

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

CAPTION HEALTH, INC.
Petitioner

v.

UNIVERSITY OF BRITISH COLUMBIA
Patent Owner

U.S. PATENT NO. 11,129,591

Inter Partes Review No.: IPR2025-01066

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

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Ex1005	U.S. Patent Application Publication No. 2005/0251013 (“Krishnan”)
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Ex1007	U.S. Patent Application Publication No. 2017/0262982 (“Pagoulatos”)
Ex1008	U.S. Provisional Patent Application Publication No. 62/305,980 to Pagoulatos
Ex1009	U.S. Provisional Patent Application Publication No. 62/313,061 to Pagoulatos
Ex1010	Chen et al., “Automatic Fetal Ultrasound Standard Plan Detection Using Knowledge Transferred Recurrent Neural Networks,” Medical Image Computing and Computer-Assisted Intervention, MICCAI 2015, Vol. 9349, pp. 507-514 (November 18, 2015) (“Chen”)
Ex1011	Miller et al., “Review of neural network applications in medical imaging and signal processing,” Medical & Biological Engineering & Computing (30):449-464 (September 1992) (“Miller”)
Ex1012	RESERVED
Ex1013	U.S. Patent No. 5,906,578 (“Rajan”)
Ex1014	U.S. Patent Application Publication No. 2009/0074280 (“Lu”)
Ex1015	U.S. Patent Application Publication No. 2007/0055153 (“Simopoulos”)
Ex1016	González et al., “Echocardiogram Image Recognition Using Neural Networks in Recent Advances on Hybrid Approaches for Designing Intelligent Systems,” Studies in Computational Intelligence 547:427-435 (March 2014) (“González”)
Ex1017	Donahue et al., “Long-term Recurrent Convolutional Networks for Visual Recognition and Description,” arXiv:1411.4389v1 [cs.CV] (November 2014) (“Donahue”)
Ex1018	Caruana, “Multitask Learning: A Knowledge-Based Source of Inductive Bias,” Proceedings of the 10th International Conference on Machine Learning, ML-93, University of Massachusetts, Amherst, 1993, pp. 41-48.

Ex1019	Complaint, <i>University of British Columbia v. Caption Health, Inc., GE Healthcare Technologies Inc.</i> Case No. 3:24-cv-3200-PBS, Dkt. 1, May 28, 2024
Ex1020	Lang RM et al, American Society of Echocardiography's Guidelines and Standards Committee; European Association of Echocardiography. "Recommendations for chamber quantification: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology." <i>J Am Soc Echocardiogr.</i> 2005 Dec;18(12):1440-63. doi: 10.1016/j.echo.2005.10.005. PMID: 16376782 ("Lang")
Ex1021	Salomon LJ et al. A score-based method for quality control of fetal images at routine second-trimester ultrasound examination. <i>Prenat Diagn.</i> 2008 Sep;28(9):822-7. doi: 10.1002/pd.2016. PMID: 18646244 ("Salomon")
Ex1022	LeCun et al., "Backpropagation Applied to Handwritten Zip Code Recognition". <i>Neural Computation.</i> 1 (4): 541–551. doi:10.1162/neco.1989.1.4.541. ISSN 0899-7667. S2CID 41312633 ("LeCun")
Ex1023	A. Bouzerdoum, et al., "Image quality assessment using a neural network approach," <i>Proceedings of the Fourth IEEE International Symposium on Signal Processing and Information Technology, 2004.</i> , Rome, Italy, 2004, pp. 330-333, doi: 10.1109/ISSPIT.2004.1433751 ("Bouzerdoum")
Ex1024	Vignesh, S & Priya, K. & Channappayya, Sumohana. (2015). Face image quality assessment for face selection in surveillance video using convolutional neural networks. 577-581 ("Vignesh")
Ex1025	Long, Mingsheng & Wang, Jianmin. (2015). Learning Multiple Tasks with Deep Relationship Networks ("Long and Wang")
Ex1026	S. Hochreiter, J. Schmidhuber, Long short-term memory, <i>Neural Comput.</i> 9 (8) (1997) 1735–1780 ("Hochreiter")
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Ex1040	Scheduling Order, ECF No. 82, Aug. 13, 2025
Ex1041	Declaration of Jeffrey C. Metzcar in Support of Petitioner's Opposition to Patent Owner's Request for Discretionary Denial

I. INTRODUCTION

Petitioner, Caption Health, Inc., respectfully requests the Director to refer IPR2025-01066 to the Board and deny the request by the University of British Columbia (“Patent Owner”) for discretionary denial. *Inter partes* review in this case is an appropriate use of the Board’s resources and will undoubtedly conserve the resources of the Federal Courts.

Nearly every relevant consideration weighs against discretionary denial of review. For example, the challenged patent is relatively new, having issued on September 28, 2021. Therefore, Patent Owner, which is a non-practicing entity (“NPE”), has no settled expectations. Second, the basis of Petitioner’s challenge is a new combination of prior art that was never considered by the Patent Office. Indeed, the merits of the Petition are strong precisely because Petitioner presents a never-before-considered prior art reference that fills a specific gap to directly rebut the Examiner’s stated reasons for allowance. Third, although the challenged Patent is also the subject of ongoing litigation, a final written decision by the Board would arrive long before a trial—the date for which has not even been set by the District Court. Patent Owner’s argument to the contrary is simply not credible. The close of discovery has not been set. Expert report deadlines have not been set. Dispositive motion deadlines have not been set. In fact, the litigation, although pending since May 28, 2024, remains in its infancy due to Patent Owner repeatedly changing its

allegations to add a new patent and new accused products—moves that necessitated resetting the entire case schedule, including by pushing back claim construction approximately ten months. Therefore, Patent Owner’s cited average time-to-trial statistics are meaningless as applied to this case.

Just as important, although the Court recently denied—without prejudice—Petitioner’s *pre-institution* motion to stay the litigation, the Court has already explicitly signaled its willingness to reconsider a stay *if* review is instituted by the Board. But, even if the litigation is never stayed, Petitioner has already filed *Sotera* stipulations that would prevent Petitioner from pursuing its invalidity claims on parallel tracks. Thus, institution would unquestionably simplify and reduce the issues in the related litigation regardless of the outcome of any final written decision.

II. FACTUAL BACKGROUND

Patent Owner and Petitioner are parties to a patent infringement dispute in the Northern District of California involving two patents (*see generally*, Ex1029): the challenged ’591 patent (US11,129,591) and U.S Patent No. 10,751,029 (“the ’029 patent”).¹ Patent Owner, by its own admission, is a non-practicing entity. *See* Ex1031 (UBC’s Supplemental Response to Interrogatory No. 1 (March 7, 2025)) at

¹ Petitioner has also challenged the ’029 patent in IPR2025-01422, filed on Aug. 15, 2025. Ex1030.

2-3 (“Plaintiff has never had a Practicing Product...”); Ex1032 at 15 (UBC’s Supplemental Response to RFP No. 24 (March 7, 2025)) (“Plaintiff has not commercialized nor exploited the ’591 patent.”).

