

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUJIREBIO DIAGNOSTICS, INC.,
Petitioner,

v.

QUANTERIX CORP.,
Patent Owner.

IPR2025-01060
Patent 11,275,092

PATENT OWNER PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
2001	U.S. Patent Application No. 15/269,142 Office Action Rejection dated January 29, 2015
2002	U.S. Patent Application No. 15/269,142 Office Action Rejection dated December 31, 2018

Quanterix Corp. (“Quanterix” or “Patent Owner”) submits this Preliminary Response to the Petition for *inter partes* review of U.S. Patent No. 11,275,092 (the “’092 patent”) (“Petition”) filed by Fujirebio Diagnostics, Inc. (“Fujirebio” or “Petitioner”).

I. INTRODUCTION

The Petition should be denied institution under 35 U.S.C. § 314(a) because Petitioner has failed to demonstrate a reasonable likelihood of prevailing against any of the Challenged Claims. The Petition proposes grounds nearly identical to the obviousness combinations the Examiner considered and fails to address the Examiner’s findings of patentability over such combinations.

Specifically, the Petition should not be instituted because of at least the following two deficiencies:

First, institution should be denied because the Petition fails to address the Examiner’s findings that a person of ordinary skill in the art (“POSA”) would not be motivated to combine, nor have a reasonable expectation of success in combining, Patent Owner’s ultrasensitive assay technology with references suggesting tau as a biomarker (the “Quanterix assay + tau reference” combinations). Like the Examiner, Petitioner also proposes grounds consisting of Quanterix assay + tau

reference combinations. But Petitioner does not refute the Examiner's findings or otherwise show the Examiner erred in allowing the '092 patent to issue over Quanterix assay + tau reference combinations. As a result of these failures of proof, the Petitioner cannot demonstrate a reasonable likelihood of prevailing on its nearly-identical proposed grounds against any of the Challenged Claims.

Second, the Petition should be denied because it fails to address the Examiner's additional finding of patentability based on secondary considerations of non-obviousness. Again, Petitioner's Quanterix assay + tau reference proposed grounds are nearly identical to those the Examiner considered, and Petitioner's failure to refute or show error in the Examiner's additional findings of patentability further illustrates why the Petition fails to meet the requirements of § 314(a).

Thus, the Petition's deficiencies, as further detailed below, warrant denial of institution of *inter partes* review.

II. BACKGROUND

A. The '092 Patent Issued Over Art that Disclosed Patent Owner's Ultrasensitive Assay Methods and that Identified Tau Protein as a Potential Blood-Based Biomarker Target

The '092 patent claims methods of preparing bodily fluid samples for quantification of tau protein that is present in exceedingly low concentrations in a

patient's blood sample. (*See, e.g.*, Ex. 1001, '092 patent, claim 1; Petition at 1; *see also* Ex. 1002 at 555.) The '092 patent issued after the Examiner and Patent Owner resolved obviousness rejections raised in the only office action made during prosecution, which were based on combining Patent Owner's ultrasensitive assay technology with references suggesting tau as a potential biomarker target (i.e., Quanterix assay + tau reference combinations).

1. The Examiner's Obviousness Rejections Were Based on Quanterix Assay + Tau Reference Combinations

The Examiner relied on the combination of "Duffy" (Ex. 1015), which discloses Quanterix ultrasensitive assay technology, and "Quanterix 2010a" (Ex. 1033), which references tau as a potential biomarker target, as the primary basis of rejection for pending claims 11, 20-24, and 92-102. (Ex. 1002 at 496.) Both Duffy and Quanterix 2010a originate from and describe or relate to Patent Owner's ultrasensitive protein assay, and Duffy is cited in the '092 patent specification. (Ex. 1001, '092 patent, 16:48-53.) The Examiner also rejected these same claims in further view of either "Wunderlich" (Ex. 1017) or "Mortberg" (Ex. 1018), which reference tau as a potential biomarker target, and rejected pending claim 103 based on Duffy in view of Quanterix 2010a and Wunderlich. (Ex. 1002 at 500-02.)

Each of the obviousness combinations upon which the Examiner based his rejections comprised Quanterix ultrasensitive assay technology alone, or in combination with a reference suggesting tau as a potential biomarker target (i.e., a Quanterix assay + tau reference combination). In the rejection, the Examiner asserted that Duffy teaches an ultrasensitive assay for measuring proteins in blood, which alone discloses each claim limitation except that “the protein being detected is tau” and obtaining a sample “from a patient recovering from a brain injury.” (Ex. 1002 at 496-97.) The Examiner further asserted that even if Duffy alone did not render obvious the claim limitations that “the protein being detected is tau” and obtaining a sample “from a patient recovering from a brain injury,” the combination of Duffy and Quanterix 2010a did so. (*Id.* at 497.) According to the Examiner, Quanterix 2010a teaches “detect[ing] tau in a blood sample . . . and suggests doing so in a subject recovering from a brain injury” (*Id.* at 498.)

The Examiner also rejected pending claims 11, 20-24, and 92-102 based on the combination of Duffy and Quanterix 2010a in further view of either Wunderlich or Mortberg. (Ex. 1002 at 500-01 (in further view of Wunderlich), 501-02 (in further view of Mortberg).) The Examiner found both Wunderlich and Mortberg teach quantifying tau following brain injury (including injuries resulting from the specific

events recited in the pending claims, e.g., hypoxic and ischemic events), and therefore fill that potential gap in Quanterix 2010a. (*E.g., id.* at 501 (“Wunderlich teaches that approximately 30 pg/mL of tau are detected in blood . . . after a stroke”); *id.* (“Mortberg teaches measuring tau in plasma after cardiac arrest”).)

