—let alone to understand “where” the Petition believes “each element of the claim is found in the prior art patents or printed publications relied

³ Although the Petition lists Grounds A through L (12 lettered grounds), several of the grounds appear to present alternative combinations, resulting in a higher count of total presented grounds.

upon.” 37 C.F.R. § 42.104(b)(4). The Board is clear that a Petition cannot leave the Patent Owner and the Board to guess at which potential sub-combination applies to each element. *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1001-02 (Fed. Cir. 2023). Yet that is exactly what the Petition does.

For example, the Petition asserts that claim 5 is anticipated or rendered obvious by six different grounds (A, B, C, G, H, and J). Pet., 8. But lurking within those six grounds is a convoluted constellation of potential sub-combinations. With Ground C, for example, the Petition suggests that Renisch anticipates, but if not, then Renisch in view of Wu in view of AAPA covers it, or if not, then Renisch in view of Wu in view of D’Souza covers it, or if not, then Renisch in view of AAPA covers it, or if not, then Renisch in view of D’Souza covers it. Pet., 31-33. If none of those works, then the Petition suggests that Sprencz covers it, but if not, then Sprencz in view of AAPA covers it, but if not, then Sprencz in view of D’Souza covers it. Pet., 51-53. If that does not work, then Suehling covers it. Pet., 67-68. Petitioner’s choose-your-own-adventure-style Petition impermissibly relinquishes control to the reader by failing to guide the Board to any particular combination of invalidating art.

Similar issues recur for Grounds A-F. For these grounds, the Petition oscillates between treating Renisch alone as allegedly anticipatory, and then combining Renisch with other references as obviousness grounds. The Petition first

asserts that Renisch anticipates claim 1, for example, then shifts to an alternative theory that Wu might be combined with Renisch, then shifts back to how Renisch anticipates—all without specifying which arguments apply to Ground A (anticipation by Renisch) and which arguments apply to Ground B (obviousness over Renisch in view of Wu). *See, e.g.,* Pet., 21, 22-23. For the dependent claims, meanwhile, the Petition frequently asserts that “Renisch discloses [x], rendering the claim anticipated and/or obvious over Renisch in view of [x].” *See, e.g., id.*, 29, 30, 31, 33, 36, 39, 41.

The Petition’s multitude of combinations is so confusing that it even confused the Petitioner. Per the chart above, the Petition asserts that Renisch anticipates Claim 13 (alongside other claims, Ground A). *Supra*, 18. Yet the Petition does not contend that Claim 13 is invalid under Grounds B-F, even though those claims also rely on Renisch as the primary reference. *See id.* Petitioner’s omission of Claim 13 in Grounds B-F makes no sense. If Petitioner believes that Renisch anticipates Claim 13, then why did Petitioner exclude Claim 13 from its Renisch-based combinations? Petitioner applied this basic dynamic for every other claim (e.g., Claims 1-7, 9-10) that Renisch allegedly anticipates in Ground A, but not Claim 13. *See id.* The omission of claim 13 is a result of the lack of particularity with which the Petitioner presents its multitude of obviousness combinations.

Petitioner tries to fall back on a myriad of obviousness combinations in a scattershot effort to cover every conceivable base. Petitioner’s scattershot strategy is obvious, but it does not work. Rather, the Petition fails to provide a clear explanation of which combinations apply to which claim elements, thereby failing to meet the requirements of Section 312(a)(3). *Smaxtec Inc. v. ST Reproductive Techs., LLC*, IPR2024-01067, Paper 7, 31 (PTAB Jan. 21, 2025) (denying institution where “[t]he Petition does not explain what reference is the primary versus secondary reference, what elements are missing from the primary reference, what elements should be added from the secondary reference to reach the claimed invention, or why those particular elements would be obvious to add”) (quoting *Sisvel Int’l S.A. v. Sierra Wireless, Inc.*, 82 F.4th 1355, 1364 (Fed. Cir. 2023)); *Intelligent Bio-Sys.*, 821 F.3d, 1369 (“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.’”).

(ii) Petitioner cannot make so many arguments and stay within the Petition’s word count limit.

Second, 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 this Petition, that combine an excessive number of 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.⁴ In doing so, Petitioner

⁴ While the Petition certifies that the word count is 14 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 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

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 prevail in any unpatentability challenge would place a significant burden on the

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) (“The 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). The Petitioner’s expert declaration, upon which the Petition relies heavily, contains more than 40,000 words. *See* EX1002.

