

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

**PETITIONER'S AUTHORIZED RESPONSE TO
PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW**

Petitioner’s Authorized Response to Patent Owner’s Request for Director Review

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I. INTRODUCTION

Patent Owner's Request for Director Review ("Req.") improperly seeks to introduce new arguments and evidence and fails to identify any errors, let alone any abuse of discretion, in the Board's well-supported Final Written Decision ("FWD").

Patent Owner's untimely "divergent claim construction" argument violates the rules governing Director Review, which is limited to evidence and arguments previously made part of the record. Patent Owner offers no excuse for failing to present the evidence to the Board, evidence that was known to Patent Owner well before Patent Owner's written submissions and argument in this proceeding. But even if the Director were to consider the evidence Patent Owner elected not to offer below, no divergent claim construction exists. Because the district court terminated the claim construction process more than six months ago, the parties never conferred on their preliminary proposals, and they never submitted any claim constructions to the district court. Further, Petitioner has informed Patent Owner that Petitioner will not advance a claim construction in litigation different from that used in the Board's Final Written Decision, and it will not contend that any claim term is indefinite.

Nor is there any merit to Patent Owner's strained attack on the credibility of Petitioner's expert witness based on the spurious assertion that parts of his testimony were "inconsistent." The expert's testimony discussing several different prior art buffers was offered in different contexts and for different purposes, and it was not

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contradictory. The Board was well positioned to assess the expert's credibility, and its findings were amply supported. Patent Owner's claim that the Board abused its discretion has no basis. The Director should deny this Request.

II. BACKGROUND

U.S. Patent 11,970,746 ("the '746 patent") is directed to the separation of a fecal sample into two portions to perform two standard, complementary diagnostic tests for colorectal cancer ("CRC"), one for detecting blood proteins and the other for detecting nucleic acids. As the Board correctly determined in its detailed, 80-page decision, nothing in these claims is inventive. By the '746 patent's priority date, separating a fecal sample into portions to test for different disease biomarkers had been standard practice for decades. Fecal tests for detecting blood proteins and nucleic acids were routine. The prior art recognized that combining fecal blood tests with fecal nucleic acid tests resulted in improved sensitivity for detecting CRC. The record evidence, including prior art literature and hundreds of pages of expert declarations and deposition testimony, overwhelmingly supports the Board's factual findings and its determination that the claimed method is obvious.

Claims 12 and 13 of the '746 patent require that the nucleic acid extracted from the fecal sample be tested for RNA expression. As the Board found, the prior art taught that testing for expression of RNA biomarkers potentially provides improved sensitivity and specificity for CRC. FWD at 56, citing Kanaoka (EX1007).

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The prior art also recognized that “preserving fecal samples . . . in ***a medium suitable for DNA and RNA analysis*** is feasible.” EX1024 at 131 (emphasis added). As Patent Owner's expert conceded, buffers for stabilizing RNA were known in the art and commercially available. EX1089 at 42:6-11; EX2048.

The Board previously found all claims of the '746 patent's parent, U.S. Patent 11,634,781 (“the '781 patent”), unpatentable as obvious in IPR2024-00459 over the same prior art combinations. EX1087. That the Board reached the same conclusion in the two related IPR proceedings is unsurprising, since the claim scope of the '746 patent is broader than that of its invalidated parent. Thus, the Board's reasons for finding the claims of the '781 patent unpatentable in IPR2024-00459 apply equally to the claims of the '746 patent found obvious here.

On November 17, 2023, Patent Owner asserted the parent '781 patent against Petitioner in the U.S. District Court for the District of Delaware (“Court”), and on May 15, 2024, Patent Owner asserted the later-issued '746 patent. On April 11, 2025, pursuant to the Court's Scheduling Order (D.I. 208)¹, Petitioner and Patent Owner exchanged proposed constructions for a handful of claim terms in the two asserted patents. Petitioner proposed that two of these terms were indefinite. Each party

¹ All “D.I.” citations are to *Exact Sciences Corp. v. Geneoscopy, Inc.*, No. 23-cv-1319-MN (D. Del.) (consolidated), unless stated otherwise.

