

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRECISION CANCER TECHNOLOGIES INC.

Petitioner,

v.

ONCOUSTICS INC.,

Patent Owner

Case IPR2024-00242

U.S. Patent No. 11,602,330

PETITIONER'S REQUEST FOR DIRECTOR REVIEW

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.75, Precision Cancer Technologies Inc. (“Petitioner”) requests Director Review of the decision denying institution of *inter partes* review of claims 1-20 (“the Challenged Claims”) of U.S. Patent No. 11,602,330 (“the 330 Patent”), which is purportedly assigned to Oncoustics Inc. (“Patent Owner”). The Board’s decision turned on a single issue—the Board found that Petitioner had not proven in the Petition that its primary reference, PCT Publication No. WO 2018/127498 A1 (“Hope-Simpson”), discloses processing a “single static set of raw ultrasound radio frequency (RF) data forming a single frame.” Paper 7, Institution Decision at 14-16.

Petitioner, however, *did* provide evidence that Hope-Simpson discloses processing a “single static set of raw ultrasound radio frequency (RF) data forming a single frame.” Petitioner pointed to evidence including expert declaration testimony explaining that Hope-Simpson was describing a standard ultrasound—and that standard ultrasound methods process images one frame at a time (i.e., a single static set), not multiple frames at a time. What the Board’s decision really amounts to is holding that Petitioner was required to disprove, by more than expert testimony, the speculative possibility that Hope-Simpson *could have* instead been referring to processing a time series—despite no evidence indicating that Hope-Simpson even remotely could have been referring to processing time series data—simply because

Hope-Simpson did not use the specific claim language “single static set...forming a single frame.”

The Board’s finding in this regard, however, places an unrealistic and legally unsupported burden on petitioners. It is improper to require a petitioner (1) to be prescient in predicting where a Patent Owner might dispute basic, undisputed technological principles or semantics and preemptively rebut them and (2) to provide independent proof (e.g., third-party documentation) to support every basic technological proposition or technological synonym. That is not the law.

For the reasons discussed below, the Director should grant review of the Board’s decision to not institute *inter partes* review and should order institution.

II. LEGAL STANDARD

“Requests for Director Review of a Board’s decision on institution under 35 U.S.C. §§ 135, 314, or 324, or decisions granting rehearing of such a decision, shall be limited to decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” *See* USPTO, Director Review Process at 2.B, Availability of Director Review: Proceedings under part 42 of 37 C.F.R. (last modified March 18, 2025), <https://www.uspto.gov/patents/ptab/decisions/director-review-process#RIDRP>.

“An abuse of discretion is found if [a] decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly

erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its discretion.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (quoting *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1121 (Fed. Cir. 2004) (citations omitted)).

