

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED
STATES PATENT AND TRADEMARK OFFICE**

MIM SOFTWARE INC.,
Petitioner

v.

PROGENICS PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: IPR2025-00726

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

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EXHIBIT LIST

No.	Description
Ex1001	U.S. Patent No. 11,894,141 (“the ’141 patent”)
Ex1002	<i>Reserved</i>
Ex1003	<i>Reserved</i>
Ex1004	Prosecution History File of the Patent (Application No. 17/862,528)
Ex1005	U.S. Patent Application Publication No. 2016/0203263 (“Maier”)
Ex1006	U.S. Patent Application Publication No. 2007/0081712 (“Huang”)
Ex1007	PCT Patent Application Publication No. 2015/058151 (“Armor”)
Ex1008	U.S. Patent No. 10,112,974 (“Neumaier”)
Ex1009	U.S. Patent No. 10,815,200 (“Cardinale”)
Ex1010	Giesel et al., “ ¹⁸ F-Labelled PSMA-1007 shows similarity in structure, biodistribution and tumour uptake to the theragnostic compound PSMA-617,” <i>European Journal of Nuclear Medicine and Molecular Imaging</i> 43(10):1929-1930 (June 2016) (“Giesel”)
Ex1011	Weineisen et al., “ ⁶⁸ Ga- and ¹⁷⁷ Lu-Labeled PSMA I&T: Optimization of a PSMA-Targeted Theranostic Concept and First Proof-of-Concept Human Studies,” <i>Journal of Nuclear Medicine</i> 56(8):1169-1176 (2015) (“Weineisen”)
Ex1012	RESERVED
Ex1013	RESERVED
Ex1014	Second Amended Complaint, Progenics Pharmaceuticals, Inc. v. MIM Software Inc., Case No. 1:24-cv-10437-PBS, Dkt. 25, April 5, 2024
Ex1015	Kaur, “Various Image Segmentation Techniques: A Review,” <i>International Journal of Computer Science and Mobile Computing</i> 3(5):809-814 (May 5, 2014) (“Kaur”)
Ex1016	Sharma, “Automated medical image segmentation techniques,” <i>Journal of Medical Physics</i> 35(1):3-14 (2010) (“Sharma”)
Ex1017	Greenspan, “Deep Learning in Medical Imaging: Overview and Future Promise of an Exciting New Technique,” <i>IEEE</i>

	Transactions on Medical Imaging, 35(5):1153-1159 (May 2016) (“Greenspan”)
Ex1018	Litjens, “A Survey on Deep Learning in Medical Image Analysis,” Medical Image Analysis 42:60-88 (Dec. 2017) (“Litjens”)
Ex1019	Shen, “Deep Learning in Medical Image Analysis,” Annual Review of Biomedical Engineering 19:221-248 (2017) (“Shen”)
Ex1020	Seifert et al., “Hierarchical Parsing and Semantic Navigation of CT Data,” Medical Imaging 2009: Image Processing, Proceedings of SPIE Vol. 7259, pp.725902-1 to 725902-8 (2009) (“Seifert”)
Ex1021	Afshar-Oromieh et al., “Radiation dosimetry of 68Ga-PSMA-11 (HBED-CC) and preliminary evaluation of optimal imaging timing,” European Journal of Nuclear Medicine and Molecular Imaging 43:1611-1620 (2016) (“Afshar-Oromieh”)
Ex1022	RESERVED
Ex1023	RESERVED
Ex1024	RESERVED
Ex1025	RESERVED
Ex1026	Electronic Order, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 69 (D. Mass. Oct. 8, 2024).
Ex1027	Amended Joint Statement, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 75 (D. Mass. Jan. 31, 2025).
Ex1028	Scheduling Order, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 85 (D. Mass. Mar. 5, 2025).
Ex1029	Declaration of Marla R. Butler in Support of Motion for Admission <i>Pro Hac Vice</i>
Ex1030	Declaration of Jesse L. Jenike-Godshalk in Support of Motion for Admission <i>Pro Hac Vice</i>
Ex1031	Defendant’s Motion to Dismiss the Second Amended Complaint, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 43 (D. Mass. June 17, 2024).
Ex1032	Order on Motion to Dismiss, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 72 (D. Mass. Jan. 14, 2025).
Ex1033	RESERVED
Ex1034	Order on Motion to Stay, <i>Progenics Pharms., Inc. v. MIM</i>

	<i>Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 102 (D. Mass. May 13, 2025).
Ex1035	Transcript, Hearing on Motion to Dismiss, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS (D. Mass. Oct. 8, 2024).
Ex1036	Transcript, Hearing on Motion to Stay, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS (D. Mass. May 12, 2025).
Ex1037	Petitioner's <i>Sotera</i> Stipulation, <i>MIM Software Inc. v. Progenics Pharms., Inc.</i> , IPR2025-00726, Paper 6 (PTAB Apr. 30, 2025).
Ex1038	Defendant's Memo of Law in Support of its Motion to Stay, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 89 (D. Mass. Apr. 8, 2024).
Ex1039	Complaint, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 1 (D. Mass. Feb. 23, 2024).
Ex1040	First Amended Complaint, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 14 (D. Mass. Mar. 15, 2024).

I. INTRODUCTION

Petitioner, MIM Software Inc. (“Petitioner”), respectfully requests the Director to advance IPR2025-00726 to the Board for consideration on the merits and deny the request of Patent Owner, Progenics Pharmaceuticals, Inc. (“Patent Owner”), for discretionary denial. IPR2025-00726 is closely related to IPR2025-00725 and IPR2025-00630, which are presently before the Director, and for which Petitioner also recently filed oppositions to requests for discretionary denial.

Inter partes review in this case is an appropriate use of the Board’s resources. The relevant discretionary denial factors, including the factors set forth in *Apple Inc. v. Fintiv, Inc.*, favor institution and demonstrate the need for the PTAB’s expert review. *See* IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential). First and foremost, the District Court has preemptively stayed all litigation related to the challenged U.S. Patent No. 11,894,141 (“the ’141 patent”)—as well as three other patents (collectively “the challenged patents”)—pending the Board’s resolution.¹ Ex1034 at 2-3. Because of this stay, the distinct portion of the litigation relevant to the ’141 patent (and its related family members) remains frozen in its

¹ The District Court stayed the parties’ case with respect to the ’141 patent as well as U.S. Patent Nos. 10,665,346 (IPR2025-00630), 11,424,035 (IPR2025-00725), and 11,941,817 (IPR2025-00827).

infancy: there have been no exchanges of invalidity contentions, claim constructions, or search terms for discovery. Thus, contrary to Patent Owner's assertion, if institution is granted, a Final Written Decision from the Board will undoubtedly issue before trial; indeed, no trial date has been set for *any* of the patents asserted in the litigation, and no trial date *will be set* with respect to the '141 patent pending the Board's resolution. Ex1028 at 4. Second, because of (i) the litigation stay, (ii) Petitioner's *Sotera* stipulation, and (iii) the District Court's expressly stated interest in the PTAB's expert opinion on validity, there is no risk of inconsistent outcomes in two fora. And third, the merits of the Petition warrant institution because the Petition presents multiple strong grounds for invalidity while demonstrating that the Examiner overlooked and/or did not appreciate the most pertinent prior art, instead citing less far less relevant art as being "the closest prior art." Ex1004 at 278.

Additionally, the discretionary considerations announced by Acting Director Stewart further illustrate the appropriateness of PTAB review. The challenged patents—which are all relatively new—are ripe for challenge. Patent Owner seeks, through its litigation, to pull from the U.S. market Petitioner's innovative cancer diagnosis and treatment solution. Removing Petitioner's products could affect millions of Americans and should only be permitted after careful review of the validity of the challenged patents. The Office, rather than a lay jury, is best suited to make the invalidity determination since, as previously stated, the Office overlooked

the most pertinent prior art.

Contrary to Patent Owner's assertions, the Petition satisfies all statutory and regulatory requirements for Board review. Although Patent Owner's request attempts to muddy the waters, the content-heavy Petition clearly and concisely presents its arguments in a logical format. Headings and subheadings guide the reader through each claim element of each ground. And established legal rationales, bolstered by expert testimony, accompany each combination.