Petitioner's Authorized Response to Patent Owner's Request for Director Review expressly reserved the right to amend their proposed constructions. As they both recognized, their respective proposals were preliminary in nature given that, under the Scheduling Order, the next step in the claim construction process would have been to meet and confer on those constructions to see if the parties could reach agreement prior to submitting final constructions in a joint claim construction submission to the Court due October 6, 2025. *Id.* ¶ 11. But the parties never did meet and confer, and no proposed constructions were ever submitted to the Court, much less briefed. Instead, on October 9, 2025, following the Board's Final Written Decision in IPR2024-00459 and Patent Owner's notice of appeal to the Federal Circuit, the Court entered an agreed-upon Amended Scheduling Order vacating all claim construction deadlines. D.I. 360 at 2; D.I. 208 at 7-9. Patent Owner's appeal of the IPR2024-00459 decision is currently pending.

Seven weeks after the parties exchanged preliminary proposed constructions, on May 30, 2025, Patent Owner filed its Response in this proceeding. It filed a Sur-Reply on October 3, 2025, and the Board heard oral argument on November 20, 2025. Despite these three opportunities, Patent Owner never asserted that there were inconsistencies between Petitioner's positions before the Board and its earlier-exchanged claim construction proposals. Instead, Patent Owner told the Board, and the Board agreed, that claim construction was unnecessary to resolve patentability. Paper 19 at 20; FWD at 14. At no time did Patent Owner communicate to Petitioner

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its current contention that Petitioner's unfiled, preliminary constructions were inconsistent with its positions before the Board.

Most recently, on February 19, 2026, the Court vacated all other deadlines and stayed the entire litigation pending the outcome of private mediation between the parties. D.I. 425. The parties' agreed-upon schedule in the event the mediation does not resolve the litigation does not include claim construction, and Patent Owner continues to pursue its appeal from the Board's decision in IPR2024-00459.

Finally, on March 12, 2026, out of an excess of caution, Petitioner provided Patent Owner a written commitment that, in the unlikely event that claim construction proceedings later take place in the Court, Petitioner will not seek claim constructions that are different from the claim constructions adopted by the Board, nor will Petitioner contend that any asserted claim is indefinite.

III. ARGUMENT

A. Patent Owner Has Waived Its "Divergent Claim Construction" Argument

Patent Owner unfairly asserts that the Board abused its discretion and made erroneous findings of material fact while withholding from the Director the fact that, despite ample opportunity, Patent Owner never presented its "divergent claim construction" argument to the Board. This alone should defeat its Request. Under applicable USPTO rules, "[t]he Director will not consider new evidence or new arguments not part of the official record." Patent Owner has waived its divergent

Petitioner's Authorized Response to Patent Owner's Request for Director Review claim construction argument. Director Review Process, § 3.E. <https://www.uspto.gov/patents/ptab/decisions/director-review-process>.

Patent Owner learned of Petitioner's preliminary claim construction positions on April 11, 2025, more than a month before filing its Patent Owner Response. *Cf. Carbyne, Inc. v. Tritech Software Sys.*, IPR2025-00959, Paper 20 at 4 (Director Feb. 19, 2026) ("Although I agree with Petitioner that, typically, a party should not raise an issue for the first time in a request for Director Review, here, Petitioner did not present its different district court position until after Patent Owner already filed its Preliminary Response.") Patent Owner had further opportunity to raise its divergent claim construction argument in its Sur-Reply, filed on October 3, 2025, and at the November 20, 2025 oral hearing. It never did.

Petitioner's unfiled claim construction proposals exchanged with Patent Owner on April 11, 2025 are not part of the official record in the litigation or in these proceedings. Because these documents are evidentiary in nature and were not filed, administrative notice is not available. *Cf. Carbyne*, IPR2025-00959, Paper 20 at 2. Patent Owner conceded this in seeking permission to enter new evidence. Req. at 1. Petitioner objects to this untimely request to admit new evidence.

Rather than present its claim construction evidence and argument to the Board, Patent Owner chose to await the outcome of the Board's Final Written Decision. Only after the Board found the '746 claims unpatentable did Patent Owner

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assert divergent claim construction. Patent Owner's gamesmanship and attempt to reserve for itself a second bite at the apple if needed should be firmly rejected.