The Examiner additionally rejected then pending claim 103, which recited collecting the patient sample within 12 hours of a brain injury, based on the combination of Duffy, Quanterix 2010a, and Wunderlich. (Ex. 1002 at 501.) The Examiner found that Quanterix 2010a provided “the teachings to make obvious measuring tau in the blood of a subject with a brain injury[,] . . . Wunderlich provides a reasonable expectation of detecting tau in said blood within 12 hours of a brain injury” (*Id.*)

2. The Examiner Withdrew Rejections After Considering Patent Owner’s Evidence that a POSA Would Not Be Motivated to Combine, nor Have Reasonable Expectations of Successfully Combining, Quanterix Assay + Tau References

The Examiner allowed the ’092 patent claims after holding an interview with Patent Owner’s representatives and reviewing Patent Owner’s rebuttal evidence

showing lack of motivation to combine and lack of reasonable expectation of success.

The Examiner and Patent Owner's representatives discussed the obviousness rejection over Duffy and Quanterix 2010a during an interview attended by Dr. David Duffy, the inventor on Duffy and the presenter of the Quanterix 2010a slides, who then served as Patent Owner's Chief Technology Officer. (Ex. 1002 at 554.) Among other issues, Dr. Duffy explained why a skilled artisan would not have been motivated to pursue the claimed tau protein assay method in light of the conventional wisdom in the art, and how it was only after the underlying patent application published that the field experienced a "sea-change" in the approach to measuring tau in blood samples. (*Id.* at 555, 627.) This was evidenced by an article—Ding, Ex. 1019—that catalogued a dramatic, post-publication uptick in the use of Patent Owner's ultra-sensitive assay (Simoa® assays), and other sensitive assays, to detect tau in blood. (*Id.* at 556, 627.)

Patent Owner also addressed the obviousness rejections in written remarks, emphasizing the lack of motivation to produce an analytically-quantified sample from blood containing tau at the levels claimed or using an assay with the level of sensitivity claimed, and the lack of reasonable expectation of success in attempting

to do so. (Ex. 1002 at 555, 558.) More specifically, Patent Owner explained that at the time of the invention, there was no clear motivation in the field to use ultrasensitive assay methods to detect tau in part because “conventional wisdom at the time was that tau was not reliably present in blood . . . or at least [not] at levels that were consistent and meaningfully correlated to any neurological disorder.” (*Id.* at 555.) Indeed, Patent Owner explained that “samples derived from cerebrospinal fluid (CSF) were conventionally believed to be required” to diagnose neurological injury through measuring tau; and to the extent a “skilled person had attempted to measure tau in blood or was aware of such attempts, conventional ELISA assays useful for measurement of tau in CSF were believed to be sufficient” (*Id.* at 555-56.)

In fact, as Patent Owner pointed out to the Examiner, references suggesting tau as a potential biomarker target, such as Quanterix 2010a, Mortberg, and Wunderlich, only suggested measuring tau using such *conventional* techniques. (Ex. 1002 at 555-57, 559.) Underlying the Examiner’s initial, non-final rejection of the pending ’092 claims was the Examiner’s belief that Quanterix 2010a disclosed using Patent Owner’s ultrasensitive assay technology to measure tau. (*Id.* at 497-98.) However, Patent Owner explained that Quanterix 2010a reported tau measurements

using *conventional* techniques—not Patent Owner’s ultrasensitive assay—and only in hindsight was it recognized that those results lacked reliability and erroneously overestimated tau concentration. (*Id.* at 557, 559.) As stated by Patent Owner in remarks to the Examiner, “the measurements of tau in . . . Quanterix 2010a cited in the Office Action are actually in line with [Patent Owner’s] description of the state of the art at the time [because] the early-stage experimental results . . . were produced using a conventional ELISA . . . rather than any ultrasensitive technique” (*Id.* at 557.) Patent Owner then reiterated that it was only *after* publication of the underlying application that the field overcame its “substantial skepticism” and adopted a reasonable expectation of success detecting tau in blood, thereby departing from the gold-standard method of quantifying tau in cerebrospinal fluid. (*Id.* at 559-61.) That adoption was accompanied by praise for—and rapid, widespread use of—Patent Owner’s ultrasensitive tau assay. (*Id.* at 561-62.)

After considering Patent Owner’s arguments, the Examiner allowed the claims. In particular, the Examiner acknowledged that the alleged *prima facie* case presented in the non-final office action could not stand given that no group had used Patent Owner’s ultrasensitive Simoa® assay to detect tau until after the effective filing date. (Ex. 1002 at 659.) As succinctly put by the Examiner:

In this case, no group prior to the effective filing date had done more than *perhaps* suggest using Simoa to detect tau (see Quanterix document previously discussed),¹ while dozens of groups utilized Simoa to detect tau after the date of Applicant’s contribution. It is on this fact that the Examiner finds the argument persuasive and concludes that the rebuttal evidence is sufficient to overcome the obviousness rejection.

(*Id.* at 660 (emphasis added).)