II. FACTUAL BACKGROUND

Patent Owner and Petitioner are parties to a patent dispute in the United States District Court for the District of Massachusetts. Ex1039 at 1. Shortly after it was announced that Petitioner would be acquired by GE HealthCare, Patent Owner accused Petitioner of infringing seven patents, including the challenged patents. Ex1014 at 17-18, 67-74; *see also* Ex1039, Ex1040. In June of 2024, Petitioner moved to dismiss all claims under Federal Rule of Civil Procedure 12(b)(6) and 35 U.S.C. § 101. Ex1031. The District Court did not rule on the motion to dismiss until January of 2025, partially granting Petitioner's motion but denying the motion, on § 101 grounds, with respect to the challenged patents. Ex1032. In the three short months between the District Court's ruling and the respective statutory IPR deadlines, Petitioner prepared and filed four petitions for *inter partes* review directed at each of the challenged patents, including the present Petition.

After filing the last of its petitions, Petitioner promptly moved to stay the district court litigation. *See* Ex1038. The District Court made several key findings in support of its decision to stay the case with respect to the challenged patents. First, the “litigation is still in its early stages.” Ex1034 at 1. Indeed, there have been no invalidity contentions served, claim constructions exchanged, or discovery search terms agreed upon with respect to the challenged patents. Nor has a trial date been set. Ex1028 at 4. Second, the District Court reasoned, “any decisions by the Patent Trial and Appeal Board [] will simplify the issues in this case.” Ex1034 at 1. Third, because Patent Owner would not experience significant, non-compensable harm during the stay, it would suffer no undue prejudice. *See id.* at 1-2. Finally, the District Court acknowledged its “limited resources” to address “this massive and complex patent infringement suit” (*id.* at 2) after also having characterized the case as a “patent thicket” that is “extremely difficult” and “very confusing for a judge trying to walk through the differences” (Ex1035 at 4:7-9, 6:11-12, 35:12-18).

In deciding to proceed on the two remaining patents not challenged by Petitioner at the PTAB, the District Court reasoned:

I don't have the bandwidth to do six patents.... I don't have it. ... And so I thought that that was a way for me to just take a tiny bite with this, learn the case, let the rest of it go to the PTAB, and basically get things moving on

Ex1036 at 3:21-4:2; *see also id.* at 5:6-9, 7:7-12.² When asked whether the possibility of the Board construing terms of the challenged patents would pose a problem with respect to moving ahead on the two non-challenged patents, the District Court responded:

[I]ndeed I have been known to change claim constructions if I find something persuasive, so nothing will stop me from changing it because I do view [the PTAB] as more expert than I am. On the other hand, by the time you brief claim construction and we have a hearing, and then it takes me three to six months to write it up, I may well have rulings from the PTAB one way or another.

Id. at 9:8-14.

III. ARGUMENT

A. **The vast majority of discretionary considerations demonstrate that this case is an appropriate use of the Office’s resources.**

Whether discretionary denial is appropriate “is based on the totality of the evidence and arguments the parties have presented.” *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00217, Paper 9 at 2 (PTAB June 13, 2025). As further explained in the following sections, Petitioner identifies the following relevant discretionary factors as either weighing in favor of institution or being neutral:

Factors in favor of institution	Other factors
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² The District Court distinguished itself from “that speedy docket ... in Texas.” *Id.* at 10:2.

<p><i>Fintiv</i> Factor 1: whether the District Court granted a stay.</p>	<p><i>Fintiv</i> Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party. (neutral)</p>
<p><i>Fintiv</i> Factor 2: proximity of the District Court’s trial date to the Board’s projected statutory deadline for a final written decision (FWD).</p>	
<p><i>Fintiv</i> Factor 3: investment in the parallel proceeding by the District Court and the parties.</p>	
<p><i>Fintiv</i> Factor 4: overlap between issues raised in the petition and in the parallel proceeding.</p>	
<p><i>Fintiv</i> Factor 6: other circumstances, including:</p> <ul style="list-style-type: none"> • the merits of the petition; • the risk of inconsistent claim construction positions; • whether the patent owner has settled expectations in its issued claims; • the size and scope of the asserted and challenged patents; • whether the petitioner has filed a <i>Sotera</i> stipulation; • public policy considerations. 	<p><i>Fintiv</i> Factor 6: other circumstances, including:</p> <ul style="list-style-type: none"> • reliance on expert testimony; (neutral) • prior adjudication of validity; (neutral)

Fintiv, IPR2020-00019, Paper 11 at 6-15.

On balance, these discretionary considerations favor institution.

1. The District Court deferred to the Board to simplify this complex dispute.

One of Congress’s goals in establishing inter partes review was to “provide a more efficient system for challenging patents that should not have been issued.” *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1290-91 (Fed. Cir. 2015) (cleaned up). In granting Petitioner’s motion to stay, the District Court acknowledged the size and complexity of the case and signaled that the PTAB could simplify the issues before the District Court. Ex1036 at 1-2.

- a) *The District Court does not have the capacity to adjudicate all of Patent Owner’s asserted patents.*

A goal of the Leahy-Smith America Invents Act, 35 U.S.C. § 100 *et seq.*, is to reduce the burden of litigation on district courts. *See, e.g., Smith Sport Optics, Inc. v. Burton Corp.*, 601 F. Supp. 3d 936, 939 (D. Colo. 2022). “A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts” and “has strongly weighed against exercising the authority to deny institution.” *Fintiv*, IPR2020-00019, Paper 11 at 6 (*Fintiv* Factor 1). Even without a stay, inefficiency is less likely if the petitioner presents “materially different grounds” than those in the district court (*Fintiv* Factor 4), *id.* at 12-13, and the timely filing of a *Sotera* stipulation that eliminates the possibility of duplication is “highly relevant” to the Board’s exercise of discretionary institution.

See Mem. from Scott R. Boalick, Chief Admin. Patent Judge to Members of the Patent Trial and Appeal Board, *Guidance on USPTO's rescission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation"*, at 2-3 (USPTO Mar. 24, 2025), https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_rescission_20250324.pdf.

The District Court stayed the litigation with respect to each challenged patent, including the '141 patent. Ex1036 at 2-3. As the motion to stay hearing transcript makes clear, the District Court does not have the bandwidth to adjudicate such a massive case. See Ex1036 at 4:18-20; see also *id.* at 4:20-22 (“And this is sort of overkill in terms of the District Court’s docket. I’ve never seen a case bring six patents and so many claims and expect me to rule on them.”); 5:6-9; 7:7-15; 8:12-15; 9:17-10:3; 10:23-25 (“But let me return to the basic fact: I don’t have the staffing to handle the volume of claims and the number of patents.”). Thus, according to the District Court, it “make[s] sense [] to stay the portion that’s in front of the PTAB ... and keep the two patents that are not pending before the PTAB.” *Id.* at 3:18-21.

Because of the stay, Petitioner has not taken a position on the '141 patent's validity under 35 U.S.C. §§ 102-103 in the District Court. Indeed, the District Court stayed the litigation before Petitioner's invalidity contentions were due. Ex1034; Ex1028 at 1. Therefore, the Petition cannot include the same or substantially similar

“claims, grounds, arguments, and evidence as presented in the [litigation],” *Fintiv*, IPR2020-00019, Paper 11 at 12, and the parties are not “litigating the validity of the same patent in two fora,” as Patent Owner asserts. Patent Owner’s Request for Discretionary Denial (“DD Req.”) at 10. Furthermore, if the Board institutes review of the ’141 patent, Petitioner’s *Sotera* stipulation will prevent it from litigating these grounds in the District Court. *See* Ex1037. By (i) moving to stay the case before validity contentions were due and (ii) filing a *Sotera* stipulation, Petitioner has demonstrated its preference to have the PTAB resolve this dispute. And, by granting the stay, the District Court has likewise demonstrated its preference to have the PTAB resolve the validity of the challenged patents.

b) *The PTAB is best suited to review Petitioner’s robust challenge to several patents.*

A “large number and vast scope of [] patents asserted in the district court litigation” weighs against discretionary denial. *Tesla*, IPR2025-00217, Paper 9 at 3. Following dismissal of a seventh patent, Patent Owner now asserts six patents against Petitioner in the district court litigation. Petitioner challenges four of those in *inter partes* review proceedings. *See* IPR2025-00630, IPR2025-00725, and IPR2025-00827. Because the Board can quickly and efficiently adjudicate multiple challenges—decluttering what the District Court calls an “enormous” case (Ex1036 at 9:23)—this factor weighs against discretionary denial. *Tesla*, IPR2025-00217, Paper 9 at 3 (“[T]he Board is better suited to review a large number of patents

involving diverse subject matter.”).