B. Patent Owner's Divergent Claim Construction Argument Is Wrong and Misrepresents the District Court Record

Patent Owner's argument also fails on the merits, because Petitioner never presented any claim construction position to the Court and never will.² *See Samsung Elecs. Co. v. Wilus Inst. of Standards & Tech., Inc.*, IPR2025-00988, Paper 14 at 5-6 (PTAB Jan. 5, 2026) (vacating Decision denying institution where at time of the Decision, claim constructions had not been filed in district court). Patent Owner omits that the parties only exchanged preliminary claim construction proposals and never filed them. These constructions were tentative positions, subject to revision after seeing the other side's proposals and after meeting and conferring to negotiate final claim constructions for filing with the Court.

² Patent Owner also cites Petitioner's final noninfringement and invalidity contentions because they included Petitioner's April 11, 2025 claim construction proposals. But the deadline for serving these documents was well before claim construction had even advanced to the meet and confer stage. Petitioner expressly reserved the right to amend its "final" contentions given that the claim construction process was ongoing. As with Petitioner's April 11 claim construction proposals, the contention documents cited by Patent Owner were never submitted to the Court.

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Even had Petitioner presented its claim construction positions to the Court and urged their adoption, Patent Owner has not established that they are inconsistent with Petitioner's arguments in this proceeding or the Board's Final Written Decision, not least because "notwithstanding the alleged indefiniteness of the claim term, an ordinarily skilled artisan would understand that the asserted art satisfies the claim limitation." *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 at 3-4 (Director Nov. 5, 2025) (informative). In particular, the Board here found that "stabilizing buffer"—one of the claim terms in question—includes the "DNA stabilizing buffer" disclosed in the Itzkowitz prior art. FWD at 21, 54-55; EX1006. The same DNA stabilizing buffer is used in the '746 patent's examples, confirming that this buffer is a "stabilizing buffer." EX1002 at 38:5. Yet this term remains indefinite under §112 because the '746 patent fails to otherwise inform a POSA about the full scope of the invention with reasonable certainty, i.e., what other buffers besides DNA stabilizing buffers would also be a "stabilizing buffer."

Similarly, the Board found that the phrase "solution that prevents denaturation or degradation of blood proteins" includes the "Hb stabilizing buffer" disclosed in the Vilkin prior art. FWD at 18, 53; EX1005. The '746 patent's examples use the same Eiken-manufactured fecal hemoglobin test as Vilkin, confirming that the claimed "solution" at least includes Vilkin's Hb stabilizing buffer. This term also remains indefinite because it is unclear what other solutions would be considered a

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“solution that prevents denaturation or degradation of blood proteins.”

Petitioner's alternative proposed construction of “stabilizing buffer” to mean a “buffer for maintaining integrity of the DNA in the first portion of the fecal sample” is also consistent with its arguments in this proceeding. This is because each “stabilizing buffer” in the asserted prior art *is a DNA stabilizing buffer*. This includes the buffer used in Nechvatal mentioned by Patent Owner, which stabilizes DNA as well as RNA. EX1024 at 131. Petitioner's alternative construction would have no effect on the Board's finding that claims 12 and 13 are obvious.³

In sum, the preliminary claim constructions Petitioner exchanged with Patent Owner were not inconsistent with Petitioner's positions in this proceeding, nor were they relevant to the Board's obviousness finding. Patent Owner itself agreed that no claim construction was needed to resolve the Petition.

Nevertheless, out of an excess of caution, Petitioner has committed in writing that it will not pursue any claim construction in District Court different from the claim constructions adopted by the Board or contend that any asserted claims are indefinite. This step “resolves any potential inconsistency in claim construction positions between forums.” *Caption Health, Inc. v. Univ. of Brit. Columbia*,

³ Petitioner's proposed “extracting nucleic acid” construction is also consistent with its obviousness positions in this proceeding.