3. The Examiner Made an Independent Finding of Non-Obviousness Based on Secondary Considerations and Concluded the Claims Were Patentable for That Additional Reason

The Examiner also concluded that Patent Owner’s evidence of lack of motivation to combine and lack of expectation of success supported his independent finding of non-obviousness based on secondary considerations. Specifically, the Examiner found that Ding, Ex. 1019—which catalogued a dramatic, post-

¹ As explained above, the “Quanterix document” that the Examiner points to as “*perhaps* suggest[ing] using Simoa to detect tau” refers to the Quanterix 2010a presentation, (Ex. 1002 at 660 (emphasis added)), which reported tau measurements using conventional techniques and not Simoa®. (*Id.* at 557, 559.)

publication uptick in the use of Patent Owner’s ultrasensitive assay (Simoa® assay), and other sensitive assays, to detect tau in blood—was convincing evidence that the ’092 application resulted in rapid adoption of the claimed assay. (Ex. 1002 at 659-60 (Examiner discussing Ding and uptick in use of Patent Owner’s claimed method); *id.* at 556, 560-61 (Patent Owner remarks discussing Ding).) Recognizing that “per MPEP § 2145, rebuttal evidence [against obviousness determination] may be in the form of establishing commercial success, including ‘evidence that the claimed invention was copied by others’” (*Id.* at 659-60 (citing *In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1380 (Fed. Cir. 1986))), the Examiner made an independent finding of patentability based on his conclusion that Ding offered credible evidence as to the non-obviousness of the then-pending claims.

B. The Petition’s Obviousness Grounds Mirror Those Raised and Overcome During Prosecution

The Petitioner now presents two grounds of obviousness, each a Quanterix assay + tau reference combination:

Ground	Basis	Claims	Reference(s)
1	§ 103	1, 6-21	Rissin in view of Todd
2	§ 103	1, 6-21	Rissin in view of Voorheis

Each of Petitioner’s grounds uses the same base reference, Rissin (Ex. 1005), which discloses Patent Owner’s ultrasensitive assay technology, combined with a reference (Todd/Voorheis) to potentially suggest tau as a biomarker. The Petitioner’s resort to Rissin as a primary reference, rather than the Duffy reference cited by the Examiner in his non-final rejection, is a distinction without a difference. The contents of Rissin and Duffy are very similar, which is no surprise. The authors of Rissin worked for Patent Owner Quanterix and Rissin’s author list includes every one of the named inventors of the Duffy reference (i.e., David Duffy, Evan Ferrell, Jeff Randall, David Rissin, and David Walt). (*Compare* Ex. 1005, *with* Ex. 1015.)

According to Petitioner, Rissin “teaches performing a SMA [single molecule assay] (digital ELISA) to measure low concentrations of protein biomarkers in blood and blood serum” by ““us[ing] arrays of femtoliter-sized reaction chambers’ that ‘can isolate and detect single enzyme molecules’” (Petition at 28 (citation omitted).) According to Petitioner, Rissin discloses all elements of the challenged claims except targeting tau. (*See, e.g., id.* at 38, 61-62.)

According to Petitioner, Todd “describes the use of a SMA technology . . . that could be used to detect tau biomarker in the blood plasma of patients for early detection of [Alzheimer’s Disease].” (Petition at 31.) The Petitioner also relies on

Todd as identifying Alzheimer's Disease as an area where ultrasensitive assay techniques might be used, and pointing to tau as a known biomarker candidate for clinical diagnosis of Alzheimer's Disease. (*Id.* at 33-34.)

According to Petitioner, Voorheis "is directed to methods and kits for diagnosing [Alzheimer's Disease] and other neurological disorders by screening for tau in the blood of a patient." (Petition at 56.) Petitioner also describes Voorheis as "recogniz[ing] the need for early detection and diagnosis of [Alzheimer's Disease]," and as having "developed a blood-based diagnostic assay using tau as a method for doing so" that involves diluting a blood sample and performing an immunoassay. (*Id.* at 57.)

For Ground 1 combining Rissin and Todd, Petitioner asserts that "[a] POSA would have been motivated to use the SMA procedure of Rissin to quantify endogenous tau in the blood of patients suspected of having a neurological disorder as taught by Todd to arrive at the inventions claimed by the Challenged Claims for several reasons[,]" including a shared field of endeavor and their common disclosure of use of SMAs to quantify ultra-low concentration of analytes in blood. (Petition at 34.) In other words, Petitioner argues that a skilled artisan would have been motivated to apply the ultrasensitive assay technique of Rissin to detect tau protein

as suggested by Todd, which allegedly suggests use of ultrasensitive assays for detection of biomarkers relevant to diagnosis of Alzheimer's disease. (*Id.* at 38-44.)

For Ground 2 combining Rissin and Voorheis, Petitioner asserts that “[a] POSA would have been motivated to combine the teachings of Rissin with the teachings of Voorheis in order to quantify endogenous tau in the blood of patients suspected of having a neurological disorder as claimed by the '092 Patent,” because a POSA allegedly would know that an ultrasensitive technique to detect trace amounts of analyte in blood, like in Rissin, would be beneficial for detecting early Alzheimer's Disease, and in particular tau, as allegedly described in Voorheis. (Petition at 58-60.)

