**No. 2023-1342, 2023-1345**

# United States Court of Appeals for the Federal Circuit

LABORATORY CORPORATION OF AMERICA HOLDINGS,

*Appellant*,

*v.*

RAVGEN, INC.,

*Appellee.*

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2021-00902, IPR2021-01054

## LABORATORY CORPORATION OF AMERICA HOLDINGS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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# CERTIFICATE OF INTEREST

Case Nos. 2023-1342, 2023-1345

*Laboratory Corporation of America Holdings v. Ravgen, Inc.*

Filing Party/Entity: Laboratory Corporation of America Holdings

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: March 7, 2025 Signature: */s/ Gregory A. Castanias*

Name: Gregory A. Castanias

**1. Represented Entities** (Fed. Cir. R. 47.4(a)(1)) – Provide the full names of all entities represented by undersigned counsel in this case.

Laboratory Corporation of America Holdings

**2. Real Party in Interest** (Fed. Cir. R. 47.4(a)(2)) – Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None/Not Applicable

**3. Parent Corporations and Stockholders** (Fed. Cir. R. 47.4(a)(3)) – Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Laboratory Corporation of America Holdings is wholly owned by Labcorp Holdings Inc., more than 10% of which is owned by Vanguard Group, Inc. The stock of Labcorp Holdings Inc. is traded on the New York Stock Exchange.

**4. Legal Representatives** – List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

**Kilpatrick Townsend & Stockton LLP:** Kathryn Wade, Allison Dobson, Cynthia Rothschild, Leland Black

**5. Related Cases** – Other than the originating case(s) for this case, are there other related or prior cases that meet the criteria under Fed. Cir. R. 47.4(a)(5)?

Yes. See separate notice filed pursuant to Fed. Cir. R. 47.5(b).

**6. Organizational Victims and Bankruptcy Cases** – Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable

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# TABLE OF ABBREVIATIONS

The following abbreviations are used in this petition. All emphasis is supplied unless otherwise indicated.

***Parties***

| Abbreviation | Term |
|---|---|
| Labcorp or petitioner | Laboratory Corporation of America Holdings |
| Ravgen or patent owner | Ravgen, Inc. |

***Citations***

| Abbreviation | Term |
|---|---|
| Appx__ | Joint Appendix at page(s) ___ |
| Opening Br. | Opening Brief of Appellant Laboratory Corporation of America Holdings, Doc. 20 |
| Reply Br. | Reply Brief of Appellant Laboratory Corporation of America Holdings, Doc. 29 |

***Terms***

| Abbreviation | Term |
|---|---|
| ’277 patent | U.S. Patent No. 7,332,277 (Appx123-402) |
| Board | Patent Trial and Appeal Board |
| 902 IPR | IPR2021-00902 |
| 1054 IPR | IPR2021-01054 |
| cffDNA | cell-free fetal DNA, also referred to as “free-floating fetal DNA” |
| Bianchi | U.S. Patent No. 5,648,220 to Bianchi & DeMaria, issued July 15, 1997 (Ex. 1004) (Appx17645-17649) |
| Chiu | Chiu et al., Effects of Blood-Processing Protocols on Fetal and Total DNA Quantification in Maternal Plasma, 47:9 *Clinical Chemistry* 1607-1613 (2001) (Ex. 1003) (Appx17638-17644) |

| | |
|---|---|
| Rao | International Publication No. WO 03/018757 A2 to Rao et al., published March 6, 2003 (Ex. 1005) (Appx17650-17687) |
| POSA | person of ordinary skill in the art at the time of the invention |

## STATEMENT OF COUNSEL

Based on my professional judgment, the panel's decision is contrary to Supreme Court and this Court's precedent on the proper standard for evaluating obviousness, including *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), this Court's recent decision in *Honeywell Int'l Inc. v. 3G Licensing, S.A.*, 124 F.4th 1345, 1348 (Fed. Cir. 2025), and other precedent, including *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006); and *Novartis Pharms. Corp. v. W.-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051 (Fed. Cir. 2019).

Based on my professional judgment, I also believe this appeal requires an answer to a precedent-setting question of exceptional importance: Where "'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness,' of the claimed invention," *Honeywell*, 124 F.4th at 1355 (quoting *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992)), may the legal conclusion of obviousness nonetheless be negated by evidence that the proposed combination might have had "disadvantages" (*Medichem*, 437 F.3d at 1165)?

*/s/ Gregory A. Castanias*

Gregory A. Castanias
Counsel for Appellant

## INTRODUCTION

The challenged claims of the '277 patent involve using a known agent, such as formaldehyde (the most well-known lysis inhibitor), to prevent the known problem of maternal cell lysis in samples containing both maternal cells and fetal DNA. One of the challenged claims in this IPR became the basis for a district-court judgment in excess of $400 million.

This Court's cases uniformly hold that applying known solutions to known problems need not be "the best option," or "the preferred, or the most desirable, combination" to be obvious as a matter of law, so long as "there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of the claimed invention." *Honeywell Int'l Inc. v. 3G Licensing, S.A.*, 124 F.4th 1345, 1355 (Fed. Cir. 2025) (cleaned up; citing cases). Indeed, in *Honeywell*—argued before a different panel of this Court one day before this case was argued, and decided in a precedential opinion only days prior to this decision—the panel held that, "[b]y failing to recognize that the claimed modification needed only to be desirable in light of the prior art and not the 'best' or 'preferred' approach, the Board committed *legal error*." *Id.* (emphasis added).

Yet this panel affirmed the Board's decision that Labcorp failed to establish a motivation to combine, reasoning that the Board's findings were supported by substantial evidence and dismissing Labcorp's legal arguments as an improper

attempt to reframe factual issues. In doing so, the panel both overlooked critical arguments warranting panel rehearing and adopted a flawed legal framework that conflicts with this Court's decisional law and compels en banc review.

