

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.

EXINI DIAGNOSTICS AB
Patent Owner

Inter Partes Review No.: IPR2025-00827

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

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Ex1003	Dr. Rosen Curriculum Vitae
Ex1004	Prosecution History File of the Patent (Application No. 18/127,991)
Ex1005	U.S. Patent Application Publication No. 2012/0123253 (“Renisch”)
Ex1006	U.S. Patent Application Publication No. 2011/0007954 (“Suehling”)
Ex1007	U.S. Patent No. 10,140,544 (“Zhao”)
Ex1008	U.S. Patent Application Publication No. 2018/0144828 (“Baker”)
Ex1009	Eiber, “Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE): Proposed miTNM Classification for the Interpretation of PSMA-Ligand PET/CT,” <i>The Journal of Nuclear Medicine</i> 59(3):469-478 (March 2018) (“Eiber”)
Ex1010	U.S. Patent Application Publication No. 2010/0032575 (“Iagaru”)
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Ex1014	U.S. Patent No. 8,855,387 (“Hamadeh”)
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 Transactions on Medical Imaging</i> 35(5):1153-1159 (May 2016) (“Greenspan”)
Ex1018	Litjens, “A Survey on Deep Learning in Medical Image Analysis,” <i>Medical Image Analysis</i> 42:60-88 (Dec. 2017) (“Litjens”)
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Ex1020	Gandaglia, “Distribution of metastatic sites in patients with

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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	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).
Ex1034	Order on Motion to Stay, <i>Progenics Pharms., Inc. v. MIM 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> , IPR2025-00827, Paper 5 (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).
Ex1041	Corporate Disclosure Statement, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 3 (D. Mass. Feb. 23, 2024).
Ex1042	Corporate Disclosure Statement, <i>Progenics Pharms., Inc. v. MIM Software Inc.</i> , Case No. 1:24-cv-10437-PBS, Dkt. 4 (D. Mass. Feb. 23, 2024).

I. INTRODUCTION

Petitioner, MIM Software Inc. (“Petitioner”), respectfully requests the Director to advance IPR2025-00827 to the Board for consideration on the merits and deny the request of Patent Owner, EXINI Diagnostics AB (“Patent Owner”), for discretionary denial. IPR2025-00827 is closely related to IPR2025-00630, IPR2025-00725, and IPR2025-00726, each of which the Director recently advanced to the Board after rejecting substantially identical requests for discretionary denial. *See, e.g.*, IPR2025-00630, Paper 13. The Patent Owner’s request for discretionary denial of IPR2025-00827 should be denied for the same reasons. Nevertheless, for completeness, and to avoid any argument of procedural default, Petitioner responds fully to Patent Owner’s request 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. 11,941,817 (“the ’817

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 ’817 patent remains frozen in its 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 ’817 patent pending the Board’s resolution. Ex1033 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 validity while demonstrating that the Examiner overlooked and/or did not appreciate the most pertinent prior art, instead citing far less relevant art as being “the closest prior art.” Ex1004 at 323.

Additionally, the discretionary considerations announced by Acting Director

¹ The District Court stayed the parties’ case with respect to the ’817 patent as well as U.S. Patent Nos. 10,665,346 (IPR2025-00630), 11,424,035 (IPR2025-00725), and 11,894,141 (IPR2025-00726).

Stewart further illustrate the appropriateness of PTAB review. The '817 patent is newly issued and 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 apparently just 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 1.² Shortly after it

² The district court litigation involves the '817 Patent and three other challenged patents at issue in IPR2025-00630, IPR2025-00725, and IPR2025-00726, (*cont'd*)

was announced that Petitioner would be acquired by GE HealthCare, Patent Owner accused Petitioner of infringing seven patents, including the challenged patents. Ex1013 at 17-18, 67-74; *see also* Ex1039, Ex1040. In June of 2024, Petitioner moved to dismiss all claims under Rule 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 applicable statutory 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

respectively. Progenics Pharmaceuticals, Inc. is the patent owner in each of these related IPRs. Patent Owner and Progenics Pharmaceuticals, Inc. are owned by the same parent corporation and are co-plaintiffs in the district court litigation. Ex1041, Ex1042.

date been set. Ex1033 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, 7:7-12.³ 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

³ The District Court distinguished itself from “that speedy docket ... in Texas.” *Id.* at 10:2.

