

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No: IPR2024-01330
U.S. Patent 11,970,746

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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Patent Owner respectfully requests Director Review of the Final Written Decision, Paper 39 (“FWD”), in this *inter partes* review (“IPR”) because the FWD is based on abuses of discretion, erroneous findings of material fact, and erroneous conclusions of law, and presents important legal and policy issues. 37 C.F.R. § 42.75; www.uspto.gov/patents/ptab/decisions/director-review-process.

First, without ***any*** explanation, Petitioner took divergent claim construction positions in this IPR (seeking no construction) and in parallel Delaware District Court litigation (arguing indefiniteness of two claim terms and seeking alternative narrowing constructions that differ from plain and ordinary meaning to support non-infringement).¹ This directly defies the Director’s stated principle that the “Board’s claim construction rules are designed to ensure that the Board correctly construes claim terms and to minimize inconsistency in claim construction between forums.”

¹ *Exact Sciences Corp. v. Geneoscopy, Inc.*, No. 23-cv-1319-MN (D. Del.) (consolidated), D.I. 73 at 25 (answer and counterclaims asserting indefiniteness); D.I. 300 at 8:21-9:7 (hearing transcript noting indefiniteness arguments). Petitioner also contended the claims were indefinite and narrow in its March 7, 2025 Initial Invalidity Contentions; April 11, 2025 proposed claim constructions; and September 12, 2025 Final Invalidity Contentions. Pursuant to 37 C.F.R. § 42.75(c)(3), Patent Owner requests the Director’s authorization to file these documents as exhibits.

Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc., IPR2025-00632, Paper 20 at 3-4 (Director Nov. 3, 2025) (precedential) (“*Revvo I*”). “[W]hen a petitioner takes alternative positions before the Board and a district court, that petitioner should, at a minimum, explain why alternative positions are warranted.” *Id.* Here, Petitioner took alternative claim construction positions but never offered an explanation. The Director recently vacated reviews for this reason, and should reverse the FWD here. *See, e.g., Carbyne, Inc. v. Tritech Software Sys.*, IPR2025-00959, Paper 20 (Director Feb. 19, 2026); *Generac Power Sys., Inc. v. Champion Power Equip., Inc.*, IPR2025-00805, Paper 40 (Director Feb. 3, 2026); *Revvo Techs., Inc. v. Tire Stickers LLC*, IPR2025-00631, Paper 34 (Director Feb. 3, 2026); *Revvo*, IPR2025-00632, Paper 36 (Director Jan. 26, 2026) (“*Revvo II*”); *see also Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 (Director Nov. 5, 2025) (informative).

Second, the Board committed reversible legal error by crediting the testimony of Petitioner's expert, Dr. Duncan Whitney, without addressing the irreconcilable contradictions in his opinions. When the party bearing the burden of proof rests its case on self-contradictory expert testimony, that evidence is legally insufficient. *Finesse Wireless LLC v. AT&T Mobility LLC*, 156 F.4th 1221, 1227 (Fed. Cir. 2025). The Director recently reversed a Final Written Decision on this precise ground as well. *Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 at 3-4 (Director Oct. 9, 2025). The same result is warranted here.

I. TECHNOLOGICAL BACKGROUND

The claims of U.S. Patent No. 11,970,746 (“’746 Patent”) recite non-invasive methods of at-home stool sample collection followed by analysis that are useful for detecting health conditions including colorectal cancer (“CRC”). Prior non-invasive approaches to testing stool samples for CRC fell into two general categories: tests for hemoglobin (a blood protein) in stool, and nucleic acid-based tests that analyzed cancer-associated DNA or RNA biomarkers. While combining blood and nucleic acid-based marker classes had been theorized, it had not been demonstrated to be reliably effective, and the practical challenges of stabilizing both nucleic acids and blood proteins in a fecal sample—particularly outside a clinical laboratory setting and without freezing the sample—remained unsolved.

The claimed invention addressed this long-felt and unmet need with a method for at-home collection of a single fecal sample that is divided into two portions in separate containers, each stabilized without freezing in an appropriate buffer—one preserving nucleic acid integrity and the other preventing denaturation of blood proteins. This approach enabled simultaneous testing for nucleic acid markers and fecal occult blood from a single home collection event without freezing.