In sum, both Grounds 1 and 2 merely repackage the Quanterix assay + tau reference combinations that the Examiner repeatedly considered and relied upon.²

² The Examiner was fully aware of Rissin's teachings during examination of the '092 patent, having used Rissin coupled with tau references to reject claims during prosecution of two of the '092 patent's parent applications, U.S. Patent Application Nos. 14/111,326 and 15/269,142. (Ex. 2001 at 15; Ex. 2002 at 6-8.) The Examiner's

III. ARGUMENT

The “Director may not authorize an *inter partes* review to be instituted unless the Director determines . . . that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (emphasis added). While a petitioner is generally obligated to address evidence of patentability, it is especially critical that a petitioner address specific evidence previously used to overcome art or arguments materially similar to the Petitioner’s.

For the reasons discussed below, denial of institution is warranted here because Petitioner cannot show a reasonable likelihood of prevailing as to any of the Challenged Claims. Petitioner fails to address evidence of patentability, including (1) evidence presented by Patent Owner and relied upon by the Examiner concerning

arguments during prosecution of U.S. Patent Application Nos. 14/111,326 and 15/269,142 mirror Petitioner’s argument here—that a Quanterix assay + tau reference combination using Rissin (i.e., Patent Owner’s ultrasensitive assay) allegedly would have been obvious. (Ex. 2001 at 15; Ex. 2002 at 6-8.)

a POSA's lack of motivation to combine Quanterix Assay + tau references, and lack of expectation of success in doing so; and (2) the Examiner's independent findings of secondary considerations of non-obviousness of the Challenged Claims.

A. The Proposed Grounds Are Cumulative of the Art & Arguments Considered by the Examiner During Prosecution & Petitioner Fails to Refute Evidence of Patentability Relied Upon by the Examiner

As explained above, the Petition's proposed grounds comprise Quanterix assay + tau reference combinations, which are materially the same as the obviousness combinations and arguments that Patent Owner already overcame during prosecution.

1. Petitioner's Base Reference Is Materially the Same as the Primary Reference Raised During Prosecution Disclosing Quanterix Assay Technology

Petitioner's primary obviousness reference, Rissin, is cumulative of Duffy, the primary obviousness reference raised in prosecution. Both describe Patent Owner Quanterix's ultrasensitive assay for detection and measurement of proteins.

Rissin describes Patent Owner Quanterix's "single-molecule enzyme-linked immunosorbent assay (digital ELISA)" and discloses the method's ability to measure certain proteins in serum at subfemtomolar concentrations. (Ex. 1005 at 1; Petition at 28.) Rissin describes this digital assay as using "arrays of femtoliter-sized

reaction chambers” “that can isolate and detect single enzyme molecules.” (Ex. 1005 at 1, 6; Petition at 28.) As alleged by Petitioner, the assay operates by forming a sandwich antibody complex on microscopic beads, after which bound antibodies are labeled with enzymes. The sample is then introduced to the labeled complex, whereby the labeled antibodies capture the target proteins of interest. (Ex. 1005 at 1, 6; Petition at 30.) These complexes are then put into femtoliter-volume wells for isolation and detection of single molecules. (Ex. 1005 at 1, 2, 6.) According to Petitioner, Rissin’s Figure 1 depicts this setup. (Ex. 1005 at 2; Petition at 28.) The Petition alleges that Rissin discloses assay results for detecting two proteins, PSA and TNF- α , and generally states a belief that the “digital ELISA has the potential to facilitate earlier diagnosis and treatment of disease.” (Ex. 1005 at 3, 5; *see also* Petition at 37.)

Duffy, titled “Ultra-Sensitive Detection of Molecules on Single Molecule Arrays,” also describes Patent Owner Quanterix’s ultrasensitive assay technology for detecting analyte molecules or particles in a fluid sample like blood, and determining their concentration, including in subfemtomolar ranges. (Ex. 1015 at 1, 29, 43, 51, 57 (table 1).) Like Rissin, Duffy describes capturing the target molecule in a complex that can include beads associated with capture antibodies and a

detectable label. (*See, e.g.*, Ex. 1015 at 57 (Example 11).) Duffy also makes use of arrays comprising a plurality of reaction vessels to isolate and detect the analyte molecule. (*See id.*) Duffy also describes application of the ultrasensitive assay to the detection of PSA and TNF- α , just like Rissin. (Ex. 1015 at 57 (Examples 11-12).)

As is evident from the above, Rissin is cumulative of Duffy, and Rissin's content largely mirrors Duffy's teachings of Examples 11 and 12, which use Patent Owner's ultrasensitive assay to detect TNF- α and PSA, respectively. And what is more, just as the Examiner asserted that Duffy disclosed all limitations of pending independent claim 92 but tau protein, (Ex. 1002 at 496-97; Petition at 8), Petitioner asserts that Rissin discloses that same exact scope for that same claim, which issued as claim 1, (Petition at 37-44, 61-65 (identifying Rissin for all limitations of claim 1 except tau)). To reiterate, Rissin's teachings are cumulative of and materially the same as Duffy's.

2. Petitioner's Secondary References Are Materially the Same as the Secondary Reference Raised During Prosecution Suggesting Tau as a Potential Biomarker

Todd and Voorheis serve a singular purpose in the Petition: addressing the claim limitations that require detection of tau in a blood sample, which Rissin (like

Duffy, the primary reference raised during prosecution) does not disclose. (*See, e.g.*, Petition at 34, 38, 42-43, 58, 61-65.) As demonstrated below, Todd and Voorheis are duplicative of multiple references already considered by the Examiner, including Quanterix 2010a, Mortberg, and Wunderlich, which disclosed attempts to detect and quantify tau in blood samples.