- c) *PTAB review will not interfere with the district court litigation, in which there has been and will be only minimal investment.*

To avoid “duplicative costs,” the Office prioritizes challenges that are not in “advanced” stages of litigation. *See Fintiv*, IPR2020-00019, Paper 11 at 10. Accordingly, discretionary denial is disfavored if the court’s trial date is set for “substantially after” the projected statutory deadline (*Fintiv* Factor 2) and/or if the District Court has not “issued substantive orders related to the patent at issue in the petition” (*Fintiv* Factor 3). *Id.* at 9-10.

After the District Court’s order on the motion to dismiss, Ex1032, the District Court stayed the case with respect to the ’141 patent—before the parties exchanged invalidity contentions and before the parties exchanged claim terms from the ’141 patent to be construed. Ex1034; Ex1028 at 1-2. Thus, the current list of terms to be construed by the District Court is limited to terms in the unchallenged patents. In short, the District Court has not issued substantive orders (e.g., claim construction) related to the ’141 patent (and will not).

Although Patent Owner contends that “the trial may occur around the same time as the Board’s FWD” (DD Req. at 12), that possibility is irrelevant since, most critically, the litigation is stayed with respect to the ’141 patent (and other challenged patents) and is progressing only for unrelated, unchallenged patents. Indeed, Patent

Owner concedes that no trial date has been set with respect to the '141 patent. *Id.*

Bifurcation was intentional and, according to the District Court, inevitable. Ex1034, 2 (“[I]t would be necessary to tackle this massive and complex patent infringement suit in stages regardless of the pending IPR petitions. Proceeding with the two patents for which MIM has not sought IPR is a logical way to bifurcate the case.”). Regardless of how far the litigation progresses during IPR, it will only progress with respect to the two unchallenged patents. There is no risk that the District Court will concurrently adjudicate the '141 patent.

Furthermore, Patent Owner’s trial date prediction is not only irrelevant, but also flawed. A FWD in this challenge is presently due by October 14, 2026. Meanwhile, in the district court litigation, *Daubert* and summary judgment motions will not be fully briefed until December 4, 2026. Ex1028 at 3.

Relying only on median statistics, Patent Owner speculates “the trial may occur at the end of 2026.” DD Req. at 12. It is extremely unlikely, however, that the District Court will: (i) hold hearings on the parties’ *Daubert* and summary judgment motions; (ii) announce rulings on the same; and (iii) commence a patent infringement trial, all between December 5th and December 31st. Moreover, the District Court has already signaled that the current schedule is likely to be extended, acknowledging that just completing claim construction on the two unchallenged patents will take “three to six months to write [] up.” Ex1036 at 9:13-14. Therefore,

in all likelihood, even the unchallenged patents are not likely to reach trial in the district court litigation before the Board's FWD on the '141 patent.

Patent Owner also incorrectly speculates that there will be inconsistent claim constructions if the Board institutes review of the '141 patent. DD Req. at 1-2, 10-11. Patent Owner has not identified a single term that has been identified in the Petition for construction by the Board that has also been identified for construction by the District Court. This is unsurprising, of course, since, as explained above, the District Court stayed all litigation with respect to the challenged patents before the parties exchanged lists of terms to be construed. Accordingly, there is no reason for the District Court to construe any terms of the '141 patent.

Regardless, any terms construed by the Board would be welcomed by the District Court rather than create a conflict. The District Court was clear that it "ha[s] been known to change claim constructions if [it] find[s] something persuasive" and it views the PTAB as more of an expert than the District Court with respect to these matters. Ex1036 at 9:8-11.

In all, there is no likelihood of disruption to the district court litigation if the Board institutes review.

2. Other circumstances, including the merits, favor institution.³

The Director’s “exercise of discretion [is] part of a balanced assessment of all the relevant circumstances in the case, including the merits.” *Fintiv*, IPR2020-00019, Paper 11 at 14 (*Fintiv* Factor 6). Here, several other discretionary considerations favor institution, including: (a) the merits of the Petition; (b) the lack of “settled expectations” in the ’141 patent; and (c) the lack of a national policy interest favoring denial.

a) *The merits of the Petition favor institution.*

“[I]f the merits of a ground raised in the petition seem particularly strong on the preliminary record,” this fact favors institution. *Id.* at 14-15. If the merits are a closer call, that fact favors denying institution “when other factors favoring denial

³ Here, Petitioner seeks only “to address all relevant considerations, which may include ... the strength of the unpatentability challenge,” and recognizes that a discretionary denial opposition is not “an additional opportunity for merits briefing.” USPTO, *FAQs for Interim Processes for PTAB Workload Management* (“Interim Process FAQs”) at No. 25; Mem. from Coke Morgan Stewart, Acting Under Secretary of Com. for Intell. Prop. and Acting Director of the USPTO to All PTAB Judges, *Interim Processes for PTAB Workload Management*, at 2 (USPTO Mar. 26, 2025) (“Stewart Memorandum”), <https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>. Petitioner is not providing additional or different arguments not found in the Petition. Nor would Petitioner even expect the Board to consider this particular filing in assessing the merits. Therefore, Petitioner only repeats or summarizes information here for the convenience of the reader.

are present.” *Id.* at 15 (emphasis added).

During examination, the Examiner misidentified the “closest prior art” and listed, in his reasons for allowance, claim elements not present in the closest available prior art. As detailed in the Petition, however, other prior art references, including references that were of record but not addressed by the Examiner, explicitly disclose those claim limitations the Examiner found missing in the purported “closest prior art.” Petition at 3-4, 8-9, 12-77. This fact contradicts the Examiner’s reasons for allowance and presents a strong case for unpatentability.

Accordingly, because the merits are strong and because, as discussed above, the remaining *Fintiv* factors favor institution, this factor weighs in favor of institution or is at worst neutral.

b) *Public policy favors institution.*

The Acting Director’s recent guidance memorandum encourages parties to assess the “[s]ettled expectations of the parties” and any “[c]ompelling economic, public health, or national security interests.” Stewart Memorandum at 2.

Patent Owners do not have strong “settled expectations” in patents that have been in force for less than seven years. *Cambridge Indus. USA, Inc. v. Applied Orthoelecs., Inc.*, IPR2025-00433, Paper 11 at 2-3 (PTAB June 26, 2025). “Early challenges favor robust, predictable patent rights and weigh against discretionary denial.” *Ajinomoto Co., Inc. v. Abtis Co., Ltd.*, IPR2025-00283, Paper 13 at 2 (PTAB

July 2, 2025) (“Furthermore, the challenged patent issued on February 13, 2024. ... Accordingly, Petitioner challenges the patent early in the life of the patent.”). Like the patent in *Ajinomoto*, the ’141 patent only issued in February of 2024. This factor thus weighs against discretionary denial.

There are no economic, public health, or national security interests that support a discretionary denial of the Petition. Patent Owner insinuates that the ’141 patent’s subject matter—cancer treatment improved by machine learning—should shield it from scrutiny. This argument fails. First, a patent should not be unassailable simply because it contributes to the fight against cancer in some way. If implemented, Patent Owner’s suggestion would create an unfair caste system of patents.

Second, the ’141 patent’s alleged public health benefit should encourage thorough review, not foreclose it. In the district court litigation, Patent Owner asserts the ’141 patent to remove Petitioner’s established products from the commercial market. Petitioner’s products also improve a patient’s medical scans to optimize cancer treatment. *See* DD Req. at 13-14. As a matter of policy, the Board should prioritize review of challenged patents implicating the national public health interest to ensure that patients are not wrongly prevented from accessing improved medical treatment.