Dependent claims 12 and 13 require the nucleic acid to be human RNA, which provides a further layer of technical complexity according to Petitioner’s cited art. Petitioner’s references, particularly Kanaoka (relied upon in Grounds II, IV, and VII

as providing the RNA elements of claims 12 and 13), taught that RNA presents unique and significant handling challenges compared to DNA. EX1007 at 3. Kanaoka reported that RNA is inherently more unstable than DNA and is at risk of degradation. *Id.* Kanaoka further taught that earlier attempts to use RNA as a tumor marker in fecal testing had been unsuccessful because it was “impossible to extract RNA easily and efficiently from a small amount of feces.” EX1007 at [0009].

Kanaoka's only “working example” required freezing samples with liquid nitrogen and storing them at -80°C (EX1007 at [0057])—a protocol incompatible with the claimed at-home collection. While a later reference, Nechvatal, speculated that preserving fecal samples at room temperature “in a medium suitable for DNA and RNA analysis is feasible” (EX1024 at 8), that study tested only DNA stability and reported *no* data on RNA preservation. At most, Nechvatal speculated that bacterial RNA from feces *might* be stable in a buffer. A POSA in 2009 would not have reasonably expected that Kanaoka's preservation of RNA by freezing could be replaced by an at-home collection method while still preserving the human RNA.

II. ARGUMENT

A. Petitioner Failed to Explain Its Divergent Claim Constructions in the IPR and District Court in Violation of the Director's Policy

By taking a position that no construction was needed in this IPR (*see generally* Paper 1; *see also* FWD at 14) but arguing for indefiniteness and alternative narrow claim constructions in the parallel District Court litigation, Petitioner violated the

Director's policy requiring it to explain inconsistent claim construction positions to the Board. *Revvo I*, IPR2025-00632, Paper 20 at 3-5 (precedential); *Tesla*, IPR2025-00340, Paper 18 at 3-4 (informative); *Revvo II*, IPR2025-00632, Paper 36 at 4. Indeed, Petitioner has failed to explain how, “notwithstanding the alleged indefiniteness of the claim term, [a POSA] would understand that the asserted art satisfies the claim limitation.” *Tesla*, IPR2025-00340, Paper 18 at 3-4.

“Although the Board's trial rules ‘do not necessarily prohibit petitioners from taking inconsistent claim construction positions before the Board and a district court,’ when a petitioner takes alternative positions before the Board and a district court, that petitioner should, at a minimum, explain why alternative positions are warranted.” *Revvo I*, IPR2025-00632, Paper 20 at 3-4 (quoting *Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 at 8-9 (PTAB Dec. 13, 2024) (informative)). Petitioner has not provided and cannot provide a justification for its irreconcilable positions—particularly given the chronology of events.

Petitioner filed its Petition on August 20, 2024, seeking no claim construction. Paper 1. Patent Owner filed its Preliminary Response in November 2024, noting that it “does not believe that the Board must construe any claim terms” Paper 9 at 20. Petitioner never disputed that position in this IPR.

Almost five months later, on April 11, 2025, after the Board instituted review in February 2025, the parties exchanged proposed claim constructions in the District

Court. There, Petitioner took the position that the terms “stabilizing buffer” and “a solution that prevents denaturation or degradation of blood proteins found in a fecal sample” in claims 1 and 3 are *indefinite*. That is, Petitioner contended that these two terms could not be construed because a POSA could not reasonably ascertain their meaning. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). By Petitioner's logic, a POSA would not have understood that the asserted art in this IPR satisfies these claim limitations. *See Tesla*, IPR2025-00340, Paper 18 at 3-4.

In the same April 11, 2025, District Court exchange, Petitioner argued, alternatively, for narrowing constructions, that: (a) the allegedly indefinite term “stabilizing buffer” meant “a buffer for maintaining the integrity of the **DNA** in the first portion of the fecal sample,” and (b) “extracting nucleic acid from the first portion of the fecal sample” in claim 3 meant “removing and thereby purifying nucleic acid **directly** from the first portion of the fecal sample.” In this IPR, Petitioner never disclosed these constructions, nor did it make any showing that its prior art combinations would satisfy obviousness under Petitioner's constructions. Indeed, if the Board had adopted Petitioner's District Court narrowing of “stabilizing buffer” to only DNA (and not RNA), the Board could not have found that Nechvatal's allegedly **RNA**-stabilizing buffer covers claims 12 and 13. Certainly Petitioner never met its burden to explain how it could. The Board's “rules discourage petitioners from seeking broader constructions at the Board to support a patentability challenge

while seeking narrower constructions in litigation to avoid infringement liability.”
Revvo I, IPR2025-00632, Paper 20 at 4.