**1.** The panel failed to address critical arguments presented in Labcorp's briefing that directly contradict its decision, warranting rehearing and reversal of the Board. *First*, Labcorp showed that the Board utterly misread Bianchi, a critical prior-art reference, distorting its teachings and undermining the Board's entire motivation-to-combine analysis. The panel *never addressed* this issue. *Second*, the panel dismissed the Board's failure to consider a key component of Rao as a "fleeting reference or minor argument," Op.10-11, when it was anything but fleeting or minor. *Third*, the panel failed to even mention crucial evidence from Labcorp's expert, Dr. Edwards, whose testimony directly contradicted the Board's findings.

**2.** Regardless of these errors, en banc review is necessary to resolve and harmonize this Court's decisions on a legal issue fundamental to obviousness law: May courts circumvent the legal principle of obviousness law that, so long as "there is something in the prior art as a whole to suggest the desirability, and thus the obviousness," of the claimed invention, *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992), there is a motivation to combine, by instead characterizing such challenges as virtually unreviewable factual disputes? In taking the latter

approach, the panel's nonprecedential decision conflicts with *KSR* and a welter of this Court's precedential decisions—including *Honeywell*, which, as noted, was argued the day before this case in front of a different panel, and decided *just days before the panel's decision*. Given its fundamentally different approach and outcome on a nearly identical issue, there is little doubt the *Honeywell* panel would have decided this case differently.

Such panel-dependent outcomes are not tolerable for the Court charged with harmonizing this Nation's patent law. When Congress in 1982 consolidated patent appeals before a single court, it was to avoid just this kind of balkanization, then taking place among the Circuits: Greater consistency was supposed to be the result, with the goal to "strengthen the United States patent system in such a way as to foster technological growth and industrial innovation." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1981) (citation omitted). Left uncorrected, the present state of affairs will create less consistency and, ultimately, a weaker patent system. En banc review should be granted.

## BACKGROUND

All scientific principles underlying this case—the existence of cell-free fetal DNA (cffDNA) in maternal blood and plasma samples, and cell lysis inhibition—were well understood before the early 2000s. By the late 1990s, researchers knew fetal DNA circulates in maternal plasma, enabling noninvasive prenatal testing.

Appx67-68. However, maternal cell lysis could release excess maternal DNA, overwhelming the sample and complicating fetal DNA analysis. Chiu's 2001 study confirmed this issue and explored centrifugation and filtration to mitigate it. Appx17638-17644.

Preventing cell lysis from happening in the first place was another known solution. Around that time, scientists like Bianchi (1997 patent) and Rao (2003 application) recognized the problem of cell lysis in blood samples and proposed solutions, including adding formaldehyde. Appx17647; Appx17653-17656. These methods kept cells intact, preventing DNA release and interference with analysis. Appx17647.

In 2008, Ravgen obtained the '277 patent, which related back to a 2003 application, combining these two well-known principles: (a) analyzing free-floating fetal DNA in blood samples (b) with the use of an agent that inhibits lysis of cells present in the sample. Appx399-400 (472:66-473:5; 474:52-57).

In 2020, after Ravgen sued multiple companies for infringement, Labcorp filed the IPR petitions at issue here, challenging as obvious the '277 patent's independent claims. Appx424; Appx440; Appx16494; Appx16512. Specifically, Labcorp cited Chiu on fetal DNA analysis and maternal cell lysis, along with Bianchi and Rao on cell stabilization, to show a POSA's motivation to combine. Appx424; Appx440; Appx16494; Appx16512.

The Board initially agreed. Instituting IPR, it concluded that the prior art disclosed all claim limitations and that a POSA would have been motivated to combine the references. Appx620; Appx16689. The Board acknowledged maternal cell lysis as a known issue in fetal DNA testing and formaldehyde as a known solution. Appx16730-16735.

However, in its final written decision, the Board reversed course, concluding that Labcorp had not established a motivation to combine. Appx2; Appx63. The Board concluded that a POSA would have been discouraged from using formaldehyde due to concerns that it could degrade DNA or allow maternal DNA to leak into the sample. Appx99; Appx114.

Labcorp appealed, urging, *inter alia*, that the Board committed legal error by improperly heightening the burden for proving motivation to combine. It contended that the Board legally erred by requiring an optimal or flawless combination, contrary to precedent establishing that there need only be "something in the prior art as a whole to suggest the *desirability*, and thus the obviousness, of making the combination, not whether there is something in the prior art as a whole to suggest that the combination is the *most desirable* combination available." Labcorp Opening Br. 31 (citation omitted). Labcorp further asserted that the Board selectively read prior art, disregarding key disclosures in Bianchi and Rao that directly undermined its conclusions. *Id.* at 41-46. Finally, Labcorp argued the

Board's evidentiary analysis was legally flawed for dismissing clear expert testimony on motivation to combine. *Id.* at 52-58.

A panel of this Court affirmed in a nonprecedential opinion, concluding that substantial evidence supported the Board's findings, in that the Board had properly weighed prior art and expert testimony and determined that Ravgen's evidence outweighed Labcorp's motivation-to-combine showing. The panel stated that Labcorp's argument that the Board had imposed an improperly heightened standard for obviousness "mischaracterizes the analysis of the Board in an attempt to reframe factual issues as legal ones." Op.5.

## ARGUMENT

### I. THE PANEL SHOULD GRANT REHEARING BECAUSE IT OVERLOOKED KEY FACTS AND ARGUMENTS

The panel failed to engage with key evidence and arguments offered by Labcorp, making panel rehearing appropriate. Selective consideration of the record, or ignoring directly relevant evidence, runs afoul of proper substantial-evidence review, which "involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency's decision." *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1384 (Fed. Cir. 2019) (citation omitted).