Petitioner's Authorized Response to Patent Owner's Request for Director Review IPR2025-01422, Paper 15 at 3 (Dec. 18, 2025); *see also Samsung*, IPR2025-00988, Paper 14 at 6. The rationale expressed by the Director in *Revvo* that "the 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" is thus of no concern here. *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3-4 (Director Nov. 3, 2025) (precedential).

C. The Board Did Not Abuse Its Discretion in Crediting Dr. Whitney's Consistent and Well-Supported Testimony

The Board did not abuse its discretion in crediting the testimony of Petitioner's expert, Dr. Whitney, testimony that was substantiated by supporting evidence and not at all contradictory. There is nothing inconsistent about his opinions (1) that a POSA would be motivated to use separate, well-known DNA and protein stabilizing buffers described in the prior art instead of Patent Owner's proposed untested single buffer; and (2) that a POSA would have a reasonable expectation of successfully stabilizing fecal RNA using a commercially available RNA stabilizing buffer, where the prior art expressly states that preserving RNA in a fecal sample using such a buffer is feasible. Far from constituting abuse of discretion, the Board's findings on these questions of fact are supported by detailed, credible evidence, including not only Dr. Whitney's expert testimony but also express statements in the pertinent prior art.

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The facts at bar are completely unlike those in *Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465. Patent Owner relies on *Interactive* as a case in which the Director reversed a Final Written Decision because the Board relied on self-contradictory expert testimony that “the Board found lacked credibility at least in certain respects.” *Id.*, Paper 40 at 3. Here, by contrast, and despite Patent Owner's assertions, the Board did not agree that any aspect of Dr. Whitney's testimony lacked credibility. Moreover, in *Interactive* the testimony in question was contradictory on its face: the expert testified that the same exhibit both “does” and “does not” represent “a modification described in his declaration.” *Id.* As shown below, not only is the testimony cited by Patent Owner not facially self-contradictory, it is not self-contradictory at all. The Board as factfinder could reasonably reject Patent Owner's arguments questioning Dr. Whitney's credibility, and it was not abuse of discretion for the Board to do so.

1. Dr. Whitney's testimony was consistent and well supported

Nothing in the Whitney testimony identified by Patent Owner is contradictory. It simply concerns Dr. Whitney's analysis of three different buffers, each designed to stabilize different types of biomolecules and each being considered in a different context for different purposes.

The first buffer discussed in Dr. Whitney's testimony is an untested buffer that Patent Owner proposed was possibly capable of stabilizing both fecal DNA and

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blood proteins. Patent Owner cites Dr. Whitney's testimony that (a) he was unaware of any buffer known as of the Priority Date that had been tested for stabilizing both fecal nucleic acid and fecal blood proteins (EX1086 ¶ 70; EX2057 at 15:9-20); and (b) a POSA would typically want some data to predict whether a buffer would be effective to detect CRC before concluding that the buffer would be suitable for use clinically. (EX2057 at 17:14-19; 18:2-19:18). This testimony is uncontradicted by the record and supports Dr. Whitney's opinion that a POSA would be motivated to separately use proven DNA and blood protein stabilizing buffers instead of an untested single buffer. EX1086 ¶ 73. The Board reached a consistent conclusion based on substantial evidence and found "it *may* have been possible to use a single buffer solution to preserve both hemoglobin and DNA" but "the obviousness of a single-preservative buffer solution does not mean that the two-portion and respective preservative-buffers taught by the art was not also obvious." FWD at 58-59.

The second buffer discussed in Dr. Whitney's testimony is a DNA stabilizing buffer he helped develop while employed by Patent Owner, a buffer that is disclosed in the '746 patent. In this testimony, Dr. Whitney explains that extensive effort had been required to develop such a buffer (EX2052 ¶¶ 52-53) and that the DNA stabilization buffer he helped develop would **not** be expected also to effectively stabilize RNA (*Id.* ¶¶ 54-55). This testimony, given in Court in connection with Petitioner's written description invalidity defense, likewise is uncontradicted. Dr.

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Whitney there testified that the '746 patent's disclosure of DNA stabilizing buffers, including the one he helped develop, "does not convey possession of buffers that stabilize **RNA**." EX2052 ¶ 245 (emphasis added). Dr. Whitney did not opine in either venue that buffers for stabilizing fecal RNA were unknown or not enabled. EX2052.