Patent Owner claims that it learned that Petitioner was practicing claims of the challenged ’591 patent “[i]n early 2022, not long after the ’591 patent issued.” Ex1029, ¶28. On May 5, 2022, Patent Owner sent a letter to Petitioner accusing it of infringing at least one claim of the challenged ’591 patent. *Id.* at ¶30. On November 11, 2022, Patent Owner then sent Petitioner an infringement claim chart for Claim 1 of the challenged ’591 patent. *Id.* at ¶35. Patent Owner alleges that it never heard back from Petitioner after that. *Id.* at ¶36.

Patent Owner waited another year-and-a-half—until May 28, 2024—to file suit for infringement of the ’591 patent. *See generally*, Ex1019. This was more than two years after Patent Owner’s initial letter to Petitioner and also after Petitioner had been acquired by a Fortune 500 company, GE HealthCare. *Id.* at ¶37.

Petitioner responded to Patent Owner’s Complaint on August 30, 2024, with detailed counterclaims for declaratory judgment of noninfringement and invalidity. Ex1033 at 15-32. Shortly thereafter, on September 16, 2024, the parties jointly stipulated to Alternative Dispute Resolution (“ADR”). Ex1034 at 6. By October 11, 2024, the Court had quickly referred the case for private mediation to be completed by February 21, 2025. Ex1035 at 2. Progress in the litigation stalled.

On the deadline to amend the pleadings (December 20, 2024), as the parties were preparing for mediation, Patent Owner asserted, for the first time, a new claim against Petitioner for infringement of a second patent, the '029 patent. Ex1029. The parties subsequently requested an extension of the deadline for mediation, and the mediation was held on March 13, 2025. After the mediation was unsuccessful, Petitioner decided that challenging the asserted patents by IPR was the next appropriate course of action. By that time, the litigation had made little progress and approximately two months remained before the statutory deadline for challenging the '591 patent.

On May 9, 2025, while Petitioner was preparing its Petition, Patent Owner requested leave to amend its infringement contentions to include additional accused products. Petitioner opposed the request based on Patent Owner's lack of diligence and prejudice to Petitioner. *See generally*, Ex01036.

On May 28, 2025, little more than two months after the failed mediation, Petitioner filed the present Petition for review challenging all claims of the '591 patent. A filing date was according on June 24, 2025. Paper 5. Shortly thereafter, on June 27, 2025, Petitioner requested a stay of the pending litigation—even while the petition for review of the asserted '029 patent was still being prepared. Ex1037.

Directly on the heels of Petitioner's motion to stay, the Magistrate Judge granted Patent Owner's request for leave to amend infringement contentions, stating

that the amendments would not cause any prejudice “because the action is in the early stages of litigation.” Ex1038 at 6. For example, “[n]o depositions have been taken,” “there has been no claim construction,” and “[t]he District Court has not set a date for the close of fact discovery or expert discovery.” *Id.*

Subsequently, on August 6, 2025, the Court denied Petitioner’s motion to stay the litigation as premature. *See* Ex1039. Although the Court listed at least three ways in which a stay could simplify the litigation, it acknowledged that “the Court cannot assume that any of these benefits will manifest here because the PTAB has *not yet* instituted IPR on either patent.” *Id.* at 3 (emphasis added). The Court again reiterated that “this case is at a relatively early stage,” “the Court has not set a trial date,” and “substantial work still remains for this case to be ready for trial.” *Id.* at 2 (internal quotations omitted). Nevertheless, on balance, the Court found that the totality of the factors presently weighed against a stay at this time. *Id.* at 4. “The Court recognized, however, “that this balance may shift if the PTAB decides to proceed to trial on one or both of the asserted patents” and, accordingly, the Court denied Petitioner’s motion to stay “without prejudice to renewal.” *Id.*

Subsequently, and in response to Patent Owner’s amended infringement contentions, the Court entered a new scheduling order setting or resetting all deadlines in the case, including for initial disclosures and invalidity contentions:

Event	Deadlines
Amended/Supplemented Invalidation Contentions & Accompanying Production Pat. L.R. 3-3 & 3-4	August 22, 2025
Exchange of Additional Terms for Construction Pat. L.R. 4-1	September 5, 2025
Deadline to Amend/Supplement Fed. R. Civ. P. 26(a)(1) Initial Disclosures	September 12, 2025
Exchange of Preliminary Constructions and Extrinsic Evidence for Additional Terms Pat. L.R. 4-2	September 19, 2025
Plaintiff's Supplemental Damages Contentions Pat. L.R. 3-8	October 3, 2025
Joint Amended/Supplemental Claim Construction & Prehearing Statement Pat. L.R. 4-3	October 10, 2025
Completion of Claim Construction Discovery Pat. L.R. 4-4	October 24, 2025
Plaintiff's Opening Claim Construction Brief Pat. L.R. 4-5(a)	November 7, 2025

Event	Deadlines
Defendants' Responsive Damages Contentions Pat. L.R. 3-9	November 7, 2025
Defendants' Responsive Claim Construction Brief Pat. L.R. 4-5(b)	November 21, 2025
Plaintiff's Reply Claim Construction Brief Pat. L.R. 4-5(c)	December 12, 2025
Claim Construction Tutorial	February 24, 2025 [sic] at 2:00 p.m. by Zoom
Claim Construction Hearing Pat. L.R. 4-6	March 5, 2025 [sic] at 1:30 p.m. in person

Ex1040 at 2-3. Noticeably, although the Court set briefing deadlines for claim construction, as well as a claim construction hearing, the hearing date is not set until months after an institution decision is due in this proceeding in December 2025. As such, if institution is granted, the parties have plenty of time to re-brief a renewed motion to stay before the claim construction hearing. Additionally, the Court did not set any other deadlines after the pending claim construction hearing—including a discovery cutoff or a trial date.

III. ARGUMENT

A. The Petitions' Strong Merits Favor Institution

Patent Owner’s lengthy request for discretionary denial leads off by addressing the merits of the Petition—contending that “the Petition fails to comply with 37 C.F.R. §42.104(b)(4)” because it fails to “specify where each element of the claim is found in the prior art.” *See* Patent Owner’s Request for Discretionary Denial (“DD Req.”) at 6-7. In particular, Patent Owner complains that “the Petition relies on a combination of Krishnan (Ex1005) and Lee (Ex1006)” but “neither reference discloses the use of view-category-specific neural networks.” *Id.* (emphasis added). Compliance with Section 42.104(b) is a *non-discretionary* consideration (*see* Interim Process FAQs #11) that is more appropriately addressed by the Board after referral. Nevertheless, Petitioner is compelled to respond here.

As discussed below, the Petition presents a strong case on the merits because Lee—which was not considered by the Examiner—fills a specific gap in the prior art identified in the Examiner’s stated reasons allowance. It is not necessary, as Patent Owner seems to suggest, that Krishnan *or* Lee disclose, *individually*, “view-category-specific neural networks.” To the contrary, Petitioner plainly asserts in the Petition that Krishnan in combination with Lee renders that feature obvious. *See* Petition at 32-34. Lee teaches category-specific “classifiers” for evaluating the quality of images in different categories. Krishnan, which evaluates the quality of echocardiographic images in different view categories, teaches that “classifiers” for evaluating image quality—as in Lee—may be built from “neural networks.”