Patent Owner also asserts a nebulous “presidential public health priorit[y]”

implicating “emerging technologies like artificial intelligence.” *Id.* at 14 (citation omitted). The rationales discussed above relating to public health are equally applicable to AI. At bottom, there is no compelling interest that warrants discretionary denial.

3. None of the remaining discretionary considerations warrants denial.

“[T]he determination not to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented.” *Cambridge Indus.*, IPR2025-00433, Paper 11 at 3. As demonstrated in the sections above, most of the discretionary considerations announced by the Office favor institution. The remaining considerations are fewer in number and less relevant to this dispute.

a) *Fintiv Factor 5*

The Board has weighed the fifth *Fintiv* factor in favor of discretionary denial when the IPR petitioner is also the parallel litigation defendant. *See Fintiv*, IPR2020-00019, Paper 11 at 13-14. But if “the parallel District Court proceeding is stayed, and there is not substantial overlap between the invalidity contentions and the Petition challenges,” the Board may regard *Fintiv* Factor 5 as “neutral.” *Snap, Inc. v. SRK Tech. LLC*, IPR2020-00820, Paper 15 at 16 (PTAB Oct. 21, 2020). Here, Petitioner is also the defendant in the parallel litigation. But the district court litigation is stayed with respect to the challenged patents. And due to the timing of the stay and Petitioner’s *Sotera* stipulation, there is no overlap between the invalidity

contentions in the litigation and the invalidity arguments set forth in the Petition. Therefore, this factor should be regarded as neutral.

b) *Reliance on expert testimony*

The parties are also permitted to address “[t]he extent of the petition’s reliance on expert testimony.” Stewart Memorandum at 2. But Patent Owner goes too far. Contrary to Patent Owner’s editorial revisions and incomplete quotations, the Petition clearly explains its arguments within its four corners. There is no over-reliance on expert testimony or incorporation of arguments by reference, as Patent Owner contends.

Patent Owner misrepresents the Petition, claiming that the Petition “repeatedly outsources key arguments to the expert declaration.” DD Req. at 37. Specifically—as it appears in Patent Owner’s request, but highlighted here—Patent Owner states:

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

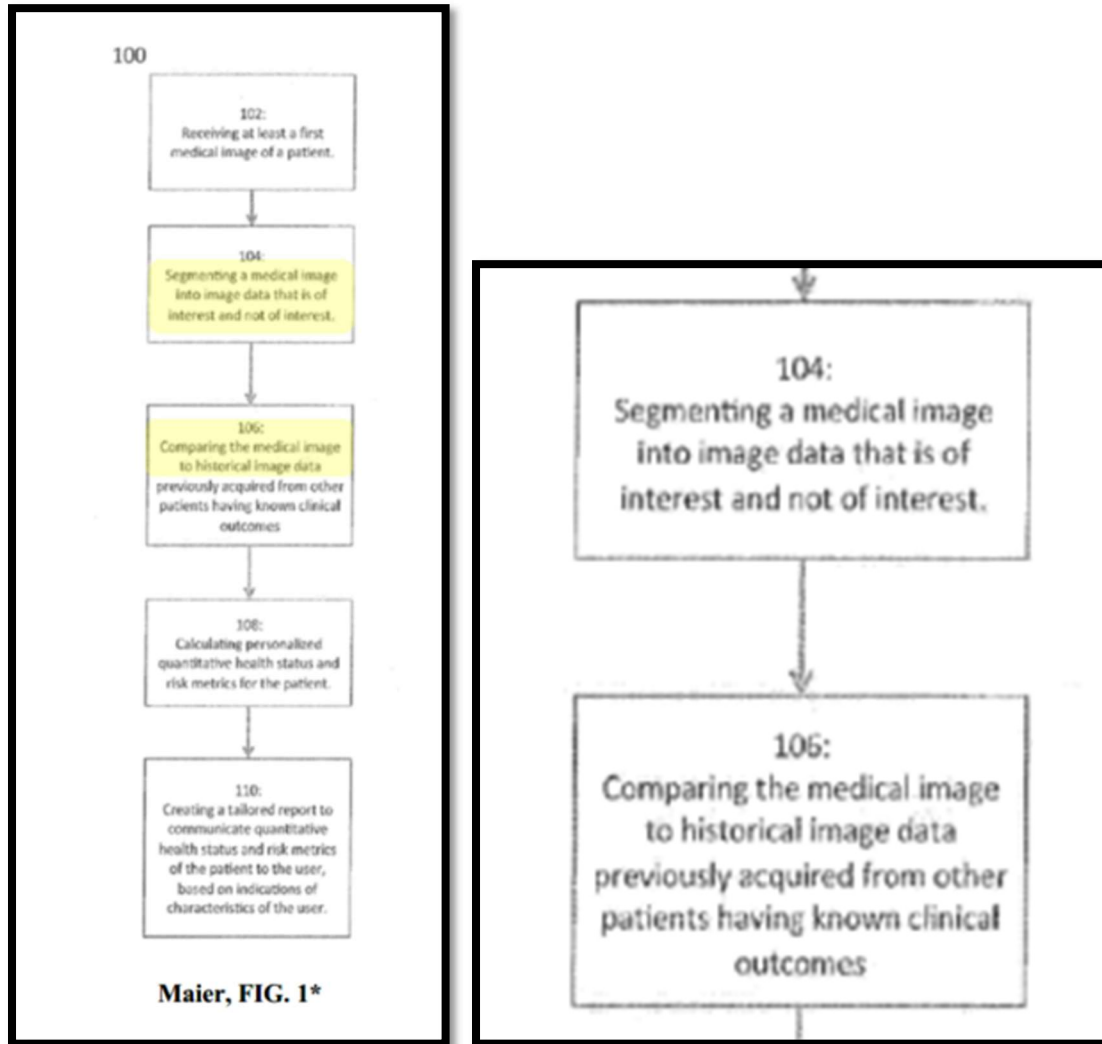
DD Req. at 38 (emphasis added by red underline)

However, the complete citation from pages 20-21 of the Petition and the accompanying analysis, as it appears in the Petition, is reproduced below to provide full context for the magnitude of Patent Owner’s misrepresentation:

- e) **[I(d)]: “(iii) automatically analyze the one or more medical images using a machine learning algorithm; and”**

Maier discloses this limitation. Ex1005, [0014], [0027], [0032]; Ex1002, ¶¶161-163. Maier’s system and method includes “receiving at least a first medical image of a patient” and “analyzing the image data of interest by comparing it to comparison image data.” Ex1005, [0027], Fig. 1 (elements 104, 106). This analysis is computer-automated. Ex1005, [0027]. Maier teaches that this comparison “may comprise... unsupervised machine learning algorithms of all varieties.” Ex1005, [0032], [0023]. This constitutes automatic analysis of the image(s) by a machine learning algorithm. Ex1002, ¶¶161-162.

Petition at 20



From left to right: Petition at 21; Maier at FIG. 1 (zoomed in)

Thus, contrary to Patent Owner’s allegation, the Petition “explain[s] why th[e] cited portions of Maier meet the claim.” DD Req. at 35. The conclusion of the excerpt above (“This constitutes automatic analysis of the image(s) by a machine learning algorithm”, Petition at 20) is supported not only by the expert declaration but by the three immediately preceding sentences (demonstrating that Maier discloses “one or more medical images,” “automatic analy[sis],” and “using a

machine learning algorithm,” respectively), as well as Figure 1 of Maier reproduced immediately following the conclusion. Patent Owner repeats these same mischaracterizations for claim 13. DD Req. at 38. Plainly, Petitioner did not simply outsource the explanation of unpatentability to the expert’s declaration.