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 Board has repeatedly denied institution (or found a petition insufficiently particular) under these circumstances. In *Adaptics*, for example, the Board refused to institute a petition, like this Petition, that included an infeasible multiplicity of obviousness combinations. *Adaptics*, IPR2018-01596, Paper 20, 18 (“Petitioner’s reliance on up to ten references connected by the conjunction ‘and/or’ results in a multiplicity of grounds, none of which is presented with sufficient particularity.”). Similarly, in *Neulion, Inc. v. Filippo Costanzo*, the Board held that a petition was insufficiently particular where, “although Petitioner asserts three grounds based on obviousness, each of these individual grounds represents groups of multiple grounds,” including “one ground represent[ing] four grounds which are asserted and argued together . . . **By presenting and arguing multiple grounds together, the Petition obfuscates the arguments as to each ground individually.**” IPR2014-00526, Paper 23, 9-10 (PTAB Sept. 3, 2014) (emphasis added). Petitioner tries the same impermissible tactic in Grounds C, D, E, and F, all of which contain “or”

connectors between prior art references. *See Arashi Vision (U.S.) LLC (D/B/A INSTA360) v. GoPro, Inc.*, IPR2024-01434, Paper 9, 11 (PTAB Mar. 31, 2025) (“by collapsing the at least 24 discrete obviousness challenges into six putative grounds, Petitioner makes difficult any meaningful explanation of the individual challenges”). The Petition’s reliance on a multitude of invalidity combinations—especially when paired with inadequate explanation of how each combination maps to each claim element—is insufficient. Institution should, therefore, be denied.

2. The Petition fails to identify with particularity which portions of the asserted references map to which claim elements.

The Board should also deny institution because the Petition fails to identify with particularity which portions of the asserted references map to precisely which claim elements. Instead, the Petition repeatedly cites references and figures from the prior art, without specifying which portions of those references or 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.*, 84 F.4th, 1001-02 (“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, for Ground A challenging independent claim 1, the Petition fails to map the required element of "a network-based system" to the asserted Section 102 reference, Renisch. Instead, the Petition merely points to Figure 1 of Renisch and provides a description that (i) is unsupported by any citation to Renisch itself (instead, the Petition merely cites the expert declaration), and (ii) fails to explain how the allegedly disclosed element of "network-based" is disclosed in Renisch. Pet., 21-22.

The Petition is similarly cursory in its treatment of limitation (b) from claim 1 involving "access[ing] one or more medical images associated with a particular patient from a **database**." (emphasis added). Nowhere in the Petition's short explanation of how Renisch allegedly anticipates (or renders obvious) this element does the Petition ever even *refer* to the word "database," let alone provide a particularized explanation of how Renisch performs or otherwise discloses or renders obvious the "database" limitation. Pet., 24. Instead, the Petition refers to "memory 36" and "memory 58" of two scanners. *Id.* But Petitioner never explains if or how the terms "memory" and "database" relate to each other. For example, Petitioner does not explain if the terms should be considered synonyms; or if the act of "accessing . . . from memory" is equivalent to "accessing . . . from a database";

or if it considers a “database” to be inherent to “memory”; or any other theory. *See id.* The Board and Patent Owner are left to guess.

The Petition fails in several other ways to map the cited prior art to claim 1 with particularity. For example, 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, 35:50-53. For limitations (b) and onwards, the Petition never explains how a processor (or even processors) of Renisch performs the recited steps. Pet., 24 (stating that “Renisch discloses this limitation, which is a generic recitation of structures present in any computer implemented system like Renisch. For example, Renisch’s hotspot detection system comprises various functional units that Renisch alternatively describes as ‘processors’ or ‘algorithms.’”). Yet the Petition never explains how “the processor” of Renisch is performing the claimed steps, or which specific processor is doing it.

Meanwhile, for claim 1 of Ground G, the Petition misleadingly paraphrases the reference. For the element of a “network-based system” in claim 1, the Petition states: “Additionally, the system disclosed by Sprencz is network-based. Referring to Fig. 1, which is reproduced below, Sprencz discloses a distributed system 10 controlled by a CPU 12 and including one or more remotely located imaging system 20, workstation 28, and image database 18. Ex1006, [0023]-[0027].” Pet., 44.

However, even a cursory review of the reference shows that the Petition misrepresents Sprencz. Sprencz never refers to system 10 as a “distributed system.” The word “distributed” never appears in Sprencz. Instead, Sprencz’s paragraphs [0023]-[0026] refer to either “imaging system 10” or “system 10.” EX1006, 10. Likewise, the term “remotely located imaging system 20” is the Petition’s creation. It does not appear in Sprencz. Instead, reference number 20 is “multi-modality imaging subsystem 20.” The Petition never even attempts to justify this inferential leap from the language of Sprencz to the Petition’s self-serving paraphrasing of Sprencz.