Here, the panel opinion rests on critical errors that materially affected the outcome: (1) a flawed interpretation of Bianchi, (2) a failure to meaningfully

engage with Rao's explicit teachings, and (3) a complete failure to address Dr. Edwards's expert testimony. It is also fundamentally wrong and warrants rehearing for the same reasons set out in Part II, as the panel decision clearly conflicts with *Honeywell*, which the panel ignored.

### A. The Panel Overlooked the Board's Clear Misinterpretation of Bianchi

Labcorp demonstrated that the Board's conclusion—that a POSA lacked motivation to combine Bianchi with Chiu—was based on the completely incorrect premise that Bianchi's paraformaldehyde was used to create permeability. Appx101. It was not. Bianchi explicitly teaches that its process of labeling molecules inside cells consists of two distinct steps: first, stabilizing the cells, and second, making them permeable for labeling the molecules. *Paraformaldehyde is used solely for the stabilization step, not for permeability*. Appx17648 (3:26-35). The panel only addressed Bianchi's permeabilizing step (Op.4, 11), not its stabilizing step, thereby repeating the Board's error and contradicting the reference's plain language.

This was no minor error—it was central to the Board's flawed rejection of Labcorp's motivation-to-combine showing. Because the Board mistakenly treated the *permeability* step as inseparable from the *stabilizing* step, it incorrectly concluded that a POSA would have avoided paraformaldehyde use altogether. Had Bianchi been read for all it discloses, the Board's reasoning collapses. A

POSA would have understood that paraformaldehyde's stabilizing effect, independent of any subsequent permeability step, addressed the exact problem at issue—preserving cell integrity and thereby preventing maternal DNA from contaminating the fetal DNA. The Board's failure to recognize this distinction undermines its entire motivation-to-combine analysis, which cannot be saved by findings the Board never made. *See, e.g.*, *Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1294 (Fed. Cir. 2018).

The panel never addressed this crucial argument.

### B. The Panel Failed to Engage with Rao's Explicit Teaching on How a POSA Would Address Formaldehyde Concerns

The Board's rejection of a motivation to combine rested on the assumption that a POSA would have been "discouraged" from using formaldehyde to prevent maternal cells from lysing due to concerns that it might degrade DNA or cause maternal DNA to leak into a sample. Appx54. Here, the Board ignored the key disclosure in Rao, which states that a POSA could easily mitigate these concerns by adjusting stabilizer concentration. Appx17658 (7:30-33) (teaching that stabilizers should be used "at appropriate concentrations or amounts, which would be readily apparent to one skilled in cell biology" to stabilize cells without damage). Rao *directly refutes* the Board's assumption that a POSA would have categorically avoided formaldehyde due to potential risks.

Labcorp demonstrated that the Board's failure to consider Rao was legal error, as obviousness law requires evaluating prior art as a whole, and that its decision lacked substantial evidence. Yet, the panel dismissed Rao's disclosure as a "fleeting reference or minor argument" (Op.10), despite its direct relevance to the alleged gap in the motivation to combine.

The panel's suggestion that the Board must have considered Rao's teaching simply because it rejected a "related argument" that a POSA could "tailor the processing conditions for using formaldehyde effectively" is equally flawed. Op.10 (quotation mark omitted). A blanket rejection of a broader argument does not mean the Board meaningfully engaged with the specific, crucial evidence at issue.[1] Actual consideration of Rao's teaching would have required explaining why a POSA, despite Rao's guidance on concentration adjustments, would still avoid formaldehyde. It did not. The panel's failure to address this oversight compels rehearing.

[1] Nor was it proper for the panel to speculate about the Board's thinking, given its concession that "the Board's consideration of these teachings were not so clear." Op.10. "[T]he Board must, as to issues made material by the governing law, set forth a sufficiently detailed explanation of its determinations both to enable meaningful judicial review and to prevent judicial intrusion on agency authority." *Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG,* 856 F.3d 1019, 1024 (Fed. Cir. 2017). The panel's need to guess at the Board's reasoning underscores its lack of clarity.

### C. The Panel Ignored Dr. Edwards's Expert Testimony, Which Directly Contradicted the Board's Findings

Labcorp also showed that the Board improperly dismissed expert testimony from Dr. Edwards, which directly contradicted the Board's conclusion that a POSA would have been deterred from using formaldehyde.

Dr. Edwards testified that formaldehyde's impact on DNA depends on concentration and that a POSA would know how to use it safely as a stabilizer. Appx28983-28986. He noted that formaldehyde and similar stabilizers were routinely used in biology and that POSAs knew how to adjust concentrations for the desired effect. *Id.*

Despite the significance of this testimony, the panel's decision never mentions Dr. Edwards. This omission is particularly striking as the Board selectively cited supporting testimony while ignoring contradictory parts. Appx101; Appx105; *see* Labcorp Opening Br. 53-55. The Board's selective use of expert testimony deprives a decision of substantial evidence, as courts have a duty to consider all relevant evidence. *OSI Pharm*, 939 F.3d at 1384.

What is more, the unconsidered parts of Dr. Edwards's testimony directly addressed the central issue in this case: whether a POSA would have been discouraged from using formaldehyde. Labcorp Opening Br. 18-19; 53-55. His expert opinion undermines the Board's premise, rendering its conclusions untenable.

By ignoring the key arguments above, the panel deprived Labcorp of any consideration from either the agency or the Court on multiple dispositive issues. That warrants rehearing.