Similarly, Patent Owner claims that, for claims 6 and 12 in Ground C, the Petition “simply assumes the reader will refer back to claim 1’s analysis for the base combination and then read the expert declaration for the rest of the explanation.” *Id.* This is a baseless accusation. First, the Petition makes clear that dependent claim 6 adds a single limitation to independent claim 1. *See* Petition at viii (“[6] The system of claim 1, wherein the nuclear medicine image is a PET scan.”) (emphasis added). Reproduced below is the Petition’s analysis of Ground C, claim 6:

D. Ground C: Maier in view of Huang and Armor, further in view of Cardinale and/or Giesel, Renders Obvious Claims 6 and 12.

1. Claim 6

The Maier-Huang-Armor combination of claim 1, further in view of Cardinale and/or Giesel, renders obvious this claim limitation. Ex1009, title, 46:44-54, 47:1-4; Ex1010, p.1929; Ex1002, ¶¶310-314. Armor teaches a “PSMA targeted radiotracer” to diagnose prostate cancer and its progression. Ex1007, [0006]. Cardinale and Giesel, which are both directed to the radiotracer ¹⁸F-PSMA-1007, expand upon this concept with “¹⁸F-tagged inhibitors of [PSMA] and their use as imaging agents for prostate cancer.” Ex1009, title; Ex1010, p.1929. Cardinale and Giesel teach using such PSMA-binding tracers in PET imaging for “primary diagnosis of prostate cancer,” Ex1009, 47:1-4, 46:44-54, and for “thera[g]nostic” treatment, for “metastatic castration-resistant prostate cancer (mCRPC),” Ex1010, p.1929; Ex1002, ¶311.

Petition at 60

Clearly, the Petition does not “assum[e] the reader will ... read the expert declaration” to understand how the references disclose the “PET scan” limitation of claim 6. DD Req. at 38. Nor does the Petition gloss over the rationale to combine as Patent Owner alleges:

a) Rationale to combine.

Teaching, suggestion, motivation

Improved tumor detection: Cardinale contrasts [¹⁸F]PSMA-1007 with “other known PSMA tracers” and reports “a very unique hepatobiliary clearance with very small clearance via the renal pathway,” Ex1009, 46:63-67, and Giesel praises ¹⁸F-PSMA-1007 PET scans as part of a “perfect theragnostic tandem” with ¹⁷⁷Lu-PSMA-617, Ex1010, p.1929 (describing staging with the former before treatment with the latter). Ex1002, ¶311. Giesel further praises ¹⁸F-PSMA-1007’s longer half-life (110 minutes compared to 68 minutes) and “the possibility for large-scale production [with higher activity] in a cyclotron.” Ex1010, 1929; Ex1002, ¶312. According to Cardinale, ¹⁸F-PSMA-1007 is “perfectly suited for the primary diagnosis of prostate cancer and local recurrence” and “showed a great potential as possible tracer for the detection of prostate cancer and its metastases.” Ex1009, 47:1-4, 46:44-54.

More accessible compound: Armor discloses ^{99m}Tc-labeled anti-PSMA inhibitors, Ex1007, [0056], but does not speak to the availability of its specific compounds. In contrast, Giesel teaches that ¹⁸F-PSMA-1007 can be produced at large-scale with high activity and “the half-life... would allow both late imaging beyond 1 h after injection and shipping to satellite institutions.” Ex1010, p.1929. Thus, in an environment where Armor’s specific compounds are not available, a

POSITA would be motivated to substitute Armor's specifically disclosed SPECT/CT imaging based on ^{99m}Tc-labeled PSMA-binding agents with Giesel's (and Cardinale's) PET/CT imaging based on ¹⁸F-PSMA-1007. Ex1002, ¶312.

- **Reasonable expectation of success**

A POSITA would have had a reasonable expectation of success in combining the Cardinale/Giesel imaging agent with the Maier-Huang-Armor combination. Ex1002, ¶313. Like Maier-Huang-Armor, Cardinale and Giesel are directed to the field of medical image processing, and describe functional imaging which occurs after administration of a physiological imaging agent – in Cardinale/Giesel, after a PSMA-binding agent. *E.g.*, Ex1009, 46:44-54; Ex1010, p.1929. Armor expressly states that “a PSMA targeted radiotracer would be an ideal imaging agent for diagnosis of prostate cancer and to evaluate the extent of disease progression in a subject harboring prostate cancer,” Ex1007, [0006], and Giesel indicates that “¹⁸F-PSMA-1007 is [] a promising alternative to ⁶⁸Ga-PSMA-11 for diagnostic purposes.” Ex1010, p.1929. *See also* Ex1009, 46:44-54, 47:1-4.

Therefore, Maier in view of Huang and Armor, further in view of Cardinale and/or Giesel, renders obvious claim 6.

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The Petition clearly explains, through multiple paragraphs, the advantages of Cardinale and Giesel compared to the combination of Maier, Huang, and Armor in claim 1. *Id.* And the Petition describes, in detail, why a POSITA would combine Cardinale and Giesel with Maier, Huang, and Armor. *Id.* Patent Owner's assertion

that the Petition “outsources” arguments to the expert declaration is demonstrably false. DD Req. at 37.

Patent Owner does not stop there. It also wrongly asserts that “Petitioner effectively outsources the actual (and required) claim mapping to the expert’s 211-page declaration.” *Id.* at 38-39 (citing Petition at 45 (analyzing claim element [13(a)])). This accusation is plainly untrue. Both immediately before, and immediately after, the citation to the expert’s declaration about which Patent Owner complains, the Petition sets forth *where—specifically—in the Petition* the pertinent analysis can be found. For convenience, the relevant passages/pages of the Petition are reproduced below:

8. Claim 13

a) **[13(a)]: “The system of claim 1, wherein the instructions cause the processor to... compute the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region; and”**

The Maier-Huang-Armor combination of claim 1 renders obvious this claim limitation. Ex1005, [0021]; Ex1006, [0009], [0114]; Ex1007, [0064], [0066]; Ex1002, ¶¶221-224. *See also* Section VIII.B.1.j). First, Huang teaches that SUV values above a specific threshold are used to generate hotspot candidates in regions, such as organs or tissues, Ex1006, [0114], and that maximum SUV values

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Petition at 44

are used to grade tumors, Ex1006, [0009]. Similarly, Armor teaches that uptake levels and T/B ratios of its compounds can be used to determine the presence and extent of prostate cancer. Ex1007, [0064]. A POSITA would have recognized that those are determined from intensity values of the nuclear medicine image, and from within the 3D boundary of, e.g., an organ, as previously explained. Ex1002, ¶¶222-223.

Rationale to combine: The reasons to combine have been explained in the context of limitation [1(i)]. Ex1002, ¶222; Section VIII.B.1.j).

Petition at 45

The Petition clearly does not outsource the claim mapping to the expert declaration; instead, it is referring back to a previous analysis within the Petition. The expert declaration merely reinforces the Petition's conclusion.

At bottom, the Petition supports its arguments within its four corners. The citations to the expert declaration merely underscore the strength of its arguments, especially with respect to what a POSITA would have understood at the time of the invention. This discretionary factor, once properly considered without Patent Owner's misleading arguments and edits, is neutral or otherwise weighs against discretionary denial.

c) *Prior adjudication of validity*

A final consideration is whether “[t]he PTAB or another forum has already

adjudicated the validity or patentability of the challenged patent claims.” Stewart Memorandum at 2. Here, no forum has determined the validity of the ’141 patent’s claims under 35 U.S.C. §§ 102-103 or otherwise made a final determination on its validity. Petitioner did move to dismiss Patent Owner’s ’141 patent cause of action for claiming ineligible subject matter under § 101. Ex1032 at 2. The District Court concluded that Patent Owner “plausibly alleges ... an inventive concept.” *Id.* at 26. But due to the procedural posture of that motion, the District Court was forced to accept as true “the allegations in the [Second Amended Complaint].” *Id.* at 25. Because the District Court’s ruling was non-final—and more importantly, because it did not concern the legal bases relied upon in the Petition—this factor should remain neutral, or else weigh against discretionary denial.