The Petition’s third challenge to claim 1 (based on Suehling, Grounds J-L) also lacks the required particularity. Claim 1(b) includes the limitation “access one or more medical images associated with a particular patient from a **database.**” The Petition states that “Suehling discloses Limitation 1(b). . . . For example, Suehling states that a 3D medical image ‘representing anatomy of a patient’ (Ex1007, [0024]) can be received directly from an image acquisition device or ‘can be received by loading a medical image that was previously stored, for example on a memory or storage of a computer system or a computer readable medium’ (Ex1007, [0025]).” Pet., 62. The Petition completely fails to tie Suehling to the required claim element of a “database.” Instead, the Petition begins with the conclusory sentence “Suehling discloses Limitation 1(b),” and then cites three figures and paragraphs of the

reference, none of which includes the word “database.” The second sentence above then quotes from two paragraphs of the Suehling reference, but, again, fails to explain why or how the quoted portions disclose the limitation “access . . . from a database” as recited in claim 1, and does not mention the words “access” or “database.” The Petition never explains what it considers to be a database, or what qualifies as “accessing . . . from a database” in the cited reference.

(ii) The dependent claims.

The Petition’s failures of particularity are not confined to the independent claims. For example, the Petition relies on Menon for dependent claim 12, which concerns automated refinement and learning from accumulated imaging data. Pet., 41. In support, the Petition generally points to nine different paragraphs in Menon for the proposition that “Menon disclosed an automated triaging decision support tool that utilizes machine learning to continuously refine the tool.” Pet., 41. But the Petition does not identify with particularity which specific parts of the nine cited paragraphs corresponds to each aspect of claim 12, such as input acquisition, analysis, or display. *See* Claim 12 (“The method of claim 1, wherein the instructions cause the processor to apply a machine learning algorithm to update a process for automatically analyzing the one or more medical images using accumulated image data in the database.”). Petitioner’s analysis is far too conclusory. *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”).

Similar issues arise for claim 10 (claiming how the cancer “radiologist report comprises the one or more medical images and the risk map”). The Petition cites Fig. 3 of Maier as a claimed “radiologist report.” But Fig. 3 of Maier disproves the Petition’s argument. Per paragraph [0026] of Maier, Fig. 3 is “a second report *for the patient his/herself*,” i.e., the report is for the patient and includes “simple lay language” with motivational messages encouraging the patient to quit smoking. EX1008, [0026] (emphasis added). A “lay person” who is looking to quit smoking is not a radiologist. Thus, Fig. 3 in Maier is plainly not a “radiologist report.”

Petition’s misinterpretation of Maier’s disclosures is not an isolated incident. The Petition repeatedly skips over the fact that, while the claims in the ’346 Patent are directed to creating risk maps that identify regions of risk of *cancer*, Maier is concerned with *emphysema*. Claim 10 of the ’346 Patent, for example, recites the limitation “wherein the radiologist report comprises the one or more medical images and the risk map.” See EX1001, 36:31-32. Independent claim 1 (from which claim 10 depends) further specifies that “the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of *risk of cancer* or *risk of recurrence of cancer*.” EX1001, 35:59-62 (emphasis added). When arguing that Maier renders claim 10 obvious, the Petition contends that “Maier

discloses the additional limitations of claim 10 because it discloses that the radiologist report it generates ‘may include a CT image with transparent color overlay indicating areas of **[disease]** . . .’” Pet., 40 (emphasis added, but bracketed word ‘disease’ is in the original). But the actual subject matter (and bracketed word) in Maier is emphysema—not disease, and certainly not cancer. *See* EX1008, [0026] (“Continuing with the above example, a report for the patient’s referring physician may include a CT image with a transparent color overlay indicating areas of ‘*likely emphysema*.’”) (emphasis added). Rather than acknowledging the distinction and providing a particularized explanation of why Maier is nonetheless relevant, the Petition sidesteps its burden and glosses over the differences between the cited prior art and the challenged claims.

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”); *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.”).

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-Sys.*, 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).” FAQs for Interim Processes for PTAB

<https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management> (last visited June 13, 2025). 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.” *Id.*; *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 example, when alleging that Renisch discloses certain claim elements, the Petition repeatedly cites an array of paragraphs from the expert declaration rather than explaining those points in the Petition. *See, e.g.*, Pet., 21-43; *id.*, 25 (“Renisch discloses these limitations. . . Ex1002, ¶¶160-163.”). In the analysis of claim 1 and its subparts, Petitioner’s argument often consists of conclusory statements followed by “Ex1002, ¶¶[x-y].” *See, e.g.*, Pet., 26 (citing to paragraphs of the expert declaration but without

substantive explanation for claim 1(c)); *id.*, 29 (same for claim 1(e)). Petitioner effectively outsources the actual (and required) claim mapping to the expert's 199-page declaration.