Todd describes a “biomarker movement” in drug discovery and disease diagnosis, and the need to develop advanced protein detection systems. (Ex. 1006 at 1-2; Petition at 32.) Among other applications, Todd asserts that protein biomarker programs in Alzheimer’s disease might benefit from immunoassay technologies with ultrasensitive detection, and identifies “beta-amyloid and tau proteins” as potentially “hopeful candidates” as clinical markers for Alzheimer’s diagnoses. (Ex. 1006 at 3; Petition at 33-34.) Despite mentioning tau as a “hopeful candidate,” Todd cautions that “further clinical validation of this new diagnostic information will be necessary to define the disease state and set the guidelines for early diagnosis and onset of AD.” (Ex. 1006 at 3.) Todd also describes “next generation immunoassay systems,” including “Single Molecule counting (SMC)-based systems” by Singulex that are capable of “quantifying biomarkers at the sub-picogram level.” (Ex. 1006 at 3; Petition at 31.)

Voorheis discloses that fragments of tau protein can be detected outside the brain and describes the use of conventional immunoassay techniques to detect tau protein fragments in patient blood samples for purposes of diagnosing Alzheimer's Disease. (Ex. 1007 at 1, 6, 10.)

Todd's identification of tau protein as a "hopeful candidate" for an Alzheimer's Disease biomarker coupled with a description of ultrasensitive assay techniques, and Voorheis's suggestion that the presence of tau protein fragments in blood might be exploited to diagnose Alzheimer's Disease, offer the same information that Quanterix 2010a, Mortberg, and Wunderlich provided during prosecution of the '092 patent. The Examiner relied on those three references for motivation to detect tau protein in blood, as the Examiner found that each suggested or reported doing so, at least with conventional assay techniques. (Ex. 1002 at 498, 501-02.) Todd and Voorheis are thus cumulative of and materially the same as those three references.

3. Petitioner’s Arguments Concerning Its Proposed Quanterix Assay + Tau Reference Combinations Are Duplicative of Those the Examiner Considered

Petitioner’s arguments based on Quanterix assay + tau reference combinations are cumulative of, and materially the same, as those raised and later withdrawn by the Examiner.

Both of Petitioner’s proposed grounds rely on combining the single molecule assay taught by Rissin, which omits quantifying tau, with references (Todd and Voorheis) that identify tau as a potential biomarker target. (*See, e.g.*, Petition at 34-38, 58-62.) In each instance, Petitioner argues that a POSA would have “been motivated to modify the teachings Rissin [sic] with the teachings of [Todd/Voorheis] in order to quantify protein concentration in blood for clinical diagnosis of neurological disease for the reasons discussed in the Motivation to Combine Section.” (*Id.* at 38, 62.)

Petitioner’s proposed grounds are duplicative of those the Examiner previously considered. Indeed, as the Petition acknowledged, “[t]he [E]xaminer found that Duffy taught a [single-molecule assay] that met the limitations of [then-pending claim 1], except measuring tau as the specific analyte of interest, and the sample being obtained from a patient ‘recovering from a brain injury’”; however,

the Examiner found “[t]hose limitations . . . disclosed in [Quanterix 2010a.]” (Petition at 8; *see also* Ex. 1002 at 497 (“Duffy teaches . . . [q]uantifying through the use of an analytical protein concentration measurement assay a concentration of protein . . .”); *id.* at 498 (Quanterix 2010a “explicitly teaches the assay can detect tau in a blood sample . . .”).) The Examiner also explicitly considered the state of the art and a skilled artisan’s anticipated success based on Duffy alone and in combination with Quanterix 2010a. (*E.g.*, Ex. 1002 at 497-98.) The Petition follows the Examiner’s rejections like a roadmap.

Petitioner’s other arguments fare no better and are similarly cumulative over the arguments that the Examiner considered. For example, dependent claim 16 recites collecting a patient sample within 12 hours of a brain injury. Petitioner argues that this would have been obvious based on Rissin in view of the “State of the Art” and either Voorheis, which generally teaches diagnostic testing, or Todd, which teaches that tau can be detected at 3-, 6-, and 12-hour intervals after a stroke. (Petition at 55, 71-72.) But these arguments are cumulative of the Examiner’s assertion that Wunderlich “teaches that . . . tau [is] detected in blood at 3, 6, and 12 hours after a stroke” (Ex. 1002 at 501.) The Examiner asserted that “Quanterix 2010a provides the teachings to make obvious measuring tau in the blood of a subject

with a brain injury while Wunderlich provides a reasonable expectation of detecting tau in said blood within 12 hours of a brain injury, making such a method of ‘producing a body fluid sample’ obvious.” (*Id.*) This is the exact argument Petitioner advances.

Similarly, Petitioner argues dependent claims 17-21, which recite collecting a patient sample following different types of brain injuries, are obvious over Rissin in view of the “State of the Art” and either Voorheis or Todd, based on general knowledge regarding quantifying tau protein for diagnosis of neurological disease. (Petition at 38, 52-55, 61-62, 71.) But again, these arguments are cumulative of those considered by the Examiner, who considered collecting patient samples following the different types of brain injuries recited by these claims to be obvious over (1) Duffy in combination with Quanterix 2010a based on a skilled artisan’s “reasonable expectation of success,” and (2) Duffy in combination with Quanterix 2010a and Wunderlich or Mortberg, which taught detecting tau following the types of brain injuries recited by the claims. (Ex. 1002 at 498, 501-02.) Thus, all of Petitioner’s grounds and arguments are cumulative of and materially the same as those already considered by the Examiner.