## II. THE COURT SHOULD GRANT REHEARING EN BANC TO CLARIFY AND HARMONIZE THIS COURT'S APPROACH TO THE MOTIVATION-TO-COMBINE FRAMEWORK

This Court's docket has shifted over the past decade. Thanks to the AIA, it is now predominantly a patent court. The lion's share of its patent cases come from IPR appeals like this one, and in turn, the major substantive issue in these cases is obviousness. The importance and recurring nature of the issue presented here—the proper motivation-to-combine framework in an obviousness case—is manifest, and is laid bare by the competing, conflicting decisions here and in *Honeywell*. *See* Dennis Crouch, *Not Quite Teaching Away: Federal Circuit Clarifies Evidence Needed to Defeat Motivation to Combine*, Patently-O, https://patentlyo.com/patent/2025/01/teaching-clarifies-motivation.html (Jan. 6, 2025) (noting that *this case* presents the "extremely common hurdle of showing a lack of motivation to combine" and involved "a similar argument *to one that worked* in *Honeywell*" (emphasis added)).

Obviousness is a legal determination based on factual findings, but here, the panel improperly blurred that distinction, which shielded the Board's legal errors from meaningful review. The Board had imposed a heightened motivation-to-

combine standard, requiring the combination to be the best or preferred option—contrary to longstanding precedent. And instead of correcting this misapplication, the panel blithely dismissed Labcorp's arguments as factual disputes beyond de novo review. This directly conflicts with *Honeywell*, which held that such an approach by the Board was "legal error." 124 F.4th at 1356. Rehearing en banc is necessary to ensure that courts apply the correct legal framework before deferring to factual findings.

### A. The Motivation-to-Combine Framework

Obviousness is a legal question based on underlying factual findings. *KSR*, 550 U.S. at 427. While factual findings are reviewed for substantial evidence, the Board's application of the relevant legal standards—including the *standard* for motivation to combine—is a legal determination reviewed *de novo*. *E.g.*, *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (reviewing Board's "failure to apply the correct legal standards" for assessing motivation to combine "de novo" and concluding Board "adopted a legally incorrect framing of the motivation-to-combine question").

This Court consistently holds that errors in applying the motivation-to-combine standard can lead to legally incorrect conclusions on obviousness, warranting reversal. *E.g.*, *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1341 (Fed. Cir. 2020) (reversing Board's conclusion of no motivation to combine

because it was "based on ... legal error"); *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1354 (Fed. Cir. 2017) (same).

This Court has further made clear that the proper legal framework for assessing motivation to combine asks only whether the prior art as a whole suggests the desirability—and thus the obviousness—of making the combination. *Fulton*, 391 F.3d at 1200. It does not require "that a particular combination [] be the preferred, or the most desirable, combination." *Id*. Nor does it require "that a person of ordinary skill would have selected [a certain prior-art method] over other prior art [] methods." *Novartis*, 923 F.3d at 1059. Nor, for that matter, must a petitioner show that a POSA would have had no concerns about trying a particular approach. *See, e.g.*, *Allied Erecting & Dismantling Co., Inc. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016). "[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem*, 437 F.3d at 1165.

Whether a POSA would have been motivated to combine specific references is a factual question, but that question can only be properly assessed *after* applying the correct legal framework—which the Board failed to do here.

### B. The Panel's Decision Misapplied the Law and Insulated the Board's Legal Errors from Review

The Board's decision misapplied the legal motivation-to-combine standard in at least two fundamental ways, conflicting with well-established precedent from

the Supreme Court and this Court. Yet instead of evaluating whether the Board correctly applied the law, the panel dismissed Labcorp's argument as a "factual" dispute. Op.5. Left uncorrected, this approach will not only severely limit appellate oversight of legally flawed obviousness determinations but also invite the Board to disregard its obligation to rigorously analyze the record, knowing it can do so with impunity under a deferential standard of review.

*First*, the Board improperly heightened the standard for motivation to combine when it found Labcorp's evidence "deficient" because its expert did not "consider whether the negative impacts of formaldehyde *might have led someone in 2002 to pick a different chemical instead*." Appx105 (emphasis added) (citation omitted). That reasoning directly contradicts this Court's precedent, which has repeatedly held that motivation to combine does not require a showing that the combination is the best or most optimal approach. *Fulton*, 391 F.3d at 1200; *Honeywell*, 124 F.4th at 1356. The proper inquiry is not whether a POSA would have chosen an alternative method but rather whether a POSA would have been motivated to try the combination at all. The Board's demand for an unnecessary showing of *preference* instead of *motivation* is legal error, one that required de novo review—not deference.

*Second*, the Board improperly treated the existence of trade-offs as an absolute bar to motivation to combine, rather than considering whether a POSA

would have balanced the risks and benefits in favor of trying the combination. The Board reasoned that a POSA would have rejected formaldehyde outright because it might cause some maternal DNA to be released from the cells. Appx102. *But this was not in dispute*—as Labcorp has repeatedly stated. Labcorp Reply Br. 11. The correct legal standard, as confirmed in *Honeywell*, *Medichem*, *Allied Erecting*, and many other cases, is that a POSA can be motivated to combine references even when the combination involves trade-offs. The key *legal inquiry* should have been whether, despite risks, a POSA still had a reason to attempt the combination. The Board failed to apply this standard, instead focusing only on disadvantages while ignoring benefits. That is legal error, not a factual finding.

Rather than recognizing these clear legal errors, the panel abdicated its responsibility to conduct *de novo* review and mischaracterized Labcorp's legal argument as a mere factual dispute, relying (Op.7) on *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017), a challenge to a black-box jury verdict where the appellant did not dispute that the jury had been correctly instructed on the law. *Id.* at 1362. The panel dismissed Labcorp's appeal as an improper attempt to "reframe factual issues as legal ones." Op.5. But that badly misunderstood the issue. Labcorp was not asking the panel to second-guess factual determinations about what a POSA would have done; it

was arguing that the Board applied the wrong legal test to the facts—a question indisputably subject to *de novo* review on the reasoned agency opinion before it.