By way of another example, in the obviousness combinations, Petitioner similarly cites the expert declaration as support for motivation to combine, with scant discussion in the Petition beyond the bald assertion that “a POSITA would have been motivated to [do x]” and a citation to the expert declaration. *See, e.g.*, Pet., 22-23, 32, 35, 41, 51-52, 58, 73. The Petition's rationale for combining Renisch with Wu, for instance, is immediately followed by a citation to paragraphs 149-154 of the expert's declaration, rather than any substantive explanation in the Petition. Pet., 22. When contending that Renisch and Wu render the preamble of claim 1 obvious, Petitioner's only argument in support of the reasonable expectation of success prong is to state that “a POSITA would have had a reasonable expectation of success implementing Renisch on a network server using the methods described in Wu,” citing to multiple paragraphs of the expert declaration. Pet., 23. And when contending for dependent claim 5 that a POSITA would have “been motivated to use Renisch to image prostate cancer and would have had a reasonable expectation of success in doing so based on the knowledge of a POSITA,” the Petition provides no explanation, instead citing to ten paragraphs of the expert declaration with no further elaboration. *Id.*, 31-32.

Petitioner’s incorporation of expert argument is impermissible and warrants denial of institution. The Board generally disregards any arguments that are not made in the Petition or 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.* (citation omitted). The Patent Owner and the Board should not need to hunt through the 199-page, 395-paragraph expert declaration (EX1002) 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 closely parallels the Petition filed in *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 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. Servs., Inc. v. Datatransury 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 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 to hunt for arguments buried in

hundreds of pages of expert declaration. Institution should thus be denied for this reason alone.

C. Grounds C and H should be denied because they impermissibly rely on alleged Applicant Admitted Prior Art (“AAPA”).

Both Grounds C and H are improper grounds for institution of *inter partes* review to the extent they impermissibly rely on alleged AAPA. The Federal Circuit recently clarified that IPR petitions cannot rely on AAPA “in combination” with prior art patents or printed publications. *Qualcomm Inc.*, 134 F.4th, 1365. In that case, the Federal Circuit concluded that the petition impermissibly relied on AAPA for Ground 2 because the “petition opened with a table that prominently labeled the ‘Basis’ of Ground 2 as ‘**AAPA in view of [other reference]**.’” *Id.*, 1366 (emphasis added).

That is exactly how the Petition relies on alleged AAPA. The Petition’s Ground C is based on “Renisch, or Renisch in view of Wu, each in view of **the Applicant’s Admitted Prior Art (AAPA)** or D’Souza.” Pet., 8 (emphasis added). Ground H is based on “Sprenicz in view of **AAPA** or D’Souza.” *Id.* (emphasis added).

Therefore, Grounds C and H fail to the extent they rely on alleged AAPA in combination with other prior art.

III. CONCLUSION

For the foregoing reasons, institution should be denied.

Date: June 13, 2025

Respectfully submitted,

By: /William R. Haulbrook/

William R. Haulbrook (Reg. No. 53,002)

Stephanie L. Schonewald (Reg. No. 72,452)

Michael H. Bunis (*pro hac vice* to be filed)

Anita M.C. Spieth (provisionally admitted
pro hac vice)

CHOATE, HALL & STEWART LLP

Two International Place

Boston, MA 02110

617-248-5000

Attorneys for Patent Owner

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 7,935 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.

Date: June 13, 2025

Respectfully submitted,

By: /William R. Haulbrook/

William R. Haulbrook (Reg. No. 53,002)

Stephanie L. Schonewald (Reg. No. 72,452)

Michael H. Bunis (*pro hac vice* to be filed)

Anita M.C. Spieth (provisionally admitted
pro hac vice)

CHOATE, HALL & STEWART LLP

Two International Place

Boston, MA 02110

617-248-5000

Attorneys for Patent Owner

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:

Jeff.Metzcar@thompsonhine.com

David.Jaglowski@thompsonhine.com

Marla.Butler@thompsonhine.com

IPDocket@thompsonhine.com

Date: June 13, 2025

Respectfully submitted,

By: /William R. Haulbrook/

William R. Haulbrook (Reg. No. 53,002)

Stephanie L. Schonewald (Reg. No. 72,452)

Michael H. Bunis (*pro hac vice* to be filed)

Anita M.C. Spieth (provisionally admitted
pro hac vice)

CHOATE, HALL & STEWART LLP

Two International Place

Boston, MA 02110

617-248-5000

Attorneys for Patent Owner