Therefore, their combined teachings suggest, and render obvious, the use of view-category-specific neural network classifiers, as claimed.

1. Patent Owner's Claim Amendments During Prosecution Overcame Krishnan Alone, Not Krishnan in View of Lee.

For the purpose of this Opposition, independent claim 1 of the Patent is representative of the remaining claims. As it was originally presented for examination, claim 1 merely required: (i) receiving first and second echocardiographic images; (ii) associating the first and second echocardiographic images with different (i.e., first and second) view categories from a “plurality of predetermined echocardiographic image view categories”; (iii) determining, based on the images and their respective view categories, view-category-specific quality assessment values for each image; and (iv) causing the first and second quality assessment values to be associated with the respective first and second echocardiographic images (*i.e.*, labeling the images according to their quality). Ex1004 at 6-7 (original), 154 (following preliminary amendment). The Examiner correctly rejected this claim as anticipated by Krishnan (Ex1005). Ex1004 at 209-212.

With reference to Figure 2, below, Krishnan describes: (i) receiving echocardiographic ultrasound images at step 200 (Ex1005 at [0009], [0019], [0033]); (ii) determining, based on the features in the images, the echocardiographic view category and quality of the images at step 202 (*id.* at [0019], [0035]); and (iii)

labeling the images according to their view category and quality score at step 203 (Ex1005 at [0036]).

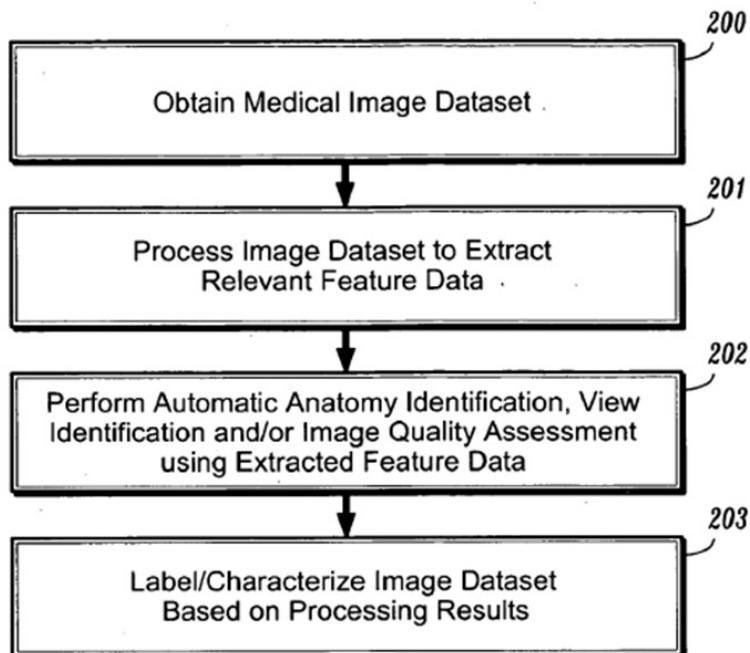


FIG. 2

To overcome the Examiner’s rejection, Patent Owner amended claim 1 to add that “each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network.” Ex1004 at 255-256 (emphasis added). In other words, as presented by Patent Owner, each predetermined view category has its own quality assessment neural network. Additionally, Patent Owner added the process requirements of: (i) “determining” which set of the plurality of sets of assessment parameters (*i.e.*, which neural network of the plurality of neural networks) is associated with the same view

category as a received image; and (ii) “in response to determining” which set of assessment parameters is associated with the same view category as the image, inputting the echocardiographic image into the neural network defined by that set of assessment parameters. *Id.* Contemporaneously, Patent Owner explained the scope of the amended claims, stating: “The claims include determining that a set of assessment parameters is associated with a respective view category and, in response, inputting a corresponding echocardiographic image into a respective neural network to determine the respective quality assessment value of each image.” Ex1004 at 266 (emphasis added).

The Examiner allowed amended claim 1, explaining that the closest prior art, including Krishnan, “does not teach or suggest the claimed invention having ‘wherein the at least one processor is configured to determine the first[/second] quality assessment value by: determining that a first[/second] set of assessment parameters of the sets of assessment parameters is associated with the first[/second] view category; and in response to determining that the first[/second] set of assessment parameters is associated with the first[/second] view category, inputting the first[/second] at least one echocardiographic image into the neural network defined by the first[/second] set of assessment parameters ...’” *Id.* at 279 (emphasis added). Importantly, the Examiner did not consider Lee. Nor did the Examiner substantively address any prior art reference materially similar to Lee.

2. The Addition of Lee to Krishnan Fills the Specific Purported Gap Identified by the Examiner.

In addition to disclosing all the base features of claim 1 (*i.e.*, the elements of claim 1 prior to amendment), Krishnan also describes performing image quality assessment using neural networks, as claimed. Krishnan states that the function of “image quality assessment” can be performed using “classifiers” where “[t]he classifiers can be implemented using machine learning methods, model-based methods, or any combination of machine learning and model-based methods.” Ex1005 at [0006] (emphasis added). For example, “templates could be constructed for different cardiac views” and “[t]he system could then assess similarity [of the acquired image] to each of these templates.” *Id.* at [0041] (emphasis added). Alternatively, Krishnan states that the quality assessment classifiers could be a “bank” or “set” of machine learning classifiers built from “neural networks.” *Id.* at [0043]-[0044] (emphasis added).

Thus, Krishnan, on its own, already suggests the use of view-category-specific quality assessment parameters (e.g., view-specific templates) and multiple neural network classifiers. Krishnan does not, however, explicitly describe the claimed process of “determining” which view-category-specific assessment parameters are associated with the same view as an acquired image and, “in response,” using just those assessment parameters to determine the quality of an acquired image. Krishnan is simply silent regarding these details.

Lee, which is in the same field of automatic image quality assessment, describes an electronic device, which may include an “an ultrasound machine” (Ex1006 at [0038]), that determines the quality of images from various image categories using category-specific “classifiers” (Ex1006 at [0009]). The device includes a memory that stores a plurality of classifiers, and a processor configured to “analyze a category of an image of which an image quality evaluation is requested” and “determine a classifier corresponding to the category of the image from among the plurality of classifiers.” Ex1006 at [0009] (emphasis added). This process is schematically depicted in Figure 6, below.