### C. The Panel's Decision Conflicts with *Honeywell* and the Decisions It Relies Upon

The panel's decision is especially troubling because it directly contradicts *Honeywell*, 124 F.4th 1345, a precedential decision issued just four days earlier. In *Honeywell*, the Board rejected a motivation to combine based on uncertainty over whether the proposed modification was the "preferred" approach. *Id.* at 1355. Instead of assessing whether a POSA would have been motivated to attempt the combination despite trade-offs, the Board had focused solely on possible drawbacks—*just as it did here*.

This Court reversed, holding that "the Board committed legal error" by requiring a combination to be the best or preferred option rather than merely a desirable one in light of the prior art:

> By failing to recognize that the claimed modification needed only to be desirable in light of the prior art and not the "best" or "preferred" approach, *the Board committed legal error*. Here, the Philips reference's disclosed goal of "giv[ing] significant extra protection to the MSB" provided the motivation for the claimed modification.

*Id.* at 1356 (emphasis added) (internal citation omitted). The Board in this case likewise "failed to recognize that the claimed modification needed only to be desirable in light of the prior art"—yet the panel ignored the identical legal error and instead dismissed Labcorp's argument as merely "factual." The speculative

language used by the Board—that a POSA in 2002 "might" have "picked a different chemical instead," Appx105—is no different than the Board's erroneous reasoning in *Honeywell* that there was "uncertainty" regarding what coding scheme was "preferred" or "would be best." 124 F.4th at 1355 (quoting Board). Both decisions relied on the same flawed premise—that motivation to combine requires finding the optimal solution rather than a reason to combine.

To put it bluntly, if the panel in this case is right, *Honeywell* is wrong. And vice versa. The Board in both cases demanded a preferred solution rather than asking whether a POSA had reason to combine. But the only precedential decision of the two—*Honeywell*—holds this to be legal error, and correctly so. This panel ignored it. Rehearing is needed to ensure consistency and prevent the Board from raising the obviousness bar beyond what the law allows.

* * *

By dismissing Labcorp's challenge as an attempt to "reframe factual issues as legal ones," the panel treated this administrative-law case, where the legal error is manifest on the face of the Board's Final Written Decision, no different from the review of a black-box jury verdict on an unchallenged legal instruction (as in *Arctic Cat*), shielding legal errors from de novo review, and undermining precedent requiring courts to independently review the pronouncement and application of legal standards.

Here, the most widely used cell-fixative—formaldehyde—was applied to address a known issue requiring cell fixation: the lysis of maternal cells. Nothing more than that was done by the putative inventor. There was unquestionably "something in the prior art as a whole to suggest the desirability, and thus the obviousness" of that approach. *Honeywell*, 124 F.4th at 1355 (cleaned up). But simply because there were some concerns about trying this desirable approach, those concerns were used by the panel as a "factual" shield from review for legal error.

This Court should correct that error en banc so that motivation to combine remains subject to meaningful legal scrutiny.

Dated: March 7, 2025

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This petition complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Federal Circuit Rule 32(b)(1) because it contains 3899 words, excluding the parts of the petition exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 in Times New Roman 14-point font.

Dated: March 7, 2025

*/s/ Gregory A. Castanias*
Gregory A. Castanias

*Counsel for Appellant Laboratory Corporation of America Holdings*

# ADDENDUM

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**LABORATORY CORPORATION OF AMERICA HOLDINGS,**
*Appellant*

**v.**

**RAVGEN, INC.,**
*Appellee*

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2023-1342, 2023-1345

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Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2021-00902, IPR2021-01054.

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Decided: January 6, 2025

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GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for appellant. Also represented by AMELIA A. DEGORY, BRENDAN D. DUFFY, TRACY A. STITT, JENNIFER L. SWIZE; GASPER LAROSA, New York, NY; JOHN C. ALEMANNI, Kilpatrick Townsend & Stockton LLP, Raleigh, NC; TINA WILLIAMS MCKEON, Atlanta, GA.

BRIAN MATTY, Desmarais LLP, New York, NY, argued for appellee. Also represented by JOHN M. DESMARAIS,

KERRI-ANN LIMBEEK; GABRIELLE E. HIGGINS, San Francisco, CA.

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Before LOURIE, BRYSON, and STARK, *Circuit Judges*.

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Laboratory Corporation of America Holdings ("Labcorp") appeals from two final written decisions of the U.S. Patent Trial and Appeal Board ("the Board") collectively holding that claims 55–63, 66–69, 80–96, and 127–133 of U.S. Patent 7,332,277 ("the '277 patent") had not been shown to have been obvious. *Lab'y Corp. of Am. Holdings v. Ravgen, Inc.*, No. IPR2021-00902, 2022 WL 16579960 (P.T.A.B. Nov. 1, 2022) (holding that claims 81–96 and 133 had not been shown to be unpatentable) ("*00902 Decision*"); *Lab'y Corp. of Am. Holdings v. Ravgen, Inc.*, No. IPR2021-01054, 2022 WL 16641665 (P.T.A.B. Nov. 1, 2022) (holding that claims 55–63, 66–69, 80, and 127–132 had not been shown to be unpatentable) ("*01054 Decision*").[1] The Board determined that Labcorp had failed to demonstrate that a person of ordinary skill in the art would have been motivated to combine the asserted prior art references. For the following reasons, we *affirm*.

