

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MIM SOFTWARE INC.,  
*Petitioner,*

v.

EXINI DIAGNOSTICS AB,  
*Patent Owner*

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IPR2025-00827  
U.S. Patent No. 11,941,817

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**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. ....  | 12 |
| B.   | The Board should deny institution as to all grounds under 35 U.S.C. § 325(d).....  | 14 |
| 1.   | The Petition presents the same or substantially the same art that the Examiner already considered.....   | 15 |
| 2.   | The Petition fails to show that the Examiner materially erred.....   | 17 |
| 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)..... | 19 |
| 1.   | The Petition fails to identify with particularity which portions of the asserted references map to which claim elements. ....  | 20 |
| 2.   | The Petition’s particularity problems are exacerbated by its overreliance on overlapping grounds and internal cross-references.....                                  | 25 |
| III. | CONCLUSION.....  | 28 |

## TABLE OF AUTHORITIES

| <b>Cases</b>  | <b>Page(s)</b> |
|---|----------------|
| <i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i><br>IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020)..... | <i>passim</i>  |
| <i>Apple Inc. v. Fintiv, Inc.,</i><br>IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....                                     | <i>passim</i>  |
| <i>Apple Inc. v. Gesture Tech. Partners, LLC,</i><br>129 F.4th 1367 (Fed. Cir. 2025) .....                                  | 20             |
| <i>Becton, Dickinson &amp; Co. v. B. Braun Melsungen AG,</i><br>IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) .....           | 15             |
| <i>Cisco Sys., Inc. v. C-Cation Techs., LLC,</i><br>IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014).....                       | 20, 24         |
| <i>Cisco Sys., Inc. v. Video Sols. Pte. Ltd.,</i><br>IPR2024-00695, Paper 10 (PTAB Sept. 5, 2024).....                      | 9              |
| <i>ClearH2O, Inc. v. Ceva Animal Health Inc.,</i><br>IPR2020-00039, Paper 21 (PTAB Mar. 18, 2020) .....                     | 17             |
| <i>Corephotonics, Ltd. v. Apple Inc.,</i><br>84 F.4th 990 (Fed. Cir. 2023) .....  | 23, 25         |
| <i>Ecto World, LLC v. Rai Strategic Holdings,</i><br>IPR2024-01280, Paper 13 (PTAB May 19, 2025) .....                      | 19             |
| <i>Elite Performance Footwear, LLC v. Reebok Int’l Ltd.,</i><br>IPR2017-01680, Paper 38 (PTAB Jan. 9, 2019) .....           | 21             |
| <i>Harmonic Inc. v. Avid Tech., Inc.,</i><br>815 F.3d 1356 (Fed. Cir. 2016) .....   | 28             |
| <i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.,</i><br>821 F.3d 1359 (Fed. Cir. 2016) .....                      | 19             |
| <i>Microsoft Corp. v. FG SRC, LLC,</i><br>860 F. App’x 708 (Fed. Cir. 2021) .....   | 22             |

|  |               |
|--|---------------|
| <i>Nearmap US, Inc. v. Pictometry Int’l Corp.</i> ,<br>IPR2024-00729, Paper 9 (PTAB Oct. 10, 2024) .....                 | 21            |
| <i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC</i> ,<br>IPR2025-00037, Paper 14 (PTAB Apr. 25, 2025) .....     | 9             |
| <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> ,<br>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> ,<br>IPR2023-01148, Paper 6 (PTAB Jan. 16, 2024) ..... | 24            |
| <i>Skechers U.S.A., Inc. v. Nike, Inc.</i> ,<br>IPR2025-00141, Paper 20 (PTAB June 3, 2025) .....                        | 16            |
| <i>Supercell OY v. Gree, Inc.</i> ,<br>IPR2021-00500, Paper 7 (PTAB Aug. 16, 2021).....                                  | 28            |
| <i>Therabody, Inc. v. Hyperice IP Subco, LLC</i> ,<br>PGR2024-00053, Paper 8 (PTAB Apr. 21, 2025).....                   | 9             |
| <i>Valeo N. Am., Inc. v. Magna Elecs., Inc.</i> ,<br>IPR2014-01206, Paper 13 (PTAB Dec. 23, 2014) .....                  | 28            |
| <i>Vital Connect, Inc. v. Bardy Diagnostics, Inc.</i> ,<br>IPR2023-00381, Paper 7 (PTAB July 11, 2023).....              | 19            |
| <i>Zetec, Inc. v. Westinghouse Elec. Co., LLC</i> ,<br>IPR2014-00384, Paper 10 (PTAB July 23, 2014).....                 | 22            |
| <b>Statutes</b>  |               |
| 35 U.S.C. § 101 .....  | 6             |
| 35 U.S.C. § 312(a) .....   | 2             |
| 35 U.S.C. § 312(a)(3).....   | 3, 19         |
| 35 U.S.C. § 314.....   | 3             |
| 35 U.S.C. § 315.....   | 6             |
| 35 U.S.C. § 325(d).....  | <i>passim</i> |