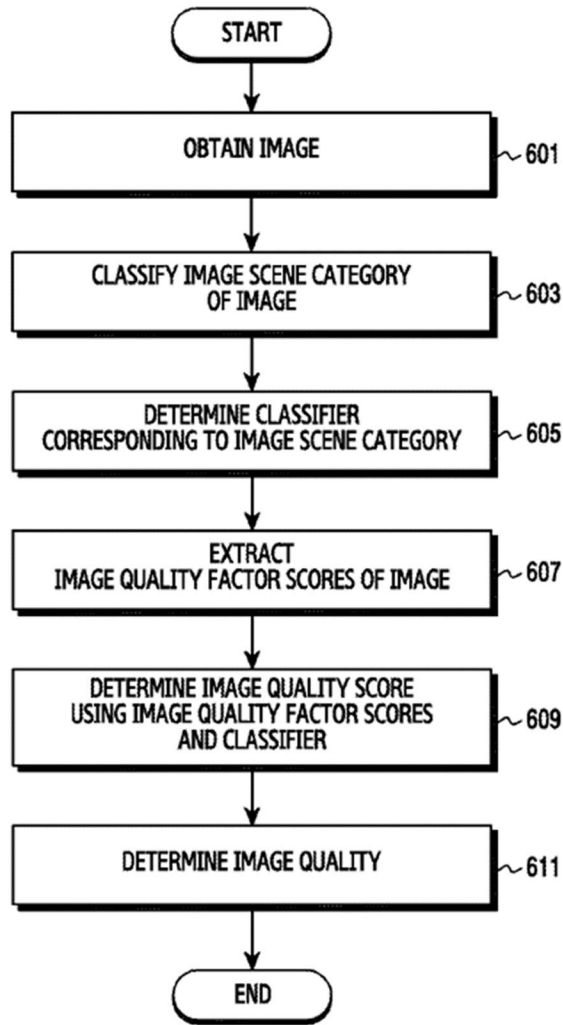


FIG.6

Thus, Lee directly addresses those steps of claim 1 that the Examiner believed missing from the prior art. Specifically, after first determining the category of an acquired image, Lee then determines which of a plurality of classifiers is appropriate to evaluate the quality of the acquired image and, in response, evaluates the image using that classifier. When the teachings of Krishnan are read in view of the later teachings of Lee, it would have been obvious to a person of ordinary skill in the art

(“POSITA”) to: (i) use a plurality of neural network classifiers to evaluate the quality of images in different echocardiographic image view categories, as taught by Krishnan; and (ii) determine which of a plurality of category-specific classifiers should be used to evaluate the quality of an image, as taught by Lee.

3. The Petition Provides a Clear Rationale for Combining Krishnan and Lee.

Patent Owner further attacks the merits of the Petition by arguing that Petitioner has failed to “adequately show motivation to combine Krishnan and Lee.” DD Req. at 10. This too is an issue that is more appropriately addressed by the Board during the next stage of the interim bifurcated process for institution. Nevertheless, Petitioner will respond here briefly. Although Patent Owner may disagree with Petitioner’s conclusions regarding obviousness to combine, it cannot be said that the Petition fails to articulate a motivation for combining the teachings of Krishnan and Lee. *See* Petition at 34-37.

Krishnan and Lee are in the same field of automatically assessing, using machine learning, the quality of images from multiple different view/scene categories. *See, e.g.*, Ex1005 at [0009] (“automated ... view identification and image quality assessment are performed in real-time during image acquisition”); Ex1006, [0009] (“determine a classifier corresponding to the category of the image from among the plurality of classifiers; ... and evaluate the image quality of the image based on ... the determined classifier”). Additionally, both are explicitly applicable

to ultrasound machines. *See* Ex 1005 at [0016] (“ultrasound image data”); Ex1006 at [0038] (“[T]he electronic device may include at least one of various medical devices (e.g., ... an ultrasound machine).”). Accordingly, the teachings of Krishnan and Lee are readily combinable, and as set forth in the Petition, a POSITA would naturally look to either reference to implement automatic quality assessment of images in distinct categories. Each reference discloses alternative and complementary techniques for first identifying the view/scene category of an image and then assessing the quality of the image based on its category.

In ultrasound medical imaging, distinct standardized “views” have been adopted that enable physicians to visualize and measure different anatomic structures (e.g., heart valve or heart chamber). The quality of an image, therefore, depends on which structures in the image are required for successful analysis. As a matter of common sense, no single set of assessment parameters is sufficient to analyze the quality of images in every view category since the view categories relate to different anatomic structures. Petitioner does not rely solely on common sense, however, to justify the combination of Krishnan and Lee. Instead, the Petition cites directly to the express teachings in Lee. *See* Petition at 36.

Krishnan states that the view category of an image, once determined, can be used to assess the quality of the echocardiographic image. Ex1005 at [0019]-[0020] (“the results of ... view identification may be used for quality assessment”). Lee

expressly adds what should already be understood—that the quality of images in different categories should be assessed using different classifiers with different assessment parameters. Ex1006 at [0009] (“determine a classifier corresponding to the category of the image”), [0152] (“differentially measuring quality based on an image scene category”), [0153] (“when the quality of an image is measured, the quality may be measured from a different perspective view based on an image scene category”). Lee, therefore, provides the motivation to combine its teachings with Krishnan since Krishnan, like Lee, evaluates the quality of images in different view categories. Moreover, a POSITA would have had a reasonable expectation of success combining Krishnan and Lee since Lee uses multiple image quality classifiers and Krishnan already describes using a “bank” or “set” of neural network classifiers.

4. The Petition is Not Over-Reliant on Expert Testimony

The third prong of Patent Owner’s attack on the merits contends that the Petition relies too heavily on expert testimony. DD Req. at 13-15. Patent Owner’s arguments, however, are contradictory. First Patent Owner argues that the Petition improperly relies on expert testimony to fill gaps in the prior art because—as Patent Owner argues again—“neither Krishnan nor Lee disclose [view-category-specific neural networks]” *Id.* at 14. But then, Patent Owner argues that “the expert simply repeats arguments from the Petition.” *Id.* That hardly amounts to “gap

filling” and is not the kind of overreliance on expert testimony that signals weakness on the merits or justifies discretionary denial.

As Petitioner has already explained above in Section III.A.2, the teachings of Lee and Krishnan, in combination, render obvious the claimed feature of view-category-specific neural network classifiers having respective quality assessment parameters. Lee teaches selecting from a plurality of category-specific image quality “classifiers” and Krishnan teaches quality assessment “classifiers” built using neural networks to assess the quality of images in different echocardiographic view categories. The testimony of Petitioner’s expert, Dr. Deo, is cited to reinforce these facts. Dr. Deo affirms what the prior art references teach and how they would be viewed by a POSITA.

B. Petitioner Acted Reasonably and Expediently in Filing for *Inter Partes* Review and Submitting *Sotera* Stipulations

Patent Owner argues that discretionary denial is appropriate here because Petitioner filed a second petition, on a different patent (i.e., the ’029 patent), “3 months” after it filed the Petition challenging the ’591 patent. DD Req. at 15. This amounts to Patent Owner faulting Petitioner for Patent Owner’s litigation conduct. Patent Owner filed suit in May 2024 and 7 months later amended its complaint to add the ’029 patent.

Although Patent Owner accuses Petitioner of delay in filing its petitions for IPR, this accusation is baseless. Patent Owner expanded the scope of the District

Court litigation by alleging infringement of the '029 patent in its First Amended Complaint. Ex1029. Then, by proposing Amended Infringement Contentions, Patent Owner presented Petitioner and its co-defendants with entirely new infringement allegations including additional products. In doing so, the District Court observed that Patent Owner, not Petitioner, “was not diligent in seeking leave to amend” and had engaged in “unjustified delay.” Ex1038, pp.3-5. Petitioner for its part, exercised its “reasonable” discretion to “wait to file its petition until it learn[ed] which claims are being asserted against it in the parallel proceeding.” *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at p.11 (PTAB March 20, 2020). As the District Court observed:

Defendants did not unduly delay in filing the IPR petition Although Defendants could have acted earlier, they timely filed the first IPR petition [for the '591 patent] within one year after this litigation commenced, and the time for filing the second IPR petition [for the '029 patent] has not yet expired.