## BACKGROUND

Ravgen, Inc. ("Ravgen") owns the '277 patent, which is directed to non-invasive methods for sampling DNA and detecting genetic disorders in a fetus. '277 patent, Abstract. The '277 patent relates to, *inter alia*, analyzing cell-free fetal DNA ("cffDNA") found in a blood sample drawn from a pregnant mother with a cell lysis inhibitor

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[1] The final written decisions share nearly identical analyses of the issues relevant to the parties' dispute on appeal. Unless otherwise indicated, we cite the *01054 Decision* as representative.

added to the sample. *Id.* at col. 89, ll. 1–15; *see also id.* at col. 26, ll. 15–24, 40–44. The '277 patent provides a list of agents that can act as cell lysis inhibitors, including formaldehyde, formaldehyde derivatives, and formalin (collectively, "formaldehyde compounds"). *Id.* at col. 31, l. 57–col. 32, l. 3. Claims 55 and 132 are illustrative for the issues on appeal.

Claim 55 reads as follows:

> 55. A method comprising determining the sequence of a locus of interest on free fetal DNA isolated from a sample obtained from a pregnant female, wherein said sample comprises free fetal DNA and an agent that inhibits lysis of cells, if cells are present, wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor.

*Id.* at col. 472, l. 66–col. 473, l. 5. Claim 132 depends from claim 60, which depends from claim 59, which depends from claim 55. Claim 59 adds "wherein said agent is a cell lysis inhibitor." *Id.* at col. 473, ll. 13–14. Claim 60 adds "wherein said cell lysis inhibitor is selected from the group consisting of: glutaraldehyde, derivatives of glutaraldehyde, formaldehyde, derivatives of formaldehyde, and formalin." *Id.* at col. 473, ll. 15–18. And finally, claim 132 reads as follows:

> 132. The method of claim 60, wherein said cell lysis inhibitor is selected from glutaraldehyde, formaldehyde, and formalin.

*Id.* at col. 478, ll. 12–14.

In two *inter partes* review petitions, Labcorp challenged claims 55–63, 66–69, 80–96, and 127–133 of the '277 patent, arguing that the claims would have been unpatentable as obvious under 35 U.S.C. § 103. Specifically, Labcorp argued that a person of ordinary skill in the art would have been motivated to combine the

maternal blood processing method disclosed in a 2001 *Clinical Chemistry* article ("Chiu")[2] with the formaldehyde compounds disclosed in U.S. Patent 5,648,220 ("Bianchi") or in International Patent Application Publication WO 03/018757 ("Rao"), thereby rendering the claims obvious.[3]

Chiu reports a study on the effects of blood-processing protocols on fetal and total DNA quantification in maternal plasma. J.A. 17638–44. Bianchi discloses a method of labeling a cell where the plasma membrane of the cell is permeabilized so that substantially all the DNA of the cell remains in the cell. Bianchi at Abstract. Bianchi's method involves the use of paraformaldehyde. Bianchi at col. 3, ll. 36–53. And Rao discloses a method of stabilizing rare cancer cells in a blood sample using paraformaldehyde. Rao at p. 3, ll. 12–15, p. 24, ll. 2–17.

The Board determined that the challenged claims had not been shown to be unpatentable. *01054 Decision*, at *22–23. The Board found that a person of ordinary skill in the art would not have been motivated to combine Chiu and Bianchi because one "would have expected Bianchi's paraformaldehyde to create gaps in the cell membranes, providing a means for maternal DNA to escape into the sample." *01054 Decision*, at *14. The Board also found that a person of ordinary skill in the art would not have been motivated to combine Chiu with Bianchi or Rao because "formaldehyde was known to damage nucleic acids." *Id.* At bottom, the Board determined that "[Ravgen]'s reasoning and evidence on [motivation to

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[2] Chiu et al., *Effects of Blood-Processing Protocols on Fetal and Total DNA Quantification in Maternal Plasma*, 47:9 CLINICAL CHEMISTRY 1607–13 (2001), J.A. 17638–44.

[3] IPR2021-01054 included an additional reference in its proposed Chiu-Bianchi and Chiu-Rao combinations; however, the additional reference is not relevant to the issues on appeal.

combine] . . . outweigh[ed] [Labcorp]'s." *Id.* Labcorp timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

## DISCUSSION

Labcorp raises both legal and factual challenges on appeal. It argues that the Board's motivation to combine analysis was legally flawed for three reasons. According to Labcorp, the Board (1) required a heightened and untenable standard for proving a motivation to combine, (2) did not adhere to precedents that require reading each reference as a whole, and (3) in effect engaged in *post hoc* claim construction to read additional limitations into the claims. Labcorp also argues that the Board's factual findings were not supported by substantial evidence. We address those arguments in turn.

### I

Obviousness is a question of law based on underlying findings of fact. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). We review the Board's legal conclusion on obviousness *de novo* and its findings of fact for substantial evidence. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1369 (Fed. Cir. 2017). What a reference teaches and the presence or absence of a motivation to combine references are questions of fact. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196–97 (Fed. Cir. 2014).

#### A

Labcorp's first argument—that the Board imposed an improperly heightened standard for obviousness—mischaracterizes the analysis of the Board in an attempt to reframe factual issues as legal ones. According to Labcorp, the Board erroneously required Labcorp's proposed combinations to be perfect, rather than merely desirable, which is all the case law requires. *See* Labcorp Br. 30–32. Specifically, Labcorp argues that the Board's

analysis of Bianchi (or its "DNA Leakage" rationale) is legally flawed because it "fixated on the fact that even the *potential* for only 1% leakage [in Bianchi] would have been 'contrary to' the goals of Chiu." *Id.* at 33. According to Labcorp, the Board's focus on "a minuscule amount of maternal DNA" leakage as opposed to the benefits of cell stabilization disclosed in Bianchi amounts to legal error by demanding "the most desirable combination," *id.* at 32–33 (quoting *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004)), and ignores that "simultaneous advantages and disadvantages . . . do[] not necessarily obviate motivation to combine," *id.* at 34 (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)).