4. Petitioner Fails to Refute Evidence of Patentability Relied Upon by the Examiner Despite Proposing Obviousness Grounds Materially the Same as Those the Examiner Considered

The Petition fails to address evidence of patentability presented by Patent Owner during prosecution to overcome Quanterix assay + tau reference combinations, such as the ones Petitioner now raises. The obviousness inquiry turns on underlying factual questions, *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009), and neither the Petition nor its accompanying expert declaration refute or show error in the Examiner's factual findings that led to the withdrawal of his rejections and the allowance of the Challenged Claims.

Nowhere does the Petition address the Examiner's findings that Patent Owner's rebuttal evidence warranted withdrawal of his previous obviousness rejection. (Ex. 1002 at 659-60.) Specifically, the Examiner relied on the Ding reference presented by Patent Owner, and explicitly Table 1 of Ding, as evidence of the uptick in use of Patent Owner's claimed invention after the effective filing date. (*Id.*) As Patent Owner had explained in remarks to the Examiner, "Tables 1 and 2 in Ding show plasma tau and p-tau reports from various research groups . . . and all reports came after the publication of [the international application], from which the

[’092] Application claims priority.” (*Id.* at 560.) Patent Owner further explained, the “[p]ublication of the claimed invention represent[ed] a clear line of demarcation in the field evidencing that it was the subject matter of [the] Application that established a reasonable expectation of success.” (*Id.*) The Examiner agreed, noting that the Ding reference showed that “no group had actually” used “Simoa to detect tau” prior the effective filing date of the ’092 Application. (*Id.* at 659.)

Rather than address the substance of Examiner’s findings, the gist of Petitioner’s criticism of the Examiner is that he accepted Patent Owner’s evidence of non-obviousness without considering other evidence that might have contributed to the uptick in usage of highly sensitive assays to measure tau in blood, apart from the publication of the underlying application. (Petition at 9-10.) The Petitioner’s argument falls far short of meeting its burden of proof, and all of the evidence Petitioner cites is cumulative of the information the Examiner *did* consider. For example, the Petition cites three Exhibits (*id.*, 10 (citing Exs. 1039, 1040, 1041)) relating to Patent Owner Quanterix’s Simoa® technology and patents which are expressly cited on the face of the ’092 patent. (*See* Ex. 1001 at 2 (listing Ex. 1040 (U.S. Pat. No. 8,236,574)); *id.* (listing three patents related to Patent Owner’s Simoa® technology issued during 2013, one of which was assigned to Patent Owner

(U.S. Pat. No. 8,415,171) and others assigned to Tufts University (U.S. Pat. Nos. 8,460,878, 8,460,879, and 8,492,098), which are described in Ex. 1041); *id.* at 4 (listing Ex. 1039).) The remaining two exhibits that Petitioner relies upon reflect nothing more than what the Examiner already knew from the Ding reference—i.e., that Patent Owner’s Simoa® assay, including as described in Rissin,³ was marketed and used to detect tau in blood after the ’092 patent’s priority date. (*See* Ex. 1034 (Patent Owner’s website page from 2013 describing its Simoa® technology and tau assay kit); Ex. 1042 (Journal article published in 2017 describing blood-based detection of tau using Patent Owner’s Simoa® platform).) The Petitioner cannot refute the Examiner’s findings by merely pointing to the same evidence that the Examiner considered—and then baselessly second-guessing the Examiner’s findings of patentability.

Petitioner also halfheartedly attacks the Ding article. (Petition at 9-10.) But those arguments are cumulative too, because the Examiner expressly considered

³ Ding cites Rissin as describing the Simoa® technology that had been used to detect tau in the studies included in its meta-analysis. (*See* Ex. 1019 at 1-2 & n.13.)

Ding, including Ding’s list of publications concerning the use of highly sensitive assays to detect tau in blood. (*See* Ex. 1002 at 556 (summary of 6/20/2021 Examiner interview during which Ding was discussed); *id.* at 567, 575-88 (6/29/2021 email from Patent Owner to Examiner attaching Ding); *id.* at 659 (notice of allowance discussing Ding).) Petitioner cites no evidence to support its speculation that the articles analyzed by Ding were published for any purpose other than to report the results of notable scientific studies, and Petitioner’s observation that 17 publications out of 66 listed an author with some connection to Patent Owner Quanterix does nothing to undermine the correctness of the Examiner’s conclusions. Thus, the Petition fails to refute the Examiner’s findings based on Ding that no group had used highly sensitive assays to detect tau in blood before the effective filing date of the ’092 patent, and at least 42 groups did so afterwards. (*See* Ex. 1002 at 659.)⁴

⁴ The only other quibble offered by the Petitioner with respect to the Examiner’s reliance on Ding is that the Examiner “incorrectly” wrote in his Reasons for Allowance that “Ding table 1 lists Applicant’s claimed assay (tau Simoa) used by at least forty-two (42) groups after the effective filing date of 4/12/11,” while “in