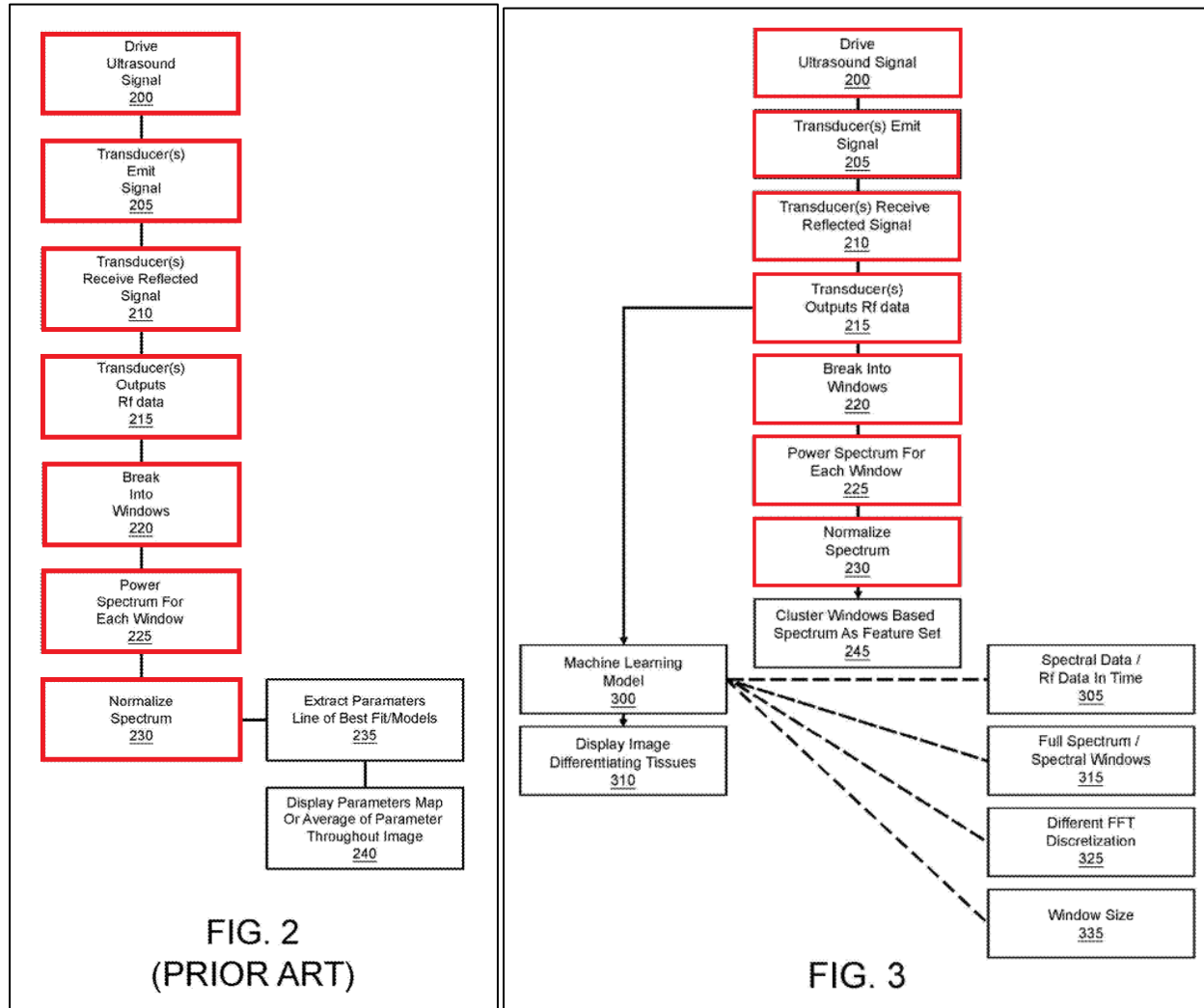
III. BACKGROUND

The 330 Patent is directed to an ultrasound system that uses a machine learning model for the classification and identification of various physiological aspects of a living organism. *See* EX1001, 1:20-23.

The 330 Patent explains that “[c]onventional ultrasound spectroscopy uses ultrasound frequency spectrums from ultrasound RF data (raw sound signal as it returns into a transducer) to extract specific, pre-defined quantitative parameters that can describe tissue state (e.g., information on the ultrasound scatter size, concentration, and change in impedance in tissue).” *Id.*, 4:22-27.

The 330 Patent purports to use “machine learning to take ultrasound images and to train machine learning models to recognize certain pathologies based on these conventionally qualitative images.” *Id.*, 4:61-64. The 330 Patent alleges that “applying the ML models to the raw data or the frequency spectrum data—rather than the images (e.g. B-mode) after processing—provides much more accurate results[.]” *Id.*, 5:12-15.

Figure 3 of the 330 Patent provides “an example of a flowchart showing a method for classification of tissue using machine learning analysis of ultrasound data.” *Id.*, 3:3-5. The steps bounded in red are applicant-admitted prior art because they overlap with the prior art flow chart of Figure 2. *Id.*, Fig. 2.



Compare *id.*, Fig. 2 (annotated), with Fig. 3 (annotated).

The claims of the 330 Patent recite a signal processing unit that receives a single static set of raw RF ultrasound data and processes that single static set of raw RF ultrasound data with a machine learning model. *See, e.g., id.*, Claim 1.