The Board did not apply an improperly heightened motivation-to-combine standard in its analysis of Bianchi. It evaluated the disclosures of Bianchi and found that a person of ordinary skill in the art "would have been dissuaded from adding Bianchi's paraformaldehyde [to the cffDNA detection method of Chiu] because the [person of ordinary skill in the art] would have expected Bianchi's paraformaldehyde to create gaps in the cell membranes, providing a means for maternal DNA to escape into the sample." *01054 Decision*, at *14. In reaching that conclusion, the Board evaluated the testimony of both experts and analyzed the teachings of Bianchi and Chiu, which ultimately led it to disagree with Labcorp's view. *See, e.g.*, *id.* at *15 ("We credit [Ravgen's expert]'s opinion that adopting Bianchi's approach to treating cells with paraformaldehyde creates a means for cellular DNA to escape."); *id.* ("As [Labcorp's expert] concedes, 'DNA leaking out of cells' is something 'Chiu tells us you do not want [] to happen.'"). The Board recognized that Bianchi "most preferably" retains "99% or greater" of the DNA in the cell but found that a person of ordinary skill in the art "would realize that releasing 1% of cellular DNA in a sample in Chiu would have a negative effect on Chiu's fetal cell-free DNA analyses." *Id.* At their core, those are

factual—not legal—determinations. *See Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017) ("The prior art, skill, and knowledge of an ordinary artisan may also provide reasons not to combine which would likewise be a question of fact."). The Board therefore did not require an improperly heighted standard for obviousness by rejecting Labcorp's positions; rather, it found that Labcorp failed to "provide persuasive argument or evidence to explain why creating holes in the cell membranes . . . would have been seen by the [person of ordinary skill in the art] as acceptable." *01054 Decision*, at *15.

Simply put, Labcorp's "disagreement with the Board's interpretations of [Bianchi] does not amount to a demonstration that the Board somehow failed to use the proper analysis." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1347 (Fed. Cir. 2021).

Labcorp makes similar arguments with respect to the Board's "DNA damage" rationale and the standard for obviousness applied by the Board. According to Labcorp, the Board legally erred because it improperly relied on generic concerns of DNA damage, failed to consider if a person of ordinary skill in the art would have pursued the invention despite those concerns, and did not follow our precedent on what constitutes teaching away. Labcorp Br. 34–40. Again, we disagree with Labcorp's attempt to recast factual issues as legal ones.

The Board did not impermissibly rely on generic concerns of formaldehyde's potential to damage DNA, as Labcorp asserts. *See* Labcorp Br. 36. Labcorp compares the Board's analysis to that in *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154 (Fed. Cir. 2022), where the Board impermissibly relied on "vague expert testimony that 'there was great skepticism for performing telesurgery.'" *Id.* at 1159. However, that is not the case here where the concerns relied on by the Board

were specific to the claimed invention. *Id*. ("[*S*]*pecific* evidence of industry skepticism related to a *specific* combination of references *might* contribute to finding a lack of motivation to combine."). The claims recite a method for "determining the sequence of a locus of interest on *free fetal DNA* isolated from a sample," '277 patent, col. 472, ll. 66–67 (emphasis added), and the industry's concerns were specific to "formaldehyde's potential effects on DNA, and cell-free fetal DNA in particular," *01054 Decision*, at *16; *see, e.g.*, *id.* at *19 ("Rao discloses that formaldehyde released from formaldehyde donors was known to 'irreversibly cross link[] nucleic acids.'"). As such, it is clear from the Board's analysis that it did not rely on general "industry skepticism," but rather relied on concerns specific to the combination of references. *See Auris Health*, 32 F.4th at 1159.

Similarly, the Board did not fail to consider whether a person of ordinary skill would have pursued the invention despite any concerns of formaldehyde's potential to damage DNA. Rather, it acknowledged the high level of skill in the art, *see 01054 Decision*, at *5, considered Labcorp's arguments relating to that high level of skill, and rejected them, *see, e.g.*, *id.* at *18 ("[I]nasmuch as [Labcorp] is suggesting a [person of ordinary skill in the art] might simply 'tailor' the processing conditions for using formaldehyde effectively, [Labcorp]'s argument fails."). And as with the Board's DNA Leakage rationale, Labcorp's "disagreement with the Board's interpretations . . . does not amount to a demonstration that the Board somehow failed to use the proper analysis." *Eli Lilly*, 8 F.4th at 1347.

Finally, with respect to Labcorp's arguments associated with the Board's analysis of Bianchi, the Board did not ignore our precedent on teaching away. *See* Labcorp Br. 38–40. The Board did not rely on a teaching away, but found that, on the balance of the evidence, "the literature would have dissuaded a [person of ordinary skill in the art] from using formaldehyde or paraformaldehyde in the

[Chiu] modified method." *01054 Decision*, at *17. Even if evidence does not "rise to the level of teaching away," it is still proper for the Board to consider evidence that "suggests reasons that a skilled artisan would be discouraged from pursuing such a combination." *Arctic Cat Inc.*, 876 F.3d at 1363. For the foregoing reasons, we find Labcorp's arguments that the Board legally erred in its analysis of the DNA Leakage rationale unpersuasive.

B

Next, Labcorp argues that the Board legally erred by failing to consider Bianchi and Rao for everything they teach. With respect to Bianchi, Labcorp argues that the Board ignored the teaching of Bianchi that "99% or greater" of the DNA should remain in the cells. Labcorp Br. 42–43. With respect to Rao, Labcorp argues that the Board ignored Rao's teaching that paraformaldehyde is "frequently used for fixing and stabilizing tumor cells in blood" despite its shortcomings and that handling those concerns would be "readily apparent to one skilled in cell biology." *Id.* at 43–44 (citing Rao, p. 3, ll. 16–18, p. 7, ll. 30–33). Again, we disagree.