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.

On July 14th, 2025, the Acting Director referred Petitioner’s petitions affecting the other challenged patents to the Board for consideration on the merits. IPR2025-00630, Paper 13 at 3 (PTAB July 24, 2025); IPR2025-00725, Paper 12 at 3 (PTAB July 24, 2025); IPR2025-00726, Paper 13 at 3 (PTAB July 24, 2025).

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
<i>Fintiv</i> Factor 1: whether the District Court granted a stay.	<i>Fintiv</i> Factor 5: whether the petitioner and the defendant in the parallel

	proceeding are the same party. (neutral)
<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).	
<i>Fintiv</i> Factor 3: investment in the parallel proceeding by the District Court and the parties.	
<i>Fintiv</i> Factor 4: overlap between issues raised in the petition and in the parallel proceeding.	
<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; • reliance on expert testimony. 	<p><i>Fintiv</i> Factor 6: other circumstances, including:</p> <ul style="list-style-type: none"> • 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. Ex1034 at 1-2.

a) *The District Court does not have the capacity to adjudicate each 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); *see also* 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 '817 patent. Ex1034 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 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 '817 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; Ex1033 at 1. Therefore, 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 9. Furthermore, if the Board institutes review of the '817 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 IPR2025-00726. 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 and will only be 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 District 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 ’817 patent—before the parties exchanged invalidity contentions and before the parties exchanged claim terms from the ’817 patent to be construed. Ex1034; Ex1033 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 ’817 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 11), that possibility is irrelevant since, most critically, the District Court litigation is stayed with respect to the ’817 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 ’817 patent. *Id.*

Bifurcation was intentional and, according to the District Court, inevitable. Ex1034 at 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 '817 patent.

Furthermore, Patent Owner's trial date prediction is not only irrelevant, but also flawed. A FWD in this challenge is presently due by November 7, 2026. Meanwhile, in the district court litigation, *Daubert* and summary judgment motions will not be fully briefed until December 4, 2026. Ex1033 at 3.

Relying only on median statistics, Patent Owner speculates "the trial may occur at the end of 2026." DD Req. at 11-12. 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 '817 patent.

Patent Owner also incorrectly speculates that there will be inconsistent claim constructions if the Board institutes review of the '817 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 '817 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.⁴

⁴ 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, <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>; 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-PTAB> (cont’d)

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

The ’817 patent describes systems and methods for automatically processing 3D images to automatically identify cancerous lesions within a subject. Petition at 3. These systems and methods use “machine learning” to automatically identify one or more “target volumes of interest (VOI)” within a “3D anatomical image,” such as CT or MRI. *Id.* These VOIs are then mapped to a “3D functional image,”

[WorkloadMgmt-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.

such as PET or SPECT, to “identify[], within the 3D functional image, one or more 3D volume(s), each corresponding to an identified target VOI.” *Id.* This specific application to 3D images is emphasized in the ’817 Patent’s claims and specification. *See id.* (“The capability of the approaches described herein to handle 3D images is an important advantage over certain other image analysis that only identify 2D regions in 2D images.”) (citing Ex1001, 3:21-24).

The ’817 patent received a Notice of Allowance less than seven months after it was filed. *See* Ex1001, 1 (filed March 29, 2023); Ex1004 at 317 (Notice of Allowance mailed October 13, 2023). During examination, the Examiner misidentified the “closest prior art” . Petition at 3-4; Ex1004 at 323. In fact, the ’817 Patent itself distinguishes the Examiner’s purported “closest prior art” from the claimed invention because its “analysis is carried out on two-dimensional scintigraphy images, as opposed to on three dimensional images.” Petition at 3-4; Ex1004 at 323. As detailed in the Petition, however, other prior art references, including references that were of record but not addressed by the Examiner, analyze 3D, not 2D, images and explicitly disclose claim limitations the Examiner listed as missing from the “closest prior art”. Petition at 4-5, 10-71. 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.”). The ’817 Patent issued in March of 2024, and is even younger than the patent in *Ajinomoto*. This factor thus weighs against discretionary denial.