IV. ARGUMENT

A. The Board Erred As a Factual Matter And Abused Its Discretion In Finding That Petitioner Had Not Provided Proof That Hope-Simpson Discloses a “Single Static Set of Raw Ultrasound Data”

The Board found that the claim term a “single static set of raw ultrasound radio frequency (RF) data forming a single frame” refers to something different from a series of frames of RF data taken consecutively over a period of time. Paper 7, Institution Decision at 10. But this is not the whole story, because *every* ultrasound is of course capable of taking a series of frames of RF data over a period of time, i.e., taking multiple images. The claims require more.¹ Importantly, the claims do not preclude *acquiring* multiple frames of RF data over a period of time—what they preclude is *processing* multiple frames together, i.e., the claims require processing a “single static set of raw ultrasound radio frequency (RF) data forming a single frame.” *See* Exhibit 1001, 330 Patent at claim 1. Otherwise, the claims would preclude any ultrasound machine that takes multiple images, because again *any*

¹ If Patent Owner is taking the position that it disclaimed any ultrasound method that involves taking more than one image frame, the claims would be meaningless.

ultrasound machine can, and traditionally does, acquire more than one image of a tissue area. The Board subsequently recognized this distinction, stating that the actual issue with respect to Hope-Simpson is what data it “*provides to the processor.*” Paper 7 at 16. In other words, the Board found that unpatentability of the 330 Patent turned on whether (1) does Hope-Simpson provide individual image frames to the processor for processing one-by-one, or (2) does it provide a group of image frames taken at different times to process together as “time series” data?

As Petitioner and its expert explained, Hope-Simpson of course processes its frames individually, and *not* as a “time series”—because that is what nearly every ultrasound does, i.e., the standard method of ultrasound image processing, and everything in Hope-Simpson is consistent with processing standard ultrasound data. *See* Paper 1, Petition at 21-23, 26-27. Hope-Simpson refers to taking signals processed from its *raw* data and feeding them into a “B-mode processor,” which the 330 Patent itself states is a processor for *individual* images—not time series data. *Compare* Exhibit 1005 at ¶40 with Exhibit 1001 at 5:11-19. It also refers to calculating the “characteristics of *an image* for display from raw channel data (RF echo signals),” processing “conventional ultrasound imaging,” and producing “an ultrasound image.” Exhibit 1005 at ¶¶25, 64, 69.

Petitioner, with support of expert testimony, explained that based on the totality of its disclosure, Hope-Simpson therefore refers to “standard transducer

output when imaging tissue using ultrasound,” i.e., a single static set forming a single frame and not time series data. Exhibit 1002 at ¶¶84-85. To a person of ordinary skill in the art, the claim term “single static set” equates to nothing more than the conventional ultrasound images described at length in Hope-Simpson. This was no different than an expert providing testimony that a medicinal reference describing a “pharmaceutical” discloses a “drug,” or that an electronics reference describing a “PCB” refers to a “printed circuit board”—simple explanations of basic concepts that experts routinely provide. This is not *ipsa dixit*, but is based on an expert’s education, knowledge, and experience.

Patent Owner in response, however, speculated that Hope-Simpson *could have* instead been processing time-series image data and criticized Petitioner for relying “only” on Hope-Simpson’s disclosure and an expert declaration. *See* Paper 6, POPR at 11-14. Yet, Patent Owner offered nothing to support its own speculation. *See, e.g., Carlisle Fluid Tech., Inc. v. Akurate Dynamics, LLC*, IPR2021-01256, Paper 11 (P.T.A.B. Jan. 11, 2023) (rejecting a Patent Owner’s speculation regarding a prior art reference; “Patent Owner speculates that ‘Kogelbauer’s reference to controlling the pumps likely references cycling them ‘on’ or ‘off’ as required when the spray lance trigger is depressed or released.’ ... Patent Owner does not cite any persuasive evidence to support its speculation.”).

For example, Patent Owner pointed to absolutely nothing in Hope-Simpson to suggest it was employing a more complex or advanced time series processing method, as opposed to a standard ultrasound processing method. *See id.* Similarly, Patent Owner pointed to nothing in Hope-Simpson to indicate that it was doing anything with any time data, such as Doppler imaging or analyzing time-dependent methods for generating elastography data or time-dependent changes correlated to tissue abnormalities. *See id.* And, Patent Owner offered no independent, third-party evidence to support that Hope-Simpson was referring to processing anything other than a standard, single static set forming a single frame.