Contrary to Labcorp's arguments, the Board did not ignore the identified teachings. The Board "acknowledge[d] that Bianchi prefers that greater amounts of DNA stay in the cells," *01054 Decision*, at *15, and cited the exact passage that Labcorp now asserts was ignored, *see id.* (quoting Bianchi's "most preferably 99% or greater" teaching). Similarly, the Board explicitly cited Rao's teaching that paraformaldehyde is "frequently used for fixing and stabilizing tumor cells in blood." *Id.* at *9. And, although less explicit, the Board's consideration of Rao's teaching that using paraformaldehyde in a concentration effective to stabilize cells without causing damage "would be readily apparent to one skilled in cell biology," was clear, *see* Reply Br. 17 (quoting Rao, p. 3, ll. 16–18) (emphasis in Reply Br. omitted), because the Board considered and

rejected Labcorp's related argument that a person of ordinary skill could "simply 'tailor' the processing conditions for using formaldehyde effectively," *01054 Decision*, at *18. However, even if the Board's consideration of these teachings were not so clear, "we have said numerous times, failure to explicitly discuss every fleeting reference or minor argument does not alone establish that the Board did not consider it." *Yeda Rsch. v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1046 (Fed. Cir. 2018).

C

In one final attempt to gain *de novo* review, Labcorp argues that the Board engaged in improper *post hoc* claim construction. According to Labcorp, the Board read into the claims additional limitations prohibiting DNA damage and requiring a certain degree of cell stabilization. Labcorp Br. 46, 49–51. Relatedly, Labcorp argues that the Board improperly evaluated whether a person of ordinary skill in the art would have incorporated a feature of Bianchi and Rao, *i.e.*, formaldehyde, into the requirements of Chiu rather than the requirements of the claims. Reply Br. 7–8, 21 (citing *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950 (Fed. Cir. 2023)). We disagree.

During the IPR proceedings, neither party identified terms in need of construction, and the Board found it unnecessary to expressly construe any terms. *01054 Decision*, at *6. Nor do we see any implicit claim construction by the Board, *post hoc* or at any time. Instead of requiring a certain degree of cell stabilization, as Labcorp unpersuasively charges, the Board properly relied on the claims' recitation of a method for "determining the sequence of a locus of interest on free fetal DNA isolated from a sample." '277 patent, col. 472, ll. 66–67. Consistent with this claim requirement, the Board focused its motivation to combine inquiry on issues specific to cffDNA. *See, e.g.*, *01054 Decision*, at *16 ("A key question presented in this case is whether a [person of ordinary skill in the art]

would have been concerned with formaldehyde's potential effects on DNA, and cell-free fetal DNA in particular.").

In fact, the parties' arguments focused on those exact issues, Bianchi's disclosure of cell permeabilization, and the potential for formaldehyde compounds to damage DNA. *See id.* at *10–12 (summarizing the parties' motivation to combine arguments). The Board's analysis, which considered the contours of those arguments and found no motivation to combine, does not amount to reading unclaimed requirements into the claims. *See, e.g.*, *id.* at *15 (finding Ravgen's expert's testimony persuasive that a person of ordinary skill in the art "would realize that releasing 1% of cellular DNA in a sample in Chiu would have a negative effect on Chiu's fetal cell-free DNA analyses."); *id.* at *17 ("[W]e have a dearth of evidence suggesting formaldehyde's use in a sample where *cell-free* DNA is the analyte, and no sufficient, persuasive evidence or technical reasoning to explain why a [person of ordinary skill in the art] would not have been concerned with potential damage to the cffDNA.").

Similarly, the Board did not err by focusing its obviousness inquiry on the context or the requirements of the prior art rather than the claims. *But see Axonics*, 73 F.4th at 958 (finding that the Board erred by limiting its obviousness analysis to the context of a specific facial nerve addressed by the prior art when the claims were not limited to that specific facial nerve). Here, as discussed above, the Board focused its obviousness analysis on the context of cffDNA, which is the context of the claims and also the context of Chiu. *See* '277 patent, col. 472, ll. 66–67 ("determining the sequence of a locus of interest on free fetal DNA"); *see* Chiu at 1608, J.A. 17639 ("[I]t is the objective of this study to investigate the effects of different blood-processing protocols on the quantitative analysis of total and fetal DNA in maternal plasma[.]"). As such, we fail to see how the Board's analysis here is analogous to the error identified in *Axonics*. *See* 73 F.4th at 958.

For those reasons, we find no legal error in the Board's motivation to combine analysis.

II

Finally, Labcorp argues that the Board's findings were not supported by substantial evidence because the Board (1) failed to account for the evidence that both justified and detracted from its decision, (2) "grossly misinterpreted Bianchi," and (3) "relied on pure conjecture." Labcorp Br. 53–58. We disagree on all three counts.

As is apparent from the discussion of the legal issues above, the Board thoroughly considered the references and expert testimony provided by both parties. Labcorp has failed to identify any factual finding by the Board that was not reasonably supported by substantial evidence. At bottom, the Board weighed the evidence both for and against a motivation to combine the references and found that Ravgen's "reasoning and evidence on those issues, separately and cumulatively, outweigh[ed] [Labcorp's] comparatively weak showing on whether a [person of ordinary skill in the art] would have combined the art in the manner proposed." *01054 Decision*, at *14. "This court does not reweigh evidence on appeal." *In re NTP, Inc.*, 654 F.3d 1279, 1292 (Fed. Cir. 2011).

CONCLUSION

We have considered Labcorp's remaining arguments and find them unpersuasive. For the forgoing reasons, we affirm the Board's decisions in IPR2021-00902 and IPR2021-01054.

**AFFIRMED**