There are no economic, public health, or national security interests that support discretionary denial of the Petition. Patent Owner insinuates that the ’817 patent’s subject matter—cancer treatment improved by machine learning—should shield it from scrutiny. *See* DD Req. at 13. This argument fails. 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 '817 patent's alleged public health benefit should encourage thorough review, not foreclose it. In the district court litigation, Patent Owner asserts the '817 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. 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.* (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 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. Patent Owner does not

assert that the Petition over-relies on the expert declaration. *See* DD Req. at 19-28.⁵ Indeed, the citations to the expert report merely underscore the strength of the Petition’s arguments, especially with respect to what a POSITA would have understood at the time of the invention. This discretionary factor thus weighs against discretionary denial or, at worst, is neutral.

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 ’817 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 ’817 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

⁵ Progenics Pharmaceuticals, Inc. did make such arguments in the related IPRs. *See* IPR2025-00630, Paper 7 at 32-37 (PTAB June 13, 2025); IPR2025-00725, Paper 7 at 33-38 (PTAB June 13, 2025); IPR2025-00726, Paper 7 at 36-41 (PTAB June 13, 2025).

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. The Acting Director recently denied the patent owner’s requests for discretionary denial of the other challenged patents for three reasons: (1) the challenged patents have not been in force for a significant period of time (issued between 2020 and 2024); (2) the related district court proceeding is currently stayed—and no trial date is set—with respect to the challenged patents; and (3) Petitioner provided persuasive reasoning that discretionary denial under 35 U.S.C. § 325(d) is not appropriate. *See, e.g.*, IPR2025-00630, Paper 13 at 2 (July 24, 2025). Because the Petition concerns the same district court litigation and contains the same operative facts, the Acting Director should refer the Petition to the Board for consideration on the merits. *See supra* Section II; *infra* Section III.B (discussing § 325(d)).

Other recent decisions offer additional support. 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 are 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.

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 et al. 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 and the second part need not be addressed. *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 only a single reference, Hamadeh, as being the “closest prior art” while at the same time acknowledging that Wu fails to teach many of the patent’s claim limitations. Ex1004 at 323-324. 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 two new prior art references not considered during prosecution. *See* DD Req. at 16-17. 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 “closes[t] prior art of record,” “Hamadeh.” *Id.* at 323. The Examiner concluded that Hamadeh failed to teach or suggest, “among other things,” the following limitations of the independent claims:

- “receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality;” (element [1(a)])
- “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 (element [1(e)])
- “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” (element [1(f)]).

See id. at 324; Petition at 7-8. The Examiner did not discuss any other prior

art in the Reasons for Allowance.

The Petition does not rely on Hamadeh at all, as the Examiner did. Instead, Petitioner argues that several other references—namely, Renisch, Baker, and Zhao—teach the elements the Examiner found missing in Hamadeh. *See, e.g.*, Petition at 19-22, 29-31 (Renisch discloses elements [1(a)], [1(e)], and [1(f)]); 48-49, 53-54 (Baker discloses elements [1(a)] and [1(f)]); 52-53 (Baker in view of Zhao renders obvious element [1(e)]). Petitioner is not merely contradicting or disagreeing with an argument made by the Examiner; the Examiner did not substantively address or rely on Renisch, Baker, or Zhao at all. Therefore, the Petition does not present the same or substantially the same arguments considered during prosecution.

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 14. Not so. Not only does the Petition present new combinations of prior art not previously addressed, the Petition also introduces two new prior art references. *See, e.g., Verizon Connect Inc. v. Omega Pats., LLC*, IPR2023-01162, Paper 12 at 14 (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 6 of the Petition’s 7 grounds and are asserted against all 25 of the challenged claims of the ’817 Patent. *See* Petition at 8 (Grounds B-G). This is a material difference from the art and arguments actually addressed during prosecution.