Over four months after proposing claim constructions in the District Court, on August 22, 2025, Petitioner filed its Reply in this IPR *without seeking any claim constructions or indicating that a POSA could not understand the claims*. Paper 22. Also notably absent from the Reply was an explanation for Petitioner's divergent claim construction positions, notwithstanding the Director's requirement for one in this situation. *See Revvo I*, IPR2025-00632, Paper 20 at 3-5. Shortly after, in September 2025, Petitioner served its *final* non-infringement contentions and *final* invalidity contentions in the District Court, relying on the proposed narrowing claim constructions and indefiniteness that it failed to disclose to the Board.

Petitioner had another chance to provide clarification at the November 20, 2025 hearing in this IPR—weeks after the Director's November 2025 guidance in *Revvo I* and *Tesla* on the impropriety of presenting conflicting claim constructions and indefiniteness arguments in an IPR and in district court without explanation. But Petitioner again remained silent. *See generally* Paper 38 (hearing transcript). The Board then issued the FWD on February 5, 2026.

Allowing Petitioner to pick and choose what claim constructions best suit its purpose is highly prejudicial to Patent Owner and contrary to the Board's goals of reducing inconsistencies in patent litigation. *Generac*, IPR2025-00805, Paper 40 at

3. Petitioner was required to “choose a single claim construction that best captures the true meaning of the patent claim.” *Id.* (cleaned up). Here, Petitioner strategically ignored this guidance despite having had ample opportunities to follow it. And Petitioner's strategic maneuvering certainly affected the outcome of the FWD, as the Board would not have had a basis for finding the '746 Patent claims unpatentable had Petitioner disclosed its contention that a POSA could not understand them sufficiently to know whether the prior art practices them. Nor would the Board have had a basis for finding the “stabilizing buffer” element of claim 3 satisfied by a reference allegedly disclosing RNA buffers (Nechvetal) in Grounds II, IV, and VII (regarding RNA-directed dependent claims 12 and 13) under Petitioner's District Court DNA-only construction of “stabilizing buffer.” Petitioner failed to explain itself, and the Director should grant review and reverse the FWD.

B. The Board Made Erroneous Findings of Fact Based upon Conflicting Expert Declaration and Deposition Testimony

The FWD relied on Petitioner's expert Dr. Whitney's opinions to establish two things, that: (1) a POSA would have been motivated to have the user separate a home-collected fecal sample into two containers and use separate buffers to preserve different portions of the sample as claimed (rather than preserve the sample in one container with one buffer) (claim 3); and (2) a POSA would have had a reasonable expectation of success in combining Kanaoka's lab-collected frozen-sample RNA

test with the other references to arrive at the claimed home-collected RNA buffer-stabilizing (non-frozen) method (claims 12-13). FWD at 41-44, 54-56, 69-71, 77.

As discussed below, Dr. Whitney's testimony on these two points is internally contradictory and conflicts with the positions he took in the District Court litigation. He applies a double standard regarding the role of "data": he demands data to support Petitioner's motivation-to-combine argument on the single container/buffer issue (claim 3), but abandons that requirement entirely when addressing Petitioner's reasonable-expectation-of-success argument on RNA stabilization (claims 12-13).

On claim 3, Dr. Whitney insisted that no data had proven a single buffer could preserve both nucleic acids and blood proteins, and on that basis concluded a POSA would have pursued the claimed method. But on claims 12 and 13, Dr. Whitney speculated, without any supporting data, that Nechvatal hypothesized a buffer could stabilize RNA, and on that basis he concluded a POSA would have had a reasonable expectation of success. Dr. Whitney required data when it cut against Patent Owner's position and dispensed with that requirement when it supported Petitioner's position.

1. The Board Abused Its Discretion in Crediting and Relying on Contradictory Testimony

The Board abused its discretion by crediting Dr. Whitney's conclusions wholesale without addressing the fundamental contradictions in his underlying testimony. FWD at 41-44, 54-56, 69-71, 77. This is the same error the Director

recently corrected when vacating a FWD and terminating the IPR in *Interactive Communications*. IPR2024-00465, Paper 40 at 3-4.