4. Recent Director decisions show that the Petition should advance to the Board.

Ultimately, this Petition is similar to many others in which the Acting Director has recently concluded that discretionary denial was inappropriate. For example, in *Resmed Corp. v. Cleveland Medical Devices, Inc.*, the Acting Director denied the patent owner’s request because “the district court proceeding involving the challenged patents has been stayed” and because of “the early challenges to the patents at issue.” IPR2025-00246, Paper 10 at 2 (PTAB June 12, 2025). Because the District Court in this dispute has stayed proceedings with respect to the challenged patents, which were all recently issued, the Acting Director should likewise refer the

Petition to the Board for consideration on the merits.

In *Imperative Care, Inc. v. Inari Medical, Inc.*, the Acting Director denied the patent owner's request because "there is no trial date scheduled in the district court," "the district court is likely to grant a stay if this proceeding is instituted," and "the challenged patent issued recently." IPR2025-00289, Paper 9 at 2 (PTAB June 12, 2025). The Petition presents even more favorable circumstances than those in *Imperative Care* because the District Court has granted a stay.

This case is also similar to *Cambridge Industries*, IPR2025-00433, Paper 11 (PTAB June 26, 2025). There, the Acting Director determined that discretionary denial of institution was not appropriate because "[t]here is no currently scheduled trial date," "[t]he District Court further vacated the scheduled Markman hearing," and "Patent Owner does not identify any portions of the expert testimony that suggest Petitioner is using its expert to fill gaps in the prior art." *Id.* at 2. Here, there is no scheduled trial date, and the District Court has vacated the *Markman* hearing for the '141 patent and all of the other challenged patents. And while Patent Owner asserts that the Petition "repeatedly outsources key arguments to the expert declaration," DD. Req. at 37, as in *Cambridge Industries*, Patent Owner here points to no portions of the expert declaration that suggest Petitioner is using that declaration to fill gaps in the prior art. *See id.* at 37-41. Thus, for the same reasons as those in *Cambridge Industries*, the Acting Director should decline Patent Owner's

request for discretionary denial.

In sum, the discretionary denial considerations quantitatively and qualitatively weigh in favor of advancing the Petition to the Board for consideration on the merits.

B. The Petition presents new arguments and evidence of material error made during prosecution.

Under the new bifurcated institution process, “[a] petitioner should raise any discretionary issues in its opposition ... including issues relating to 35 U.S.C. § 325(d).” Interim Process FAQs at No. 24; *see also* Stewart Memorandum at 2 (“discretionary considerations” include “*Advanced Bionics*”). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential), provides a two-part framework for evaluating whether denial under section 325(d) is warranted: “(1) whether the same or substantially the same prior art or argument previously was presented to the Office; and (2) if the first part is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 3 (PTAB May 19, 2025) (precedential). If the first inquiry is not satisfied, proceeding to the second inquiry is unnecessary, and discretionary denial under § 325(d) should be declined. *See, e.g., Howard Indus., Inc. v. CAPSA Sol’s LLC*, IPR2023-01275, Paper 9 at 45 (Feb. 26, 2024) (“[W]e find that the same or substantially the same art or arguments were not presented to the Office during prosecution Consequently,

we do not reach the second prong of the *Advanced Bionics* framework...”).

Although some of the individual prior art references presented in this challenge were “of record” during prosecution, and therefore presumptively “considered” by the Examiner, none of these references was substantively addressed during prosecution. Instead, the Examiner discussed two other references, Wu and Zhao, as being the “closest prior art” while at the same time acknowledging that these references fail to teach many of the patent’s claim limitations. Ex1004 at 278-79. Because the Office overlooked the most relevant prior art and failed to address obvious combinations of the most pertinent references, it erred in a manner material to the patentability of the claims. Accordingly, the Petition should advance to the Board for consideration on the merits.

1. The Petition presents new prior art and argument.

The *Becton, Dickinson* factors provide useful insight into how to apply the framework under § 325(d). *Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (informative; precedential as to § III.C.5, First Paragraph). The following *Becton, Dickinson* factors provide guidance as to whether the art or argument presented in the petition are the “same or substantially the same”:

- the similarities and material differences between the asserted art and the prior art involved during examination (factor (a));

- the cumulative nature of the asserted art and the prior art evaluated during examination (factor (b)); and
- the extent of overlap between the arguments made during examination and the manner in which the petitioner relies on the prior art (factor (d)).

Id. at 9-10 & n.10. The parties agree that the Petition presents four new prior art references not considered during prosecution. *See* DD Req. at 19. The Petition also relies on primary prior art references that were not substantively addressed by the Examiner or Applicant in any argument made during prosecution. Accordingly, the *Becton, Dickinson* factors inform whether the Petition presents “substantially the same prior art or arguments.” *Id.*

a) *The Petition presents entirely new arguments of invalidity.*

The factor that is most relevant here is *Becton, Dickinson* factor (d), which considers whether the Examiner previously relied on the prior art in the same manner asserted by the Petitioner. *Becton, Dickinson*, IPR2017-01586, Paper 8 at 23. The Examiner made no rejections during prosecution. *See* Ex1004. In the Examiner’s Notice of Allowance and reasons for same, the Examiner made an amendment to the claims based on the purported “closest prior art of record (WU and Zhao).” *Id.* at 278. Following amendment, the Examiner concluded that Wu and Zhao failed to teach or suggest, “among other things,” the following limitations of the independent claims:

- “automatically analyze the one or more medical images using a machine learning algorithm;” (element [1(d)])
- “generate a radiologist report for the particular patient[;]” (element [1(e)])
- “wherein the one or more medical images comprise a composite image of the particular patient, comprising a CT scan ‘overlaid with a nuclear medicine image’ obtained at a same time as the CT scan” (element [1(f)])
- “and following administration to the patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide,” (element [1(g)])
- “wherein the instructions cause the processor to automatically analyze the composite image by: using the ‘composite image’ to geographically identify a ‘3D boundary’ for each of one or more regions of imaged tissue within the nuclear medicine image;” (element [1(h)])
- “computing, using the nuclear medicine image with the identified 3D boundary of the one or more region, a value of each of one or more risk indices, each risk ‘index value’ indicative of cancer state or progression in the patient[;]” (element [1(i)]) and
- “wherein the system is a cloud-based system” (element 1[(j)]).

See id. at 278-79; Petition at 8. The Examiner did not discuss any other prior art in the Reasons for Allowance.

The Petition does not rely on Wu or Zhao at all, as the Examiner did. Instead, Petitioner argues that several other references—namely, Maier, Huang, and Armor—teach the elements the Examiner found missing in Wu and Zhao. *See, e.g.*, Petition at 20-23, 39-40 (Maier discloses elements [1(d)], [1(e)], and [1(j)]); 23-27, 31-39 (Huang discloses elements [1(f)], [1(h)], and [1(i)] and reasons to combine with Maier and Armor); 27-31, 38-39 (Armor discloses elements [1(g)] and [1(i)] and reasons to combine with Maier and Huang). Therefore, the Petition does not present the same or substantially the same arguments.

b) *The Petition introduces non-cumulative, materially different prior art.*

Patent Owner contends that “every ground of the Petition is based on the same prior art that was presented to the Office, considered, and overcome during prosecution.” DD Req. at 15. Not so. Not only does the Petition present new combinations of prior art not previously addressed, but the Petition also introduces four new prior art references. *See, e.g., Verizon Connect Inc. v. Omega Patents, LLC*, IPR2023-01162, Paper 12 at 14 (PTAB Feb. 21, 2024) (“[A]lthough we agree that Flick ’885 was previously presented to the Office, we determine that the combination of Flick ’885 and Flick ’561 was not previously presented. Consequently, we determine that the same or substantially the same prior art or arguments were not previously presented to the Office, and we decline to exercise our discretion under § 325(d) to deny institution of trial.”). These references make

up more than half of the Petition's grounds and are asserted against ten of the '141 patent's claims. *See* Petition at 9. This is a material difference from the art and arguments actually addressed during prosecution.