**Other Authorities**

37 C.F.R. § 42.104(b)(4).....20, 25

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 (Mar.  
24, 2025) .....4, 5, 12

Consolidated Trial Practice Guide, PTAB (Nov. 2019) .....21

Director Coke Morgan Stewart, *Interim Processes for PTAB  
Workload Management,* PTAB (Mar. 26, 2025) .....3, 13, 14

## 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  | MIM's Invalidity and Noninfringement Contentions, Civil Action No. 1:24-cv-10437-PBS.   |
| EX2003  | PACER Docket, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS (as of June 30, 2025).   |
| EX2004  | 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.   |
| EX2005  | 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.  |
| EX2006  | 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.    |
| EX2007  | 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.   |
| EX2008  | 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. |
| EX2009  | Scheduling Order, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 85, Mar. 5, 2025.  |
| EX2010  | U.S. District Courts, Judicial Caseload Profile 2024 (D. Mass. excerpted).  |
| EX2011  | <i>Cancer Control Month, 2025 – The White House</i> (Apr. 3, 2025).   |

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| EX2012 | <i>NIH Strategic Plan for Data Science FY 2025-2030, Nat'l Institutes of Health.</i> |
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## I. INTRODUCTION

Patent Owner EXINI Diagnostics AB respectfully requests that the Board discretionarily deny institution of IPR2025-00827 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”). Patent Owner sued Petitioner for infringement of six patents in the District Court Litigation—proceedings continue in that court for two of the six patents for which Petitioner did not file for IPR (while four others are stayed pending IPR institution decisions). Instituting the Petition will thus create inefficient parallel proceedings with the corresponding risk of inconsistent holdings and judgments. By Petitioner’s own admission, the patents currently litigated in the District Court Litigation present overlapping issues with the patent challenged by the Petition, including insofar as they focus on the same accused products. *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. 11,941,817 (“the ’817 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 two primary art references. Patent Owner cited both primary references on an IDS submitted to the Patent Office. *See* EX1004, 246. The Examiner signed the IDS, indicating that he had reviewed all the references. EX1004, 280. The Petition briefly suggests that the Examiner could or should have combined the asserted references to find the patent obvious, but the Petition fails to sufficiently explain how the Examiner made any clear and material error. *See* Pet., 4-5. Thus, the Board should deny institution under 35 U.S.C. § 325(d).

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). The Petition also fails to carry its particularity burden by over-relying on overlapping grounds and internal cross-references in lieu of specific and detailed argument.

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, and it 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 (e) many of the same invalidity references and claim construction issues. Petitioner’s invalidity contentions in the District Court Litigation rely on *four out of the five* same references that Petitioner relies on in the Petition (Renisch, Baker, Eiber, and Suehling). *See* EX2002, 4-6, 8-9. 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 two patents in the District Court Litigation. EX2003, Dkt. No. 1. Patent Owner amended the complaint on March 15, 2024, and April 5, 2024, thereby accusing Petitioner of infringing seven patents (adding the ’817 Patent on April 5, 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 '817 Patent) on 35 U.S.C. § 101 (“Section 101”) invalidity grounds, and dismissal of the three remaining patents on procedural grounds. EX2004, 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 EX2003, Dkt. Nos. 43-44, 48, 57, 61. The district court convened a multi-hour hearing, at which the court stated that resolving the motion to dismiss would require substantial work for the court to learn the technology and understand the asserted claims. EX2005, 2-4. 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 '817 Patent) as invalid under Section 101. EX2006, 35. Thus, the court has already addressed the validity of the '817 Patent at the pleadings stage and denied Petitioner’s motion challenging its validity.

After the decision on Petitioner’s motion to dismiss, the remainder of the case continued. 364 days after Patent Owner amended its complaint to add the '817 Patent to the District Court Litigation—*i.e.*, ***one day before Petitioner’s one-year deadline*** to file under 35 U.S.C. § 315—Petitioner filed this Petition (“Pet.”). See EX2003, Dkt. No. 1; Pet. (Paper 1). On April 8, 2025, Petitioner moved 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. EX2003, Dkt. Nos. 88-93, 97, 101, 103. At the hearing, arguing for a stay of the entire District Court Litigation, 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.”** EX2007, 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* EX2008, 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.” EX2008, 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 four of the five same references that Petitioner cites in the instant Petition (Renisch, Baker, Suehling, and Eiber). *See* EX2002, 4-6, 8-9. Thus, Petitioner has assured that the District Court Litigation will be engaging with the very same references it relies upon in this Patent Office action.