Ex1039, pp. 3-4. What’s more, Petitioner actually filed the petition for IPR of the '029 patent on August 15, 2025, much earlier than its statutory deadline of December 20, 2025. Thus, Petitioner has acted with diligence and good faith in filing its petitions for IPR despite Patent Owner’s meritless insinuations to the contrary.

Patent Owner’s attacks on Petitioner’s *Sotera* stipulation are also without merit. *First*, Patent Owner is incorrect that Petitioner’s *Sotera* stipulation “does not

bind” GE Healthcare, Petitioner’s parent company. DD Req. at 17. Petitioner’s *Sotera* stipulation explicitly invokes the statutory estoppel provision, 35 U.S.C. § 315(e), which expressly applies to the petitioner and “the real party in interest or privity of the petitioner.” As Patent Owner admits, GE Healthcare is identified as a real party in interest in the Petition. DD Req. at 17 (citing Pet. at 4.) Nevertheless, Petitioner has filed an amended *Sotera* stipulation that reiterates the application of § 315(e) as effectuated in Petitioner’s original *Sotera* stipulation: “GE HealthCare, identified in the Petition as a real party in interest, is in fact bound by [Petitioner’s *Sotera*] stipulation.” Paper 8.²

Second, Patent Owner misapplies the Director’s discretionary denial decisions involving so-called system prior art. In both of Patent Owner’s cited decisions, the petitioner’s district court invalidity position relied on system prior art. *See Motorola Sols., Inc., v. Stellar*, IPR2024-01205, Paper 19, 3-4 (Mar. 28, 2025) (“Petitioner’s invalidity arguments in the district court... include combination of the prior art

² Patent Owner also argues that Petitioner’s *Sotera* stipulation is ineffective because as of August 25, 2025, Petitioner had not yet filed a *Sotera* stipulation in the ’029 IPR. DD Req. at 18-19. The ’029 IPR was accorded a filing date on August 15, 2025. IPR2025-01422, Paper 3. Petitioner filed a *Sotera* stipulation in the ’029 IPR on September 9, 2025. IPR2025-01422, Paper 6. Therefore, Patent Owner will have over 2 months to address that stipulation in the ’029 IPR. Patent Owner fails to explain why the Director should ignore this fact.

asserted in these proceeding with unpublished system prior art.”); *Shenzen Tuozhu Tech. Co. v. Stratasys Inc.*, IPR2025-0354, Paper 11 at 2 (June 12, 2025) (same). That is not the case here. *See* Ex2003. Petitioner’s invalidity contentions in the District Court litigation only include published prior art. *Id.*

C. On Balance, the Discretionary Factors Demonstrate That This Case Is an Appropriate use of Patent Office Resources.

The discretionary denial analysis “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 set forth more fully below in this section, Petitioner identifies the following relevant discretionary factors as either weighing in favor of institution or being neutral:

Factors in favor of institution	Neutral factors
<i>Fintiv</i> Factor 1: whether the District Court granted a stay, or if there is evidence a stay might be granted if the PTAB were to institute the IPR.	<i>Fintiv</i> Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party.
<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.	

<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; • whether the patent owner has settled expectations in its issued claims; • whether the petitioner has filed a <i>Sotera</i> stipulation; • reliance on expert testimony; • whether the validity of the patent has been adjudicated previously. 	

Apple, Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 6-15.

On balance, these discretionary considerations favor institution.

1. Factor 1: The Likelihood of a Stay of the District Court Litigation is High if the Board Institutes Review.

The precedential decision in *Fintiv* states:

In some cases, there is no stay, but the district court has denied a motion for stay without prejudice and indicated to the parties that it will consider a renewed motion or reconsider a motion to stay if a PTAB trial is instituted. Such guidance from the district court, if made of record, suggest the district court may be willing to avoid duplicative efforts and await the PTAB’s final resolution.... This fact has usually weighed against exercising authority to deny institution....

Fintiv, Paper 11 at 6-7. Here, although Petitioner’s pre-institution Motion to Stay was not granted in the District Court, it was denied without prejudice to renew, and the District Court’s substantive analysis strongly suggests that a stay is more (not less) likely upon institution. Ex1039. Indeed, the District Court acknowledged at least three potential benefits that could be achieved by a stay but ultimately decided that “the potential for simplification weighs against a stay *at this time*” because “the Court cannot assume that any of these benefits will manifest here *because the PTAB has not yet instituted IPR.*” *Id.* at 2-3 (emphasis added). The District Court also observed, however, that “this balance may shift if the PTAB decides to proceed to a trial on one or both of the asserted Patents.” *Id.* at 4. Undoubtedly, the balance will shift if the Board decides to institute since the litigation will *still* be at an early stage.

If institution is granted by the statutory deadline in December (in this case) and/or in February of next year in IPR 2025-01422, Petitioner will renew its motion for stay. The District Court litigation will still be at a relatively early stage, with no substantive ruling, or even a hearing, on claim construction. And since no foreseeable change would increase the prejudice to the Patent Owner, the overall balance of stay factors would strongly support a stay.

Because “there is evidence a stay might be granted if the PTAB were to institute,” *Fintiv* Factor 1 weighs against discretionary denial. *See, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289, Paper 9 at 2 (PTAB June 12, 2025)

(denying the patent owner’s request for discretionary denial in part because evidence existed that “the district court is likely to grant a stay if this proceeding is instituted[.]”).

2. Factor 2: No Trial Date Has Been Scheduled.

The PTAB prioritizes challenges that are not in advanced stages of litigation. *See Fintiv*, IPR2020-00019, Paper 11 at 10. If the District Court’s trial will not occur until around the same time as, or after, the statutory deadline for the PTAB’s final written decision, this fact weighs against discretionary denial. *Id.* at 9-10; *see also Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289, Paper 9 at 2 (PTAB June 12, 2025) (no trial date set); *Amazon.com, Inc., et al v. NL Giken Inc.*, IPR2025-00250, Paper 14 at 2 (May 16, 2025); *Twitch Interactive, Inc. v. Razdog Holdings LLC*, IPR2025-0037, Paper 18 at 2-3 (May 16, 2025).

Here, the District Court litigation is plainly still in its early stages, with many key milestones yet to even be scheduled. **No trial date has been set.** Moreover, Patent Owner’s trial date prediction is clearly wrong.

Patent Owner cites a median time-to-trial statistic of 2 years and 7.8 months or approximately 967 days. DD Req. at 22-23. Because Patent Owner filed the District Court Case on May 28, 2024, the projected trial date, using Patent Owner’s naked time-to-trial statistic, would be January 20, 2027—not “late December 2026” as Patent Owner contends. DD Req. at 22. Therefore, even if it was appropriate to

rely on median statistics to predict the trial date for this case, that date would still be nearly a month *after* the December 26th, 2026 statutory deadline for a final written decision in this IPR and only one month before the February 20th, 2027 statutory deadline for a final written decision in the related review of the '029 patent. But, more importantly, Patent Owner's trial date prediction using median statistics is overly optimistic and wrong.