Patent Owner never asserts (because it cannot) that the Petition's primary prior art references, Maier and Huang, are cumulative of the only prior art reference substantively addressed by the Examiner—Wu. Patent Owner only contends that the Petition's new prior art references—"Neumaier," "Cardinale," "Giesel," and "Weineisen"—are cumulative of two prior art references that were of record during prosecution, Armor and "Rowe." DD Req. at 19-20. They are not cumulative, and Patent Owner provides no analysis or evidence to demonstrate that they are. Petitioner cannot be asked to prove a negative when Patent Owner has not even attempted to show where Armor and Rowe disclose the same features for which Petitioner's new references are cited against the claims.

Accordingly, the Petition does not present the same, or substantially the same, prior art or arguments. Nevertheless, Petitioner also addresses the second prong of *Advanced Bionics*.

2. The Petition presents new arguments of material Examiner error.

If a petition relies on the same or substantially the same prior art already considered by the Examiner, then at step (ii) of the *Advanced Bionics* framework, the petitioner must explain how the Examiner erred. As recently held, and as is

directly relevant here: “A petitioner may argue it satisfies the second part of *Advanced Bionics* because the asserted art was not a basis for rejection during examination, is not substantially the same as prior art the Examiner applied, and includes specific teachings that impact patentability of the challenged claims.” *Ecto World*, IPR2024-01280, Paper 13 at 5 (internal quotations omitted). “A petitioner may also point to the fact that even though the asserted prior art is listed on an IDS, the Examiner did not issue any prior art rejections during examination, so the Examiner materially erred by overlooking certain teachings in the prior art on the IDS.” *Id.* at 5-6. “[T]he Board should consider a petitioner’s argument based on the volume of references submitted to the Office during examination and any applicant information or assistance regarding the relevance of references.” *Id.* at 6-7.

Even if the Petition did present substantially the same prior art (which it does not), it also supports a finding of material error during examination. Maier, Huang, and Armor were all of record during prosecution, yet the Examiner did not issue any prior art rejections during examination. This was material error by the Examiner because, as already explained above, the Petition demonstrates, element-by-element, how these references render the claims obvious and are substantially different than Wu or Zhao—at the very least because they disclose the specific claim elements the Examiner found missing from Wu and Zhao. *See, e.g.*, Petition at 3-4 (explaining the Examiner’s error), 20-23, 39-40 (Maier discloses elements [1(d)], [1(e)], and

[1(j)]; 23-27, 31-39 (Huang discloses elements [1(f)], [1(h)], and [1(i)] and reasons to combine with Maier and Armor); 27-31, 38-39 (Armor discloses elements [1(g)] and [1(i)] and reasons to combine with Maier and Huang).

Patent Owner offers a strawman argument stating: “The Petition argues that the Examiner erred because he could or should have cobbled together the teachings of Wu and Zhao (i.e., the primary references cited in the Notice of Allowance but which are not asserted by the Petition) with Maier, Huang, and Armor to arrive at the claimed invention” DD Req. at 21 (emphasis added). Petitioner makes no such argument. As pointed out above, Petitioner does not rely on Wu or Zhao in any way. Instead, as explained above, the Petition relies on Maier, Huang, and Armor because they disclose all elements of the representative claims, including the features the Examiner explicitly found were not present in the purported “closest prior art,” Wu and Zhao. The Examiner’s error is evident by his statement that Wu and Zhao are the closest prior art when they are not.

The Director should also consider Patent Owner’s submission of more than 260 references via IDS in the determination of whether the Examiner overlooked the most material prior art. As the Board has recognized, “only 4% of applications contain more than 200 applicant-provided items of information.” *Ecto World*, IPR2024-01280, Paper 13 at 7 n.3 (citing 89 FR 91898, at 91924 (Nov. 20, 2024)). Patent Owner provided 261 references via four Information Disclosure Statements.

See Ex1004 at 176-87, 193, 199, 207. Patent Owner never attempted, however, to identify the closest reference(s) in any of these submissions. *See id.* at 191-92, 197-98, 205-06, 213-14. The fact that Patent Owner submitted a large volume of references, many times greater than the average, without attempting to highlight the most relevant references for the Examiner to consider weighs against discretionary denial. *See Ecto World*, IPR2024-01280, Paper 13 at 7. Even though some of the asserted prior art is presumed to have been considered by the Examiner, there is no evidence, due to the lack of rejections, that the Examiner ever appreciated the significance of all the disclosed prior art references.

3. Petitioner’s § 325(d) arguments are appropriately briefed for the first time in its discretionary denial opposition.

The Office has made clear that a petitioner should not address discretionary issues in its petition. Interim Process FAQs at No. 24 (“A petitioner should raise any discretionary issues in its opposition to a patent owner’s discretionary denial brief, including issues relating to 35 U.S.C. § 325(d)[.]”).

Patent Owner complains that the Petition fails to carry its burden under *Advanced Bionics*. *See* DD Req. at 21. This is both an untrue factual statement (for the reasons discussed *supra* Sections III.B.1-III.B.2) and an untrue legal statement. The Petition properly argues how the Examiner materially erred by not rejecting the challenged claims for at least the five grounds asserted. Now, Petitioner’s discretionary denial opposition brief properly explains how these arguments satisfy

the *Advanced Bionics* framework.

Accordingly, discretionary denial under § 325(d) is not appropriate, and the Petition should advance to the Board for consideration on the merits.

C. The Petition satisfies all statutory and regulatory requirements.

Patent Owner argues that institution should be denied because “the Petition fails to meet the particularity requirements of 35 U.S.C. § 312(a)(3).” DD Req. at 23 (heading for Section II.C). The Office recently clarified that this “particularity” requirement is evaluated by the Board panel in the second phase of the new bifurcated institution process, i.e., during the merits and non-discretionary phase. *See* Interim Process FAQs at Nos. 10-11.

Because Patent Owner’s arguments regarding particularity are inappropriate at this stage, they should not be considered. Regardless, because the Petition satisfies the particularity requirements, it should be advanced to the Board for consideration on the merits.

1. During discretionary review, the Director should disregard Patent Owner’s arguments regarding non-discretionary factors.

The Board’s new review process bifurcates between (i) discretionary considerations and (ii) merits and other non-discretionary considerations. Interim Process FAQs. At step (i), “[p]arties are encouraged to address any fact or circumstances they believe bears on the Director’s discretion to institute[.]” *Id.* at No. 11 (emphasis added). If the Director does not discretionarily deny the Petition,

a panel of the Board will prepare an institution decision “on the merits and other non-discretionary considerations.” *Id.* at No. 10 (emphasis added). Non-discretionary considerations include (i) statutory requirements under 35 U.S.C. §§ 311, 312, 315(a), (b), and (e), 322, and 325(a) and (e); (ii) regulatory requirements under 37 C.F.R. § 42.104(b); and (iii) “claim construction issues.” *Id.* at No. 11. “Parties must make all their arguments ... on the merits and other non-discretionary considerations in the petition [or] POPR[.]” *Id.* at No. 12; *see also id.* at No. 25 (“The parties should not treat a discretionary denial brief or opposition as an additional opportunity for merits briefing.”). Extensive briefing on the merits or non-discretionary factors blurs the line between the two stages and undermines the rationale behind the bifurcated review process.

Patent Owner argues that institution should be discretionarily denied because of “the particularity requirements of 35 U.S.C. § 312(a)(3).” DD Req. at 23 (heading for Section II.C); *see also, e.g., id.* at 24 (citing § 42.104(b)(4)). Sections 312(a)(3) and 42.104(b) are non-discretionary considerations. Interim Process FAQs at No. 11. Because Sections II.C.1-II.C.2 (*see* DD Req. at 23-36) of Patent Owner’s request are directed to non-discretionary considerations—in contravention to the Office’s instructions—they should be disregarded.

2. The Petition satisfies all statutory and regulatory requirements.

A petition for *inter partes* review must identify “with particularity, each claim

challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b). This statutory requirement requires the Petition to be “reasonably bounded in scope” and not “unduly burdensome for both Patent Owner and the Board.” *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 at 21 (PTAB Mar. 6, 2019) (informative). The Petition satisfies these requirements.