The third buffer discussed in Dr. Whitney's testimony is the commercially-available "RNAlater" buffer used in the prior art Nechvatal publication. In this testimony, Dr. Whitney opined that as of the Priority Date a POSA could use such a commercially-available buffer to stabilize fecal RNA and would have a reasonable expectation of success in doing so, as evidenced by Nechvatal's express teaching that "***preserving fecal samples at room temperature for a duration of 5 days, in a medium suitable for DNA and RNA analysis is feasible.***" EX1086 ¶ 60; EX1002 ¶¶ 223, 275; EX1024 at 131; Req. at 13.

Dr. Whitney's testimony describing Nechvatal's use of the RNAlater buffer is not contradicted by any evidence cited by Patent Owner. His opinion that a POSA would be motivated to use established DNA and protein stabilizing buffers instead of an untested single buffer does not mean a POSA would lack a reasonable expectation of success in using a commercial RNA stabilization buffer to stabilize DNA and RNA, particularly when the prior art states it is feasible to do so. Likewise, the fact that the DNA stabilization buffer Dr. Whitney personally helped develop would not be expected also to stabilize RNA does not imply that the RNAlater buffer

Petitioner's Authorized Response to Patent Owner's Request for Director Review of Nechvatal would not do so, especially where that buffer was marketed specifically for that purpose. EX2048.

2. The Board's finding of reasonable expectation of success was supported by substantial, credible evidence

With regard to claims 12 and 13, the evidence of record overwhelmingly supports the Board's factual finding that a POSA would have had a reasonable expectation of successfully using a buffer to preserve the RNA tested in Kanaoka's assay. Beyond the fact that Dr. Whitney's testimony on this point was credible and not self-contradictory, there is additional, credible evidence supporting the Board's finding. Patent Owner's attempt to frame the question around what it claims is Dr. Whitney's personal "imperative data standard" falls flat, not only because it misrepresents Dr. Whitney's testimony but also because the standard for reasonable expectation of success is set by the Federal Circuit, not by Dr. Whitney.

Patent Owner ignores that obviousness merely requires that the expectation of success be reasonable, not absolute. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). There is no requirement of testing data or proof of efficacy, and prior art teachings provide a sufficient basis to find reasonable expectation of success. *Acorda Therapeutics, Inc. v. Roxane Lab., Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018); *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Nechvatal's statement that "preserving fecal samples . . . in a medium suitable for DNA and RNA analysis is feasible" is direct evidence that a POSA would have

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reasonably expected to be successful using a buffer to stabilize fecal RNA. EX1024 at 131. Nechvatal also states that RNAlater was chosen for its likely suitability for preserving RNA. EX1024 at 125. RNAlater is even advertised as an alternative to the freezing strategy used in Kanaoka. EX2048. These direct statements of feasibility by skilled artisans in a peer-reviewed publication are compelling evidence supporting the Board's finding of reasonable expectation of success.

Patent Owner presented no evidence contradicting the Board's finding of reasonable expectation of success. Patent Owner's expert never testified that prior art buffers, such as those disclosed in Nechvatal, could not be used to preserve fecal RNA. On the contrary, he admitted that buffers for stabilizing RNA were known in the art and commercially available. EX1089 at 42:6-11. He also conceded that the '746 patent itself does not disclose any buffers for stabilizing RNA, and so a POSA *would use "a buffer that was available, known in the prior art" or "design their own" to practice claims 12 and 13.* EX1089 at 37:22-38:1, 40:8-42:11. The expert's confirmation of Dr. Whitney's testimony underscored its credibility and further supported the Board's finding of reasonable expectation of success.

IV. CONCLUSION

For the reasons stated above, the Director should deny the Request.

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Dated: March 13, 2026

Respectfully submitted,

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CERTIFICATION OF LENGTH

I hereby certify that the foregoing Petitioner's Authorized Response to 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 set forth in the Board's authorization email of March 6, 2026.

Date: March 13, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(c), the undersigned hereby certifies that on March 13, 2026, I caused a true and correct copy to be served on the following attorneys of record:

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