The median time-to-trial statistics cited by Patent Owner are not applicable to the special circumstances of this case. First, Patent Owner amended its Complaint to add an entirely new patent almost seven months after the case began. *See* Ex1019 (May 24, 2024, Complaint) and Ex1029 (December 20, 2024, First Amended Complaint). Second, Patent Owner was recently granted leave to amend its infringement contentions to add entirely new accused products approximately 13 months after this case began. *See* Ex1038, p.6 (July 2, 2025 Order Granting Plaintiff's Motion for leave to Amend Infringement Contentions, Dkt. 74). This change necessitated that the District Court reset the case schedule. *See* Ex1040. For example, whereas the deadline for Patent Owner's opening claim construction brief was originally, March 24, 2025, (Ex1035 at 3), the Court reset it for November 7, 2025 (Ex1040 at 2), i.e., more than seven months later. Similarly, whereas the Court's claim construction hearing was originally set for May 6, 2025 (Ex1035 at

3), the Court rescheduled it for March 5, 2026³ (Ex1040 at 3), i.e., approximately 10 months later. This substantial delay of claim construction, the outcome of which is a necessary predicate to other deadlines including expert reports and dispositive motions, means that median time-to-trial statistics no longer have any application to this case.

Patent Owner's cited discretionary denial decisions are also, therefore, inapposite. In *Shenzen Tuozhu Tech.*, trial was scheduled to begin in the Eastern District of Texas before the statutory deadline even though median time-to-trial statistics suggest that the trial might begin shortly after a final written decision. IPR2025-00354, Paper 11 (June 12, 2025). Here, however, no trial is set and median statistics for the District Court are not applicable such that a trial is unlikely to occur until long after a final written decision. Likewise, in *Amazon v. Kaifi*, which also involved parallel litigation in the Eastern District of Texas, even though a trial date scheduled for more than 6 months prior to the statutory deadline for a final written decision was *likely* to be *slightly* delayed, the trial in the District Court was *still* likely to occur first. IPR2025-00624, Paper 10, pp. 2-4 (PTAB July 29, 2025). Here, no trial date exists and the median statistics, even if correct, place the trial after a final

³ The Court's deadlines for its Claim Construction Tutorial and Claim Construction Hearing, as set forth in Ex1040, contain typographical errors. Both should refer to 2026 instead of 2025.

written decision. Accordingly, this case is more analogous to *Imperative Care*, in which the Director denied the patent owner’s request for discretionary denial in part because “there is no trial date scheduled in the district court[.]” IPR2025-00289, Paper 9 at 2. Thus, considering the totality of the circumstances, this factor weighs towards institution.

3. Factor 3: The Parties’ Investment in the District Court Case Has Not Been Significant at This Early Phase and the District Court Has Not Issued Any Substantive Order on the Patents

Similar to Factor 2, under *Fintiv* Factor 3 discretionary denial is disfavored when the degree of investment by the parties and the District Court in the parallel litigation has not been significant and where the District court itself has issued few or no “substantive orders related to the patent at issue in the petition.” IPR2020-00019, Paper 11, at p. 9-10. That is precisely the case here.

The District Court summarized the lack of investment and early phase of the litigation in its order regarding Petitioner’s Motion to Stay:

Overall, this case is at a relatively early stage. Although fact discovery began one year ago... the parties have not engaged in costly expert discovery or dispositive motion practice. The Court has not issued a claim construction order – though the parties are prepared to brief claim construction soon. Finally, the Court has not set a trial date. Thus, the case is at a relatively early stage, and substantial work still remains for this case to be ready for trial.

Ex1038 at p.2 (internal quotations omitted).

While Patent Owner claims to have invested substantial resources in the district court case, the facts do not support it. Patent Owner has only produced approximately 70 total documents. Ex1041 at ¶4. Nor have the parties taken a single deposition or exchanged any expert reports. Indeed, no fact or expert discovery deadlines have even been set.

Even the claim construction process is still in the early stages. Up to now, the parties have only disclosed lists of terms and proposed constructions. Although the parties will have filed claim construction briefs before the December 26, 2025, statutory deadline for institution, the technology tutorial will not happen for another two months and the claim construction hearing will not take place until March 5, 2026, at the earliest (if the case is not stayed first). Ex1040 at 3.

4. Factor 4: As a Result of Petitioner’s *Sotera* Stipulation, the Litigated Issues Will Not Overlap with the IPR If Instituted

Fintiv Factor 4 asks if there will be overlap between the PTAB proceeding and the parallel District Court proceeding. *See Fintiv*, IPR2020-00019, Paper 11 at 11-13. Where, as here, a Petitioner submits a meaningfully tailored *Sotera* stipulation in which the Petitioner agrees to forgo challenging overlapping prior art grounds at the District Court if the PTAB institutes IPR, this factor favors institution. *See, e.g.*, “Guidance on USPTO’s rescission of ‘Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,’” Scott R. Boalick, Chief Administrative Patent Judge. (March 24, 2025) (“A timely-

filed Sotera stipulation...is highly relevant, but will not be dispositive by itself. Instead, the Board will consider such a stipulation as part of its holistic analysis under *Fintiv*.”).

5. Factor 5: Even Though Petitioner is Also a Defendant in the District Court Proceeding, There Is No Overlap.

The PTAB 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 has a high probability of being stayed (*See, supra* III, C., 1) with respect to the challenged patents. The timing of such a stay combined with Petitioner’s Amended *Sotera* stipulation ensures that 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.

6. Factor 6: Additional Considerations Also Weigh Towards Institution

- a) The Newness of the ’591 Patent and Patent Owner’s Failure to Commercialize Its Claims Contradict Patent Owner’s Claim of Settled Expectations.

The “[s]ettled expectations of the parties” is a relevant consideration in the

determination of whether to discretionarily deny review. *See* 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 (USPTO Mar. 26, 2025) (“Stewart Memorandum”), (<https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>) at 2. Recent decisions make clear that the Acting Director favors challenges that are “early in the life of the patent” because “[e]arly 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). Because Patent Owner is a NPE that has never commercialized the patent, and because the ’591 patent has been issued for less than four years, Patent Owner has no settled expectation of patent rights. Thus, this factor weighs in favor of institution. *See supra*, II., *infra*, III.E.

b) The Merits of the Petition are Strong.

As set forth more fully in Section III.A., Petitioner has presented an IPR challenge with strong merits that warrant institution of review and a finding of unpatentability of every claim of the ’591 patent. This is a relevant consideration under *Fintiv* Factor 6 that also weighs against discretionary denial. IPR2020-00019, Paper 11 at pp. 14-16.

c) Petitioner’s Meaningful *Sotera* Stipulation and Further Clarification Ensure Efficiency with the District Court if IPR is Instituted.