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* EX2009, 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 (3<sup>rd</sup>), as well as the substantive overlap (4<sup>th</sup>) and the party overlap (5<sup>th</sup>) 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”). The party redundancy 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. EX2007, 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) many 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”, “hotspot”, “anatomical image”, and “functional image” appear in each of the independent claims (1 and 10), yet the Petition does not propose a construction for any of those

terms. Pet., 9-10. 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 ’817 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. EX2009, 3. Thus,

the trial may occur at the end of 2026 or the beginning of 2027.<sup>1</sup> Because the filing date was accorded to the Petition on May 7, 2025, any FWD may not arrive until Q4 2026. Even if the FWD were to precede the district court trial, 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.

**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 two factors listed in the Director’s March 26 Memorandum: “[t]he strength of the

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<sup>1</sup> 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,”* PTAB, 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.”).

unpatentability challenge” 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 relies on the same art that the Examiner already considered, is rife with conclusory assertions, fails to argue with particularity, and over-relies on internal cross-referencing. *Infra*, Section II.B-C. 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 ’817 Patent claims novel systems and methods that save lives and improve cancer care. The claims of the ’817 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 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 Patent Owner undisputedly cited the Petition’s primary references, Renisch and Baker, during prosecution of the ’817 Patent. EX1004, 246. Petitioner

acknowledges as much. Pet., 4. The Patent Owner also undisputedly cited one of the secondary references, Eiber, during prosecution and even discussed it in the specification of the '817 Patent. See EX1004, 251; EX1001, 62:24-25.

In particular, the Patent Owner listed Renisch, Baker, and Eiber on the IDS filed on June 26, 2023. See EX1004, 246, 251. On October 4, 2023, the Examiner signed the IDS, noting at the bottom that “ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.M.S./.” The Examiner did not line through the Baker, Renisch, or Eiber references. EX1004, 280, 285. 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 thus allowed the claims after considering the Renisch and Baker primary references (as well as the secondary Eiber reference). 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 does not argue otherwise. See Pet., 3-5.

Although two of the Petition’s three secondary references (Zhao and Suehling) were not presented to the Examiner, their absence does not change the *Advanced Bionics* step 1 analysis because 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 Renisch and/or Baker (both of which the Examiner considered). 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). Here, the Petition does not even argue that the secondary references add anything to Renisch and/or Baker that the Examiner did not consider during prosecution. Pet., 3-5. Therefore, the secondary references make no difference to the ultimate analysis under Section 325(d).

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 does not (and cannot) identify any clear and material error by the Examiner. Instead, the Petition briefly and cursorily argues that the Examiner must have misunderstood the Petition’s two primary references (Renisch and/or Baker) because those references teach the elements that the Examiner found lacking in the prior art. Pet., 4-5. Notably, though, the Petition does not quote the Examiner’s full explanation for what he concluded was missing:

a cancerous lesion automatic[] identification method for (d) receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality; (e) identifying, within the 3D functional image, one or more 3D volume(s), each corresponding to an identified target VOI, using the 3D segmentation map; and (f) automatically detecting, by the processor, within at least a portion of the one or more 3D volumes identified within the 3D functional image, one or more hotspots determined to represent lesions based on intensities of voxels within the 3D functional image.

EX1004, 324. Rather than argue in detail why Renisch and Baker teach this long list of limitations, the Petition dedicates a *single sentence* to why Renisch and Baker satisfy these elements. Pet., 4-5. Such cursory assertion is insufficient to

demonstrate clear material error. *See Ecto World, LLC v. Rai Strategic Holdings*, IPR2024-01280, Paper 13, 5 (PTAB May 19, 2025) (reaffirming that “a petitioner must provide an analysis” specific to step two of the *Advanced Bionics* test). Where the “Petitioner argues only that the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner,” but the Petition fails to provide “further analysis,” it “cannot persuade [the Board] of “material error.” *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 7, 19 (PTAB July 11, 2023) (denying institution at step 2). Petitioner cannot rely on its analyses of the same references elsewhere in the Petition to satisfy its burden at step 2 of *Advanced Bionics*. *Id.* The Petition thus fails to show clear error in the Examiner’s analysis.

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

**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 two ways. First, it fails to provide a particularized explanation of how the asserted references allegedly map to the claim elements. Second, the Petition improperly over-relies on overlapping grounds 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 fails to identify with particularity which portions of the asserted references map to which claim elements.**

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 July 2, 2025).

The Petition is not “concise, well-organized,” or “easy-to-follow,” especially (but not only) for the independent claims (1 and 10). Petitioner tries to cover too much ground within its word count limit.<sup>2</sup> In doing so, Petitioner provides only

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<sup>2</sup> While the Petition certifies that the word count is 392 words under the limit, the Petition reaches that count by impermissible reliance on conclusory arguments and 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 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

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 Board and contravene the efficient administration of the Office.” *Id.*, 15. “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[.]” *Microsoft Corp. v. FG SRC, LLC*, 860 F. App’x 708, 713 (Fed. Cir. 2021).