To support a motivation to combine the references to arrive at the method of claim 3 requiring two separate containers and buffers to stabilize nucleic acids and blood proteins, respectively, Dr. Whitney had to reject the notion that a POSA could use just one container (rather than separate the sample into two portions) and one buffer (rather than two) to stabilize both nucleic acids and proteins. EX1002 ¶¶ 34, 48, 74-75; EX1086 ¶¶ 14, 68-72. In rejecting the one-container/one-buffer theory, Dr. Whitney concluded that there was no experimental data to show that a single buffer could stabilize both nucleic acids and blood proteins in a stool sample and, absent such data, the POSA would have been motivated to separate the sample into two separate containers with two different buffers. *Id.*

For example, Dr. Whitney declared that he was “unaware” of any buffer “that had been tested” for stabilizing both nucleic acids and proteins. EX1086 ¶ 70. He further testified that it was “imperative” to have some data on a buffer’s ability to stabilize a particular analyte before concluding the buffer would be suitable. EX2057 at 17:14-19; 18:12-19:18. In addition, Dr. Whitney testified that he was “not aware of any data that shows there is a single buffer that could stabilize both [nucleic acids and blood proteins] in a way that’s been demonstrated to be useful in colorectal cancer screening.” EX2057 at 15:9-20; *see also id.* at 15:21-16:10.

In the District Court litigation, to support an argument that the '746 Patent claims are not adequately described or enabled under 35 U.S.C. § 112, Dr. Whitney further opined that data and extensive effort would be required to develop or identify buffers to stabilize different biomolecules:

- “Stabilization of biomolecules in fecal samples is significantly more challenging than in most other biological sources. Extensive scientific effort has therefore been required to develop buffer solutions capable of stabilizing biomolecules in stool samples.” EX2052 ¶ 52.
- “Optimal conditions to stabilize a sample depend on the type of biomarker to be recovered (*e.g.*, cells, proteins, DNA, or RNA). . . . [S]pecialized stabilization conditions often need to be developed and clinically validated to prove their effectiveness for preserving a given biomarker from a given sample type under applicable conditions.” EX2052 ¶ 53.

This tied into Dr. Whitney's District Court invalidity narrative that extensive optimization and supporting data would be required for a POSA to reasonably expect a buffer could stabilize fecal RNA in particular, because RNA is inherently unstable:

- “The optimized buffer we developed was never intended to stabilize RNA, and I would not expect it to do so effectively given RNA's increased susceptibility to degradation compared to DNA.” EX2052 ¶ 54.
- “RNA is a fragile biomolecule, exhibiting reduced stability compared to

DNA . . . RNA nucleases are abundant in biological samples, including fecal matter, and can rapidly degrade RNA if not properly inhibited. Furthermore, the complex and diverse microbiome environment in fecal samples may contribute to a high level of RNase activity, making RNA stabilization in such samples particularly challenging. Therefore, it is generally recognized that additional precautions must be taken for isolating RNA and running RNA-based testing protocols compared to DNA-based testing.” EX2052 ¶ 55.

- “RNA stabilization buffers need to be specifically formulated to address the unique challenges posed by RNA’s fragility and susceptibility to degradation by RNases, and thus differ in composition from DNA stabilizing buffers.” *Id.*

According to Dr. Whitney’s own unequivocal testimony, data is necessary to understand whether a buffer—which must be specifically formulated—will work to stabilize a particular analyte such as fecal RNA given the challenges it can present. Yet on the question of reasonable expectation of success in arriving at the methods of claims 12 and 13 by incorporating Kanaoka’s test, which involved *freezing* a stool sample to stabilize RNA, into the claimed methods that require *no freezing*, Dr. Whitney abandoned his own proffered standard. On this issue, he no longer opined that data was necessary to evidence a reasonable expectation that a buffer would work to stabilize RNA in a stool sample—speculation or hypothesis was enough.

Claims 12 and 13, which depend from claims 3 and 4, require that the nucleic

acids be human RNA. Petitioner's sole support for arguing a reasonable expectation of a buffer that could stabilize human stool RNA without freezing was Nechvatal, a reference that (1) concerns primarily *bacterial DNA*, (2) contains only limited data on *human DNA* preservation, and (3) contains *no data whatsoever* on *RNA* preservation in stool. EX1024 at 5-8; EX2044 ¶¶ 188-191. Petitioner relies only on conjecture that the "RNAlater" buffer used to stabilize *DNA* in Nechvatal could also stabilize bacterial RNA—*without any data to show it actually could stabilize any RNA, much less human RNA*. Paper 22 at 20; EX1024 at 2, 8; EX1002 ¶¶ 223, 275; EX1086 ¶¶ 60, 123. Contrary to the opinions he espoused in the District Court, Dr. Whitney offered only speculation about the "suitab[ility]" of a buffer that would stabilize RNA to carry out the methods of claims 12 and 13. EX1002 ¶¶ 223, 275.