As set forth more fully in Section III.B., above, Petitioner has submitted *Sotera* stipulations that eliminate the possibility of overlapping claims or parties with these proceedings before the PTAB. This consideration also falls under the catchall of *Fintiv* Factor 6 and weighs against discretionary denial.

d) The Validity of the Patent Has not Been Previously Litigated

Another 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 ’591 patent’s claims under 35 U.S.C. §§ 102-103 or otherwise made a final determination on its validity. Thus, this also weighs against discretionary denial under *Fintiv* Factor 6.

D. The *Advanced Bionics* Framework Favors Institution

Using the two-part *Advanced Bionics*⁴ framework and the factors delineated in *Becton, Dickinson*⁵, institution should not be denied under 35 U.S.C. §325(d).

⁴ *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential).

⁵ *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, pp.17-18 (Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph).

The first inquiry under this framework is “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.”

Advanced Bionics, Paper 6, p.8. The second inquiry is “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.* 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 Industries, Inc. v. CAPSA Solutions LLC*, IPR2023-01275, Paper 9, p.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...”). That is precisely the case here.

1. The Petition Relies on a Prior Art Combination That Was Not Addressed by the Office, Including References That Are Not Substantially the Same as the Prior Art Presented to the Office

Regarding the first inquiry, Petitioner’s challenge to every claim of the Patent relies on the underlying combination of Krishnan with Lee. *See* Petition at 11. Lee was never presented to, or considered by, the Patent Office, as Patent Owner admits. DD Req. at 30 (“Lee was not presented to the Office during prosecution of the ’591 Patent...”). Petitioner’s secondary references—Pagoulatos (Ex1007) and Chen

(Ex1010)—also were not previously presented to the Office, either alone or in combination with Krishnan and Lee.

Patent Owner admits that the Examiner rejected all claims as anticipated by Krishnan and, in response, Patent Owner amended the claims to overcome Krishnan. DD Req. at 29. Patent Owner also admits that “[t]he Examiner’s reasons for allowance state that the prior art ... does not teach or suggest the steps ... including ‘determining that a [first/second] set of quality assessment parameters ... is associated with the [first/second] view category’ and ‘in response’ to said determination” evaluating the first/second echocardiographic image with the first/second set of assessment parameters. *Id.* at 29-30 (emphasis added). As already explained in Section III.A, above, Lee explicitly describes these process steps and, thus, fills in the specific purported gap in the prior art identified by the Examiner in the Examiner’s stated reasons for allowance. Accordingly, the newly presented combination of Krishnan and Lee is not the same or substantially the same as the prior art previously considered by the Office. *See, e.g., Verizon Connect Inc. v. Omega Patents, LLC*, IPR2023-01163, Paper 12, p.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.”); *Oticon Medical AB v. Cochlear Limited*, IPR2019-00975, Paper 15 at 5, 10. 17-20 (Oct. 16, 2019)) (precedential as to §§ II.B and II.C) (finding that Petitioner’s challenge based on Westerkull ’794 *in combination* with Choi “presents different prior art than the Office was aware of” because, even though Westerkull ’794 had been addressed during prosecution, Choi was not considered and was not cumulative of art that had been considered).

Patent Owner contends that Lee “is cumulative of art considered by the Examiner because it substantially reiterates or provides no more than what was already taught by previously cited or considered art.” *Id.* at 30. Specifically, Patent Owner contends that Lee is substantially the same as Marchesotti (Ex2023), which was cited in in IDS. *Id.* at 30. Patent Owner is plainly wrong.

First, it must be noted (as is relevant to the second *Advanced Bionics* inquiry) that Marchesotti, even if it was disclosed, was not substantively addressed, or even mentioned, by the Examiner, either alone or in combination with Krishnan. But, most importantly, Marchesotti is materially different than Lee because it does not describe the exact feature for which Petitioner cites Lee. Specifically, Marchesotti does not “determine” which set of a plurality of sets of assessment parameters is associated with the same view category as an acquired image, and does not, “in

response to” such determination evaluate the acquired images using that set of assessment parameters.

Marchesotti describes two methods for performing image quality assessment: “early fusion” or “late fusion.” Ex2023 at 14:37 (“two solutions (early and late fusion) are contemplated”), 6:66-7:10, 14:52-15:38 (describing early fusion), 15:39-16:2 (describing late fusion). Under the early fusion method, which is less pertinent here, the extracted features of an image (i.e., “descriptors”) are fused before the combined features are input into a *single* image quality classifier. Under the late fusion method, an acquired image is evaluated by each of a plurality of category-specific quality classifiers and the results from each classifier are then “fused” to generate an overall quality score. Specifically, Marchesotti states:

The fusion module 112 fuses the results from the two or more classifiers 110, or fuses the descriptors 22, 24 before inputting to a classifier 110 e.g., using a late fusion or early fusion method, respectively. In one embodiment, the fusion module 112 is an early fusion module which merges the feature descriptors 22 and 24 ... into a single descriptor prior to inputting the classifier 110. In another embodiment, the fusion module 112 is a late fusion module which receives the score output by each of the classifiers 110, one per category, and generates an overall quality score 20 as a weighted function of the scores output by classifiers 110.

Ex2023 at 6:66-7:10 (emphasis added). Additionally, for late fusion, which is most relevant here, Marchesotti explains:

[A] new image ... is classified by inputting the descriptor 24 ... to all the trained N_c classifiers 110. A corresponding number of classification scores s_j is collected. The final score q is the score is a function of each of the classifier scores and their associated weights. For example, q is obtained by weighing each classifier score with the respective feature weight of the x_c descriptor 22. An average score is obtained by dividing the sum of the weighted scores by the number of content categories....

Id. at 49-58 (emphasis added).

Thus, even if Marchesotti discloses multiple category-specific classifiers, as Patent Owner alleges, it uses all of those classifiers at the same time to evaluate each image, regardless of its view category. Marchesotti does not describe determining which classifier of the plurality of classifiers is associated with the same category as the image and then, in response, using just that classifier to evaluate image quality. Accordingly, Marchesotti does not disclose the relevant features of Lee and Lee is not substantially similar to the previously considered prior art. Therefore, the combination of Krishnan with Lee presents “different prior art than the Office was aware of.” *See Oticon*, IPR2019-00975, Paper 15 at 20 (Oct. 16, 2019) (precedential as to §§ II.B and II.C)

Because the first inquiry is not satisfied, proceeding to the second inquiry is unnecessary, and discretionary denial under §325(d) should be declined.

Nevertheless, Petitioner also briefly addresses the second inquiry below.

2. The Office Materially Erred by Not Locating or Considering Lee

As a preliminary matter, Patent Owner argues that Petitioner has already—even before the filing of this Opposition—failed to carry the burden of showing material error because the Petitioner did not address it in the Petition. DD Req. at 32-33. Patent Owner argues that it was “incumbent on Petitioner to address §325(d) in its Petition” and that it should be precluded from doing so now. *Id.* at 33. Patent Owner is wrong. The Office has unambiguously directed that: “The petition should not address discretionary issues. 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), parallel proceedings, parallel petitions, serial petitions, and any other matter bearing on the Director’s discretion to institute.” *See* Interim Process FAQs #25 (emphasis added) (“Should a petitioner address discretionary issued in its petition? No.”).