- a) *The Petition is reasonably bounded in scope and imposes no undue burden on the Office or Patent Owner.*

Patent Owner goes to great lengths in its request to try to make the grounds presented in the Petition seem complicated. In reality, they are quite simple. As summarized in the chart below, the Petition asserts two “primary” references: Maier and Huang. Petition at 9; *see supra* Section III.A.2.a). The grounds progress from one primary reference to the next. *See* Petition at 9, 17-74. With respect to the Maier-based challenges, Ground A renders obvious six independent claims and several of their dependent claims. *Id.* at 9. Grounds B and C introduce additional secondary references to provide alternate bases of invalidity for certain claims as well as rendering obvious additional dependent claims. The same pattern follows for the Huang-based challenges: Ground D renders obvious two independent claims and Ground E introduces new secondary references to render obvious additional dependent claims. With only five total grounds, it is hard to understand Patent Owner’s complaint that the Petition is unduly burdensome and not reasonably

bounded in scope:

Ground	Prior Art	Claims Challenged
A	Maier in view of Huang and Armor	1-3, 6-9, 13-26, 32-35
B	Maier in view of Huang and Armor, in further view of Neumaier	6-11
C	Maier in view of Huang and Armor, further in view of Cardinale and/or Giesel	6, 12
D	Huang in view of Armor and Maier	27, 31
E	Huang in view of Armor and Maier, further in view of Giesel and Weineisen	28-30

Petition at 9

Nor does the Petition “overindulge[] in internal cross-referencing” as Patent Owner contends. DD Req. at 32. Patent Owner’s argument on this point is internally inconsistent. For example, Patent Owner concedes that “in Ground A (Maier, Huang, and Armor), Petitioner addresses claims [] 6-9[.]” *Id.* at 33 (emphasis added). But Patent Owner takes issue with claims 6-9 in Ground B (Maier, Huang, Armor, and Neumaier), arguing that the Petition “simply state[s] that prior art discloses a limitation without explanation or elaboration.” *Id.* at 36. But Ground B is clearly a continuation of Ground A which simply adds an additional secondary reference to address a limited group of dependent claims. *See* Petition at 9; *see also, e.g., id.* at 56 (Ground B, claim 6) (“The Maier-Huang-Armor combination of claim 1, further in view of Neumaier, renders obvious this claim limitation.”) (emphasis added). Thus, the Petition is not making an assertion without explanation or elaboration; it

is simply directing the Board back to the section where the same argument has already been made. Apparently, Patent Owner’s complaint is that Ground B uses an internal cross-reference rather than copying and pasting the same argument twice. This does not create ambiguity or a lack of particularity and does not weigh in favor of discretionary denial.

Patent Owner also claims the Petition gives “vague and cursory treatment” of claims 32-35. DD Req. at 33. Not so. It is beyond reasonable dispute that claims 32-35 contain the bulk of the limitations present in claim 1. For example, elements [1(pre)]-[1(i)] are identical to elements [32(pre)]-[32(i)] and [33(pre)]-[33(i)]. *Compare* Petition at vii *with id.* at xiv-xv. The additional limitation of claim 32 not found in claim 1 (i.e., [32(j)]) is identical to the additional limitation in dependent claim 2:

[32(j)]	<i>and wherein the plurality of medical images in the database comprise a series of medical images of a first patient taken over time, and wherein the instructions cause the processor to determine a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index for the first patient over time.</i>
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Petition at xiv (claim 32)

Claim 2	
[2]	<i>The system of claim 1, wherein the plurality of medical images in the database comprise a series of medical images of a first patient taken over time, and wherein the instructions cause the processor to determine a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index for the first patient over time.</i>

Petition at vii

Similarly, the additional limitation of claim 33(j) is substantially identical to the additional limitations in dependent claim 13:

[33(j)]	<i>and wherein, for at least one particular risk index of the one or more risk indices, the instructions cause the processor to compute the value of the particular risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region; and computing the value of the particular risk index based on the determined cancerous tissue levels within the one or more regions.</i>
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Petition at xv (claim 33)

Claim 13 [13]	
[13(a)]	<i>The system of claim 1, wherein the instructions cause the processor to, for at least one risk index of the one or more risk indices, compute the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region; and</i>
[13(b)]	<i>computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.</i>

Petition at viii

As the Petition analyzes in depth, claims 1, 2, and 13 are rendered obvious by Maier, Huang, and Armor. Petition at 54-55; *see also id.* at 12-38, 40, 44-45. Therefore, instead of repeating the exact same arguments, the Petition presents a concise table to clearly point the reader to the previous analysis, on an element-by-element basis. *Id.* at 55-56.

The same analysis holds for claims 34 and 35. Claim 34 is substantially identical to claim 32 except for being presented as a computer-implemented method. *Compare* Petition at xiv (claim 32) *with id.* at xv-xvi (claim 34). Likewise, claim 35 is substantially identical to claim 33. *Compare id.* at xiv-xv (claim 33) *with id.* at xvi-xvii (claim 35). The Petition makes clear that this minor difference does not affect its analysis of these method claims. *Id.* at 54-55. Therefore, the Petition properly provides an element-by-element cross-reference to the Petition’s earlier analysis, rather than needlessly repeat the exact same argument twice. *Id.* at 55-56.

b) *The Petition addresses each element of each claim with particularity.*

The petitioner must identify “with particularity”: (i) each claim challenged, (ii) the grounds on which the challenge to each claim is based, and (iii) the prior art evidence supporting each ground. *See* 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b). Prior art “need not satisfy an *ipsissimis verbis* test.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

First, the Petition identifies each challenged claim with particularity. Second, a table preceding the detailed discussion of invalidity clearly maps the relationship between each ground and the claims challenged under that ground. *See* Petition at 9; *supra* Section III.C.2.a). Third, the prior art constituting each ground is also identified with particularity, and the location in the prior art where each claim

element can be found is addressed element-by-element throughout the Petition. *See supra* Section III.C.2.a).

Apparently focusing on Section 312(a)(3)'s third requirement, Patent Owner spends much time critiquing the Petition's argument on an element-by-element basis. *See* DD. Req. at 27-31. This is a poorly disguised attack on the merits, which is not appropriate during the discretionary denial briefing. Interim Process FAQs at No. 25; *see, e.g.*, DD Req. at 27-28 (whether Maier discloses "accessing ... from the database"); 28-29 (whether Huang discloses a "CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan" or "geographically identifying a 3D boundary"); 29-30 (whether Maier or Huang compute "one or more risk indices"); 30-31 (whether Maier discloses a "processor"); 31 (whether Huang discloses the preamble of claim 27).⁴

Because the Petition clearly delineates between its grounds and provides particularized reasons why each combination of references renders obvious each element of every challenged claim, the Petition should proceed to the Board for a determination on the merits.

⁴ Furthermore, Patent Owner's merits analysis focuses on basic elements of a computer-implemented system—like a "processor" and "database"—which likely cannot be reasonably disputed.

IV. CONCLUSION

The Petition, which addresses prior art not previously considered by the Office, for a patent for which litigation has been stayed pending IPR, is precisely the type of Petition that the Board should prioritize for review. The Office's discretionary considerations—including *Fintiv*, *Advanced Bionics*, and the Acting Director's latest guidance—all lead to this conclusion. Meanwhile, Patent Owner inappropriately blurs the line between discretionary and non-discretionary considerations, and attempts to manufacture controversies around claim construction, trial dates, and expert testimony. For the foregoing reasons, Patent Owner's request should be denied, and this Petition should be advanced to the Board for further consideration on the merits.

Date: July 15, 2025

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

Pursuant to 37 C.F.R. § 42.24(a)(1)(i), I hereby certify that this paper includes 10,001 words. In accordance with 37 C.F.R. § 42.24(a)(1), this word count does not include a count of the words in 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, or claim listing. Furthermore, in accordance with 37 C.F.R. § 42.24(d), this word count is the word count based on a manual calculation of all words in any reproduced images or figures (1,382 words) in addition to the calculation from the word-processing system used to prepare the paper (8,619 words).

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2025, I served a true and correct copy of the following materials:

- Petitioner's Opposition to Patent Owner's Request for Discretionary Denial;
- Exhibits 1031 to 1032 and 1034 to 1040 (there being no 1033); and
- Petitioner's Updated Exhibit List

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