In particular, in this IPR, Dr. Whitney testified that "[a]s of the Priority Date, a known alternative to freezing a sample using liquid nitrogen would be to stabilize the fecal RNA with a buffer, such as the then-commercially available RNAlater buffer." EX1086 ¶ 60. He further opined that "[a POSA] would reasonably expect to preserve the fecal RNA in the sample without freezing because by the Priority Date it had been reported that 'preserving fecal samples at room temperature for a duration of 5 days, in a medium suitable for DNA and RNA analysis is feasible,'" citing only to Nechvatal, which included no data to support any expectation that a buffer would stabilize the human RNA in a stool sample. EX1002 ¶¶ 223, 275.

Patent Owner pointed out these significant inconsistencies (Paper 30 at 17-20; Paper 38 at 29-32, 34, 41-45). The Board nevertheless accepted Dr. Whitney's position at face value—deeming it central to finding a reasonable expectation of success as to claims 12 and 13 (FWD at 56, 71)—without reconciling it with Dr. Whitney's own: (1) demand for data on the single-buffer question as to claim 3, (2) testimony that a POSA would require extensive experimental testing and data to reasonably expect a buffer to stabilize any particular analyte in stool, and (3) testimony that different buffers would be required to stabilize DNA and RNA.

Indeed, Dr. Whitney testified at deposition that “data” on buffer stabilization is “imperative” before concluding that a buffer could work for a given analyte. EX2057 at 17:14-19. Applied consistently, this standard would require a showing of actual data demonstrating that Nechvatal's buffer preserves RNA in stool—data that indisputably does not exist in the record. The Board credited Dr. Whitney's opinions while ignoring the standard he himself declared to be “imperative.” FWD at 56, 71.

Dr. Whitney applied a self-serving, asymmetric evidentiary standard—demanding that Patent Owner's position be supported with analyte-specific data while accepting mere speculation to support Petitioner's. The Board abused its discretion in crediting and relying on Dr. Whitney's contradictory testimony.

2. The Board Made an Erroneous Finding of Material Fact on Reasonable Expectation of Success for Claims 12 and 13

The Board's finding that a POSA would have had a reasonable expectation of successfully incorporating Kanaoka's RNA test into the claimed non-frozen, at-home collection method was not supported by substantial evidence. It is Petitioner's burden to establish reasonable expectation of success. *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1348 (Fed. Cir. 2021). The only evidence Petitioner offered was Dr. Whitney's speculation, premised on Nechvatal's limited **DNA** data, that a buffer would "likely" preserve non-frozen **RNA** markers. EX1024 at 2. This does not satisfy Petitioner's burden under any standard—let alone the "imperative" data standard Dr. Whitney himself articulated. Yet the Board accepted and relied upon it. FWD at 56, 71. Had the Board rejected Dr. Whitney's testimony, as the contradictions mandate, it should have concluded that Petitioner failed to meet its burden on claims 12 and 13. *See Robert Bosch LLC v. Westport Fuel Sys.*, IPR2023-00292, Paper 37 at 22 (PTAB Feb. 3, 2025); *Xilinx, Inc. v. Analog Devices, Inc.*, IPR2020-01564, Paper 34 at 14 (PTAB Mar. 11, 2022); *C.R. Bard, Inc. v. Medline Indus., Inc.*, IPR2019-00208, Paper 57 at 22 (PTAB June 3, 2020).

III. RELIEF REQUESTED

Patent Owner respectfully requests that the Director: (1) review the FWD in IPR2024-01330; (2) reverse the FWD's finding of unpatentability; and (3) issue a decision confirming the patentability of all challenged claims of the '746 Patent.

Patent Owner's Request for Director Review

Date: March 6, 2026

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CERTIFICATE OF LENGTH

Pursuant to 37 C.F.R. §§ 42.24 and 42.75(c)(2), the undersigned certifies that the foregoing Patent Owner's Request for Director Review, exclusive of the Table of Contents, Table of Authorities, and Mandatory Notices, is within the 15-page limit.

Date: March 6, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, the undersigned certifies that on March 6, 2026, the foregoing Patent Owner's Request for Director Review was served via email on the following counsel of record for the Petitioner:

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