Moving on to the merits, the Board has stated that, *even if* a prior art reference was presented to the Examiner in an IDS—which Lee was not—“a petitioner may argue that it satisfies the second part of *Advanced Bionics* because the asserted prior 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, LLC v. RAI Strategic Holdings*,

Inc., IPR2024-01280, Paper 13, p.5 (May 19, 2025) (precedential as to §A) (internal quotations omitted). That is precisely what Petitioner has done here. As discussed in Sections III.A.2 and III.D.1, above, Lee was not used a basis for rejection during examination, is not substantially the same as prior art the Examiner applied and includes specific teachings that rebut the Examiner’s stated reasons for allowance. Thus, the Examiner materially erred by not locating and applying the most pertinent prior art. *See Oticon Medical AB*, Paper 15 at 19 (“[W]e determine that there was material error in the prosecution leading to issuance ... because Choi ... was not considered. It seems that the Examiner was simply not aware of Choi’s teachings”).

E. Patent Owner Does Not Have “Settled Expectations.”

As Patent Owner acknowledges, the ’591 patent has only been in force for “approximately 4 years.” DD Req. at 34. This is not a substantial enough amount of time for Patent Owner to have settled expectations with respect to the validity or enforceability of its patent. *Google LLC v. Withrow Networks Inc.*, IPR2025-00775, Paper 10 at 2 (Director Aug. 14, 2025) (determining that “the challenged patent [issued in 2020] has not been in force for a significant period of time” in order to enjoy strong settled expectations); *Microsoft Corp. v. Edge Networking Sys., LLC*, IPR2025-00617, -618, -619, Paper 13 at 2 (finding that “the challenged patents have not been in force for a significant period of time (issued in 2021, 2023, and 2020,

respectively” such that “Patent Owner has not developed strong settled expectations.”)

Further, Patent Owner does not practice and has not commercialized the ’591 patent. *See* Ex1031 at 2-3 (“Plaintiff has never had a Practicing Product...”); Ex1032 at 15 (“Plaintiff has not commercialized nor exploited the ’591 patent.”). Thus, even if the patent had been in force for much longer, Patent Owner would have no settled expectations as against Petitioner. *Shenzen Tuozhu Tech. Co. v. Stratasy, Inc.*, IPR2025-00438, -531, -532, -585, -611, Paper 10 at 3 (July 17, 2025) (finding no “settled expectations” on patent in force for “approximately 10 years” where, as here, the challenged patent has not been “commercialized, asserted, marked, licensed, or otherwise applied.”).

Patent Owner’s speculation as to when Petitioner (or GE Healthcare) “knew” about the PCT or original application that led to the ’591 patent does not establish “settled expectations.” The claims of the ’591 patent are not the same as those in the referenced PCT and original applications. The ’591 patent claims were amended during the course of prosecution. Ex1004, pp. 254-273. And the very nature of Patent Owner’s infringement allegations were in flux even up to the eve of filing the Petition. As detailed above, on May 9, 2025, while Petitioner was preparing its Petition, Patent Owner requested leave to amend its infringement contentions to include additional accused products. Petitioner opposed the request based on Patent

Owner's lack of diligence and prejudice to Petitioner. *See generally*, Ex1036. It cannot be the case that the mere filing of a PCT application or the publication of a patent application establishes "settled expectations" when the scope of the underlying patent is not yet known. Patent Owner identifies no authority to the contrary.

Patent Owner's self-serving recitation of the parties' pre-suit communications should also be disregarded. Patent Owner identifies no support for the proposition that discussion of "technical papers" allegedly related to a non-issued patent establish "settled expectations." Nor does Patent Owner identify authority for the bright-line rule that correspondence relaying patent infringement allegations establishes "settled expectations." If it did, a party would need to file a petition for IPR every time it receives correspondence regarding subject matter even potentially the subject of a non-public patent application. The nature and underlying merit of the patent owner's infringement allegations would be irrelevant. This makes no sense. The parties' pre-suit correspondence here shows why. Patent Owner's own exhibits demonstrate that the *earliest* identified substantive infringement to Petitioner allegations was June 11, 2022. Ex2032. And these allegations have continued to evolve, with Patent Owner amending its infringement contentions in the district court litigation just weeks before filing of the Petition.

Finally, Patent Owner's argument that it has pre-issuance "settled

expectations” because patent applications owned by one of GE Healthcare’s subsidiaries cited to the ’591 patent application is without merit. DD Req. at 37-38. Again, Patent Owner suggests a bright-line rule that makes no sense. Patent Owner conveniently ignores that the scope of the ’591 patent changed during prosecution. Ex1004, pp. 254-273. Patent Owner’s argument appears to be that GE Healthcare was supposed to operate with the understanding that a yet-to-be issued patent could be asserted against a product offered by a company it had yet to acquire. The Director’s “settled expectations” analysis to date does not support this argument.

F. Patent Owner Identifies No Compelling Economic or Public Health Interests That Support Discretionary Denial

Patent Owner’s (or the Canadian government’s) alleged investment in research “for the ’591 patent” (DD Req. at 38), does not constitute a compelling economic interest favoring discretionary denial. Patent Owner offers nothing to support its claim of “significant investments in research leading to the ’591 patent.” DD Req. at 39. Patent Owner submits what appears to be a chart of grants with titles such as “towards new frontiers in computer assisted image guidance” and “big data analytics for next generation mobile ultrasound.” Ex2046. It provides no other information about the grants or use of the grant funds.

Furthermore, Patent Owner’s claims of “meaningful” contribution to the medical field (DD Req. at 40) are entirely speculative. Patent Owner has not commercialized the ’591 patent. *See* Ex1031 at 2-3 (“Plaintiff has never had a

Practicing Product....”); Ex1032 at 15 (“Plaintiff has not commercialized nor exploited the ’591 Patent.”). And it offers nothing to support its broad declarations of importance. If anything, the breadth of the (invalid) ’591 patent threatens to stifle innovation in the public health field.

The Director has rejected the type of speculative public interest arguments Patent Owner advances here. For example, in *Amgen, Inc. v. Bristol-Myers Squibb Co.*, the Patent Owner’s discretionary denial brief featured repeated characterizations of the subject patent’s purportedly “revolutionary” contributions to public health. IPR2025-00603, Paper 6 at 1 (“[Patent Owner] and its collaborators revolutionized cancer treatment by developing novel methods...”), at 5 (“[Patent Owner’s] groundbreaking work included extensive research ...”). The Board denied Patent Owner’s request for discretionary denial on the subject patent. IPR2025-00603, Paper 8. While the Director observed that “an explanation of how an *extraordinary* amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations” may help demonstrate “strong settled explanations,” it found that Patent Owner had “not sufficiently articulated such reasons.” IPR2025-00603, Paper 8 at 2 (emphasis added). So too here.

IV. CONCLUSION

For all the foregoing reasons, review of the '591 patent claims on the merits would be an appropriate use of the Board's resources. Petitioner requests the Director to decline discretionary denial and refer this matter to the Board.

Date: September 24, 2025

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

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CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2025, I served a true and correct copy of the following materials:

- Petitioner's Opposition to Patent Owner's Request for Discretionary Denial;
- Exhibits 1029 to 1041; and
- Petitioner's Updated Exhibit List

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