Additionally, the Petition ignores the Examiner's finding that Quanterix 2010a does *not* disclose using an ultrasensitive assay, like Simoa®, to measure tau in blood. In the Examiner's initial, non-final rejection of the pending '092 claims, the Examiner understood Quanterix 2010a to disclose using Patent Owner's ultrasensitive assay technology to measure tau. (Ex. 1002 at 498.) However, as detailed in Section II.A.2 above, Patent Owner explained to the Examiner that Quanterix 2010a merely disclosed using conventional ELISA assays (i.e., not ultrasensitive assays, like Simoa®) to detect tau. The Examiner subsequently withdrew his obviousness rejections. The Petition fails to address or refute the Examiner's conclusion, and also incorrectly claims that Quanterix 2010a "instructs the use of [single molecule assays] to detect tau in the blood of patients suffering from . . . neurological conditions," and relies on this misinterpretation of Quanterix 2010a to support its "State of the Art" section concerning "SMA [single

reality," the correct term was "studies (publications), not groups." (Ex. 1003, ¶ 47 (emphasis added); *see also* Petition at 10.) Petitioner's word choice critique is not evidence of error by the Examiner.

molecule assays] and Detecting Tau.” (Petition at 8, 12, 18, 23-26.)

In summary, the Petition offers no substantive rebuttal to the Examiner’s conclusions of non-obviousness despite relying on Quanterix assay + tau reference grounds materially the same as those considered by the Examiner.

B. *Inter Partes* Review Should Not Be Instituted Because the Petition Fails to Overcome the Examiner’s Finding that a POSA Would Not Be Motivated to Combine, nor Have Reasonable Expectations of Successfully Combining, Quanterix Assay + Tau References

Where, as here, a Petition proposes grounds that are cumulative of art and arguments considered by the Examiner during prosecution, the Board has found that the Petition must directly address the Examiner’s bases for patentability or face denial of institution. *See Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 at 27 (PTAB Jan. 22, 2015) (Petitioner “was aware of the unexpected results showing which the Examiner found persuasive in showing nonobviousness in view of substantially the same prior art combinations [Petitioner] now relies upon[, and Petitioner] should have addressed unexpected results”). The Petition fails to meet this requirement, so institution should be denied.

The Board’s guidance in *Praxair Distribution, Inc. v. Ino Therapeutics, Inc.* is instructive. IPR2015-00522, Paper 12 (PTAB July 29, 2015). There, the challenged patents were directed to methods for reducing serious adverse events in

children associated with nitric oxide gas inhalation. *Id.* at 3-5. Petitioner’s proposed grounds broadly argued that the challenged claims were obvious because a POSA would have applied treatments for adults, disclosed in the prior art, to children. *Id.* at 15-16, 21-22. The Board disagreed. Notably, the Board faulted the petition’s failure across its proposed grounds to refute evidence raised during prosecution concerning a POSA’s lack of motivation to combine such treatments, and the lack of reasonable expectations of success in doing so. *E.g., id.*, 16-17, 21-23. As the Board explained across different proposed grounds, the Petitioner “should have addressed” evidence of patentability that the Examiner found persuasive in allowing the claims—“[b]ecause Petitioner failed to address . . . these arguments—despite the fact that [they] were raised during prosecution—[the Board] determine[d] that Petitioner has not established a reasonable likelihood that it would prevail in showing that [challenged] claims . . . are unpatentable” *Id.* at 17, 23.

Similarly, here, the Petition fails to address the Examiner’s bases for patentability despite proposing nearly identical obviousness combinations as those considered by the Examiner. (*Supra* Section III.A.) As detailed above, the Examiner found that Patent Owner’s evidence of lack of motivation to combine and lack of reasonable expectations of success, including the pronounced uptick in use of the

claimed method evidenced by Ding, supported a finding of non-obviousness. (*Supra* Section II.A.2.) Such evidence of unpredictability and lack of previous use weighs in favor of finding no expectation of success. *Genzyme Corp. v. Dr. Reddy's Labs. Ltd.*, 716 F. App'x 1006, 1010-11 (Fed. Cir. 2017).

The Petition fails to address this evidence, (*supra* Section III.A.4), warranting denial of institution. The Board has explained that “a party that petitions the Board for a determination of unpatentability based on obviousness must show that ‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Mylan Pharms. Inc. v. Novo Nordisk A/S*, IPR2023-00722, Paper 9 at 13 (PTAB Oct. 2, 2023) (citing *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016)). Because the Petition relies on Quanterix assay + tau refence combinations nearly identical to those considered by the Examiner, the Petitioner was obligated to rebut the Examiner's findings as part of its evidence of motivation to combine and reasonable expectations of success as to its proposed grounds. *Merial*, Paper 13 at 27; *Praxair Distrib.*, Paper 12 at 23. The Petition did not do so and therefore failed to satisfy the requirements of § 314(a). *Coal. for Affordable Drugs V LLC v. Hoffman-LaRoche*,

Inc., IPR2015-01792, Paper 14 at 15-19 (PTAB Mar. 11, 2016) (denying institution where petition did not show sufficient reason to combine references).