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 approach

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incorporation by reference of arguments in one document into another[.]”) (citations omitted).

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).

For example, claim 1 requires that the various steps (other than step (e)) be performed by “the processor.” EX1001, 79:5-33. For limitation (a), the Petition notes that Renisch’s “hotspot detection system comprises functional ‘units’ that Renisch alternatively describes as ‘processors’ or ‘algorithms’ (i.e., stored instructions).” Pet., 20. But for limitation (b) and onwards, the Petition never even mentions the word “processor,”<sup>3</sup> let alone explains how a processor (or even processors) of Renisch performs the recited steps, or which specific processor is doing it. The same problem infects the Petition’s treatment of claim 10, since the Petition incorporates its discussion of claim 1 instead of uniquely analyzing claim 10. Pet., 41-42.

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<sup>3</sup> The one cursory exception is the Petition’s reference at step (d) to how “Renisch states that its automatic hotspot detection system, which includes a processor, detects lesions . . .”). Pet., 29.

Similar issues infect the Petition’s treatment of the dependent claims. For example, for claim 5, the Petition fails to explain with particularity how Renisch and/or Zhao “determin[e] . . . an overall index value indicative of a cancer status of the subject using at least a portion of the one or more hotspot index values.” Instead, the Petition parrots the claim language. Pet., 37 (“As defined within the claim, the recited ‘overall index value indicative of a cancer status’ can be determined using a single hotspot index value (i.e., a portion of ‘one or more’).”).

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’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 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. *See Corephotonics, Ltd.*, 84 F.4th at 1001-02. Yet that is exactly what the Petition does.

For example, the Petition asserts that claims 8-9, 17-18, 22-25, and 29-32 are rendered obvious by Ground C (Renisch, or Renisch-Zhao, each in view of Baker), whereas claims 8-9, 17-18, 22, 24-25, 29, and 31-32 are rendered obvious by Ground D (Renisch, or Renisch-Zhao, each in view of Eiber). Pet., 8, 43. The Petition addresses these grounds simultaneously for each claim, without an individualized treatment of how each reference of each ground applies to each claim element. This is especially confusing because the Petition does not contend that Grounds C and D cover exactly the same claims (e.g., Ground C covers claims 23 and 30, but Ground D does not), so the Board and Patent Owner are left to try to piece the puzzle together.

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, for claims 9 and 22-25, the Petitioner's argument consists exclusively of internal cross-references to other sections of the Petition: "Claims 9 and 22-25 depend from claim 8, which is obvious over Baker-Zhao. *See* Section VIII.D.4. Baker also discloses all the limitations of claim 9 (Section VIII.C.2), claim 22 (Section VIII.C.3), claim 23 (Section VIII.C.4), claim 24 (Section VIII.C.5), and claim 25 (Section VIII.C.6)." Pet., 56.

Similar issues arise for claim 4. Claim 4 covers "[t]he method of claim 3, wherein the reference tissue regions comprise one or more members selected from the group consisting of: a liver, an aorta, and a parotid gland." EX1001, 79:58-60. For claim 4 under Grounds A and B, the Petition exclusively relies on internal cross-referencing: "Claim 4 is anticipated by Renisch and/or rendered obvious by Renisch-Zhao for the same reasons provided in Section VIII.B.3 above." Pet., 36 (citing

Renisch’s assertion that “[t]he metabolic activity of the liver can be used as a reference for comparison”). The Petition does not include any specific discussion of the unique elements of claim 4 here, including, e.g., “aorta” and “parotid gland.” *Id.* Simply relying on internal cross-referencing or Renisch’s liver example and saying “same reasons” for all the other claimed organs leaves the Board and Patent Owner guessing as to whether/how the Petitioner believes the references satisfy the other elements of the claim.

For claims 10-14, 16, and 26 under Ground A, the Petition exclusively relies on cross-referencing to the previous method claims. Here, the Petition’s penchant for internal cross-referencing creates a clear substantive shortcoming, since the Petition fails to address the unique element of the system claim (as compared to the method claim) involving “a processor of a computing device; and ***a memory having instructions stored thereon***, wherein the instructions, when executed by the processor, cause the processor to:” (emphasis added). *See id.*, 41-42. The same issue recurs in the Petition’s treatment of the system claims 10-11, 16-18, and 29-32 for Ground E. *See id.*, 56-57.

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 deficiency 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.

### **III. CONCLUSION**

For the foregoing reasons, institution should be denied.

Date: July 3, 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 6,308 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, 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 July 3, 2025 via electronic mail to the following attorneys of record:

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