Patent Owner asserts that “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.” DD Req. at 17. This statement is plainly untrue. The parties agree that these secondary references—Zhao and Suehling—were not considered by the Examiner. DD Req. at 16. And the Petition unmistakably relies upon these references to supplement Renisch and Baker. *See* Petition at 8. For example, Baker does not anticipate any of the claims, but Baker in view of Zhao renders obvious 18 of the 25 challenged claims. *See id.* (Ground E). Baker in view of Zhao in further view of Suehling renders obvious 3 more. *See id.* (Ground G). The Petition unmistakably states that Zhao and Suehling are essential to 2 Grounds challenging 21 claims, and these references clearly “make [a] difference to the ultimate analysis under Section 325(d).” *See* DD Req. at 17.

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. Renisch and Baker were both 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 Hamadeh—at the very least because they disclose the specific claim elements the Examiner found missing from Hamadeh. *See, e.g.*, Petition at 19-22, 29-31 (Renisch discloses elements [1(a)], [1(e)], and [1(f)]); 48-49, 53-54 (Baker discloses elements [1(a)] and [1(f)]). Thus, contrary to Patent Owner’s assertion, the Petition does “argue in detail why Renisch and Baker teach this long list of limitations.” DD Req. at 18.

The Director should also consider Patent Owner’s voluminous IDS submission 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)). Here, Patent Owner provided 260 references via its Information Disclosure Statement. *See* Ex1004 at 245-256. Patent Owner never attempted, however, to identify the closest reference(s) in any of these submissions. *See id.* at 243-244. The fact that Patent Owner submitted a large volume of references in an IDS 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 18. 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 seven 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 19 (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 circumstance 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 denied because of “the particularity requirements of 35 U.S.C. § 312(a)(3).” DD Req. at 19 (heading for Section II.C); *see also, e.g., id.* at 20 (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 19-28) 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: Renisch and Baker. Petition at 8. The grounds progress from one primary reference to the next. *See* Petition at 8, 18-71. With respect to the Renisch-based challenges, Ground A anticipates both independent claims and several of their dependent claims. *Id.* at 8. Ground B introduces the Renisch-Zhao combination, which renders obvious the same claims that Ground A anticipates. *See id.* Grounds C and D each introduce one additional secondary reference that, when combined with the references in Ground A or Ground B, renders obvious additional dependent claims. The same pattern follows for the Baker-based challenges.

Ground	Prior Art	Basis	Claims Challenged
A	Renisch	§102	1-5, 7, 10-14, 16, 19, 26
B	Renisch in view of Zhao (“Renisch-Zhao”)	§103	1-5, 7, 10-14, 16, 19, 26
C	Renisch, or Renisch-Zhao, each in view of Baker	§103	8-9, 17-18, 22-25, 29-32
D	Renisch, or Renisch-Zhao, each in view of Eiber	§103	8-9, 17-18, 22, 24-25, 29, 31-32
E	Baker in view of Zhao (“Baker-Zhao”)	§103	1-2, 7-11, 16-18, 22-25, 29-32
F	Baker-Zhao in view of Eiber	§103	3-5, 12-14
G	Baker-Zhao in view of Suehling	§103	19, 26, 28

Petition at 8

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. A table preceding the detailed discussion of invalidity clearly maps the relationship between each ground and the claims which that ground invalidates. *See* Petition at 8; *supra* Section III.C.2.a). Each ground is also identified with particularity. *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 individual elements. *See* DD Req. at 22-24 (Section II.C.1). Specifically, Patent Owner complains that Renisch fails to disclose a “processor.” *See* DD Req. at 23. This is a poorly disguised attack on the merits, which is not appropriate during the discretionary denial briefing. Interim Process FAQs at No. 25. Nevertheless, the presence of a “processor”—a basic element of a computer-implemented system—in the computer-based system of Renisch likely cannot be reasonably disputed.

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.

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. 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: August 7, 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 8,768 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 (1,579 words) in addition to the calculation from the word-processing system used to prepare the paper (7,189 words).

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 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 1042; and
- Petitioner's Updated Exhibit List

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