The Petitioner’s failure to acknowledge the Board’s decisions in proceedings such as *Merial* and *Praxair*, and its failure to show how its evidence of alleged motivation to combine and reasonable expectation of success overcame the evidence that the Examiner relied upon (or the Examiner’s associated findings of patentability) are fatal to its obviousness challenges. *E.g.*, *Juniper Networks, Inc. v. Correct Transmission, LLC*, IPR2021-00682, Paper 12 at 23 (PTAB Oct. 3, 2022) (denying institution where “Petitioner leaps silently over the requirement to evidence a reasonable expectation of success to establish obviousness.”); *see also Juniper Networks, Inc. v. Correct Transmission, LLC*, No. 2023-1046, 2024 WL 3517862, at *6 (Fed. Cir. July 24, 2024) (patent challenger bears burden of proof that proposed combination could be made with a reasonable expectation of success); *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1348-49 (Fed. Cir. 2021) (similar).

The Federal Circuit has repeatedly affirmed PTAB decisions upholding patent validity because the patent challenger failed to adequately address reasonable expectation of success and motivation to combine prior art as part of its § 103 challenge. *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373, 1380-

81 (Fed. Cir. 2019) (upholding Board’s decision that POSA would not have had reasonable expectation of success in combining prior art references to gap-fill missing limitation); *see also Juniper Networks*, 2024 WL 3517862, at *6 (similar). The Federal Circuit’s affirmances in *Samsung Electronics* and *Juniper Networks* underscore that the Petition here should be denied institution for failing to offer evidence to refute or show material error in the Examiner’s findings that there would have been no reasonable expectation of success in combining the teachings of the prior art, or any motivation to combine the teachings of the prior art.

C. *Inter Partes* Review Should Not Be Instituted Because the Petition Fails to Address the Examiner’s Independent Finding of Secondary Considerations of Non-obviousness

The Petition should be denied for an additional reason—it fails to address the Examiner’s independent findings of patentability based upon secondary considerations of non-obviousness.⁵

⁵ As explained in Section II(A)(2) above, the Patent Owner argued for patentability by submitting evidence and arguments showing that a skilled artisan would have lacked any reasonable expectation of success and would not have had a motivation to combine the teachings of the prior art.

Where, as here, the Examiner’s bases for patentability include secondary considerations, a patent challenger must address them as part of its § 103 challenge. *Coal. for Affordable Drugs V*, Paper 14 at 17-19 (denying institution for failure to address secondary considerations relied upon by Examiner during prosecution); *Merial*, Paper 13 at 27-28 (same). The Board has repeatedly denied institution of *inter partes* review where a petition failed to address secondary considerations when secondary considerations were a basis for patentability. *See, e.g., Stryker Corp. v. KFX Med., LLC*, IPR2019-00817, Paper 10 at 27-29 (PTAB Sep. 16, 2019) (“Petitioner’s failure to address the known evidence of secondary considerations further weighs in favor of denying institution.”); *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01751, Paper 15 at 23 (PTAB Mar. 22, 2017) (denying institution for failure to address secondary considerations presented during ITC proceeding, noting that “[w]e have cautioned petitioners in prior proceedings that known evidence of secondary considerations should be addressed in the petition”); *Omron Oilfield & Marine, Inc. v. MD/TOTCO*, IPR2013-00265, Paper 11 at 12-16 (PTAB. Oct. 31, 2013) (denying institution for failure to address objective indicia argued in a reexamination).

Here, Petitioner was aware of and failed to rebut the Examiner’s findings of

secondary considerations regarding the '092 patent. As discussed in Section III.A.4 above, the Petitioner merely second-guesses the Examiner's conclusion that the uptick in usage of ultrasensitive assays to measure tau in blood was attributable to the publication of Patent Owner's underlying application. (Petition at 9-10.) Petitioner failed to offer any evidence to rebut the Examiner's findings or to show examiner error. As a result, and as underscored by the Board's decisions in *Coalition for Affordable Drugs V, Merial, Stryker Corp.*, and *Omron Oilfield & Marine*, the Petitioner did not meet its threshold burden of proof under § 314(a). *See also Gilead Scis., Inc. v. United States*, IPR2019-01453, Paper 14 at 29 (PTAB Feb. 20, 2020) ("Petitioner's conclusory assertions about . . . a lack of a nexus are insufficient to rebut . . . specific evidence . . .").

As the Federal Circuit has explained, secondary considerations of non-obviousness "must be considered" when making a § 103 obviousness determination. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc); *see also Dome Pat. L.P. v. Lee*, 799 F.3d 1372, 1383 (Fed. Cir. 2015) ("[E]vidence pertaining to the objective indicia of nonobviousness must be considered before reaching an obviousness conclusion." (citation omitted)); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1520, 1538 (Fed. Cir. 1983) (similar); *ClassCo, Inc. v. Apple, Inc.*,

838 F.3d 1214, 1220 (Fed. Cir. 2016) (similar). By not addressing the Examiner's additional findings of patentability based on secondary considerations, Petitioner failed to meet its burden under § 314(a).

IV. CONCLUSION

For the foregoing reasons, the Petition fails to show a reasonable likelihood of success with respect to any of the Challenged Claims, so institution of *inter partes* review should be denied pursuant to 35 U.S.C. § 314(a).

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this Patent Owner Preliminary Response complies with the type-volume limits of 37 C.F.R. § 42.24(b)(3) because it contains 7,034 words, according to the word-processing system used to prepare this Preliminary Response, excluding the parts of this Preliminary Response that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), the undersigned certifies that a true and correct copy of the foregoing **PATENT OWNER PRELIMINARY RESPONSE** was served on September 22, 2025, via email to counsel for Petitioner at the following:

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