As an analogy that illustrates the issue here, one can imagine a person simply stating “I took a photo on my smartphone.” The natural conclusion is that the person took a single frame photo—not that the person took a video, played it back, and then took a screenshot of an instant of the video to make the “photo.” Yet, that is exactly the kind of speculative possibility that Patent Owner posits and insists that Petitioner disprove.

Nevertheless, the Board accepted Patent Owner’s unsupported speculation. The Board found that “Petitioner does not explain why Hope-Simpson’s ‘localized data sets’ equate with a single frame of a tissue area rather than, for example, a time series of frames taken at the same location” and that Petitioner’s expert testimony “lacks both technical reasoning and evidentiary support...” Paper 7, Institution

Decision at 15. As discussed, however, that factual finding was erroneous. Petitioner *did* provide sufficient evidence on this issue of mere semantics, whereas Patent Owner provided only technologically meritless speculation in response.

B. The Board Erred as a Legal Matter And Abused Its Discretion By Requiring the Petition to Anticipate and Disprove Patent Owner’s Technologically False Argument

The Board’s non-institution decision also applied an erroneous burden of proof on Petitioner—to not just predict, but affirmative and conclusively disprove in the Petition all possible technologically incorrect arguments that Patent Owner could raise. But that is not the standard for institution. *See, e.g., Costco Wholesale Corp. v. Robert Bosch, LLC*, IPR2016-00039, Paper 69 (P.T.A.B. March 30, 2017) (“[W]e agree with Petitioner that Petitioner could not have reasonably anticipated that Patent Owner would make such argument when it is contradicted by the disclosure of the [the challenged patent] itself. For that reason, Petitioner’s counter argument in the Reply was not required to be in the Petition.”); *see also Mylan Pharma, Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00122, Paper 83 (P.T.A.B. May 29, 2020) (holding that a party should not be faulted “for its lack of prescience or ability to predict [the other party’s] argument.”).

At the institution stage, all that is required is a “reasonable likelihood” that Petitioner’s position is correct. 35 U.S.C. 314. Any factual disputes—especially fact disputes the Petitioner has not had an opportunity to rebut—are best resolved after

development of a full record during a trial. *See Patent Quality Assurance, LLC v. VLSI Tech. LLC*, IPR2021-01229, Paper 10 (P.T.A.B. Jan. 26, 2022) (“Petitioner has not yet had an opportunity to respond to Patent Owner’s arguments Patent Owner’s arguments will ultimately depend on resolving potential factual disputes and balancing competing factors. We determine those arguments are best suited for resolution through trial.”); *Amcol Intern. Corp. v. Oil-Dri Corp. of America*, IPR2022-01107, Paper 10 (P.T.A.B. December 5, 2022) (stating in institution decision that arguments that “raise factual disputes [are] best resolved after development of the record during trial.”)

Here, Petitioner provided evidence, including an expert declaration, supporting that Hope-Simpson was describing standard ultrasound images—which are what Patentee calls a “single static set” of ultrasound images. *See supra*. In response, Patent Owner’s own evidence to the contrary consisted solely of unsupported attorney argument. Patent Owner, for example, did not submit any other affirmative evidence that Hope-Simpson was instead referring to “time series” ultrasound images. This is exactly the type of dispute over evidence that should be resolved after a fully developed record at trial—not at the institution stage.

V. CONCLUSION

Petitioner respectfully requests that the Director grant review of the decision to not institute *inter partes* review and reverse the decision of the Board and grant institution.²

Respectfully submitted,

Dated: June 30, 2025

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² Petitioner notes that a Request for Refund of Post-Institution Fees (“Refund Request”) was filed on June 20, 2025. To the extent the Refund Request is granted prior to the grant of remedy sought by this Request for Director Review, the USPTO is authorized to charge Deposit Account No. 13-0017 for fees pursuant to 37 C.F.R. § 42.15(a), as well as any additional fees necessary to institute the requested *inter partes* review.

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Request for Director Review were served on June 20, 2025, via electronic means on the following individuals:

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