

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

National Beef Packing Company, LLC,

Petitioner,

v.

Institute for Environmental Health, Inc.,

Patent Owner

U.S. PATENT NO. 8,822,143

Case No. IPR2024-00185

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

	Page
TABLE OF CONTENTS	i
TABLE OF AUTHORITIES	iv
TABLE OF EXHIBITS	viii
I. INTRODUCTION	1
II. BACKGROUND	3
A. The '584, '143, and '771 Patents	3
B. Prosecution, Reexamination, and Previous District Court Proceedings	6
1. Original Prosecution of the '584 Patent.....	7
2. Further Prosecution of the '584 Patent via <i>Inter Partes</i> Reexamination	11
3. Appeal of the '584 Patent <i>Inter Partes</i> Reexamination.....	16
4. Prosecution of the '233 Patent	18
5. Prosecution of the '143 Patent	20
6. Prosecution of the '771 Patent	21
7. <i>IEH v. Primus</i> District Court Litigation.....	23
C. Current District Court Litigation Paralleling Current Petition	26
III. LEVEL OF ORDINARY SKILL IN THE ART	27
IV. THE PETITION FAILS TO SET FORTH THE ASSERTED GROUNDS WITH PARTICULARITY.....	28
A. Petition Fails to Delineate Grounds as Argued.....	28
B. Petitioner Improperly Incorporates by Reference Dr. Dickson's 317-Page Declaration	32
C. Petitioner's Motivations to Combine Are Deficient	34

V.	CLAIM CONSTRUCTION	36
A.	The Board Should Not Construe “Lots”	37
B.	The Board Need Not Construe “Separately Sampled”	38
C.	The Board Need Not Construe “Combining/Compositing”	40
D.	The Board Need Not Construe “Enrichment/Enriching”	40
E.	Validation/Determining Releasability Limits the Claims	41
1.	“Validate” means “determining a lot is releasable”	41
2.	Validation/Determining Releasability Limits the Claims	48
3.	Petitioner Has No Support for Its Position That “for Release into Commerce” Is Non-limiting	51
VI.	NONE OF THE CITED PRIOR ART TEACHES THE VALIDATION STEP	51
A.	<i>Price</i> Does Not Teach Validation	52
B.	ICMSF-7 Does Not Teach Validation	53
C.	<i>Gombas</i> Does Not Teach Validation	56
D.	Hughes Does Not Teach Validation	57
VII.	INSTITUTION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)	58
A.	The <i>Fintiv</i> Factors	58
B.	The District Court Is More Likely to <i>Deny</i> a Stay if the Petition Is Instituted	60
C.	Trial Will Likely Precede the Board’s Final Written Decision	65
D.	The Parties and the District Court Have Already Invested Substantial Resources	67
E.	Overlap of Issues	69
F.	The Petitioner Is the Defendant in the Parallel Litigation	70

G. Petitioner Has Not Presented Compelling Evidence of
Unpatentability 71

VIII. CONCLUSION.....71

CERTIFICATE OF COMPLIANCE.....73

CERTIFICATE OF SERVICE 74

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>3G Licensing, S.A. v. HTC Corp.</i> , No. CV 17-83-GBW, 2023 WL 34553 (D. Del. Jan. 4, 2023).....	60
<i>10x Genomics, Inc. v. President & Fellows of Harvard Coll.</i> , IPR2023-01299, Paper 15 (PTAB Mar. 7, 2024).....	66, 67, 68, 71
<i>Adaptics Ltd. v. Perfect Co.</i> , IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019).....	31
<i>ADT LLC v. Vivint, Inc.</i> , IPR2022-00634, Paper 7 (PTAB Oct. 4, 2022).....	31, 32
<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	53
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....	65
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 15 (PTAB May 13, 2020).....	<i>passim</i>
<i>Arctic Cat Inc. v. GEP Power Prods., Inc.</i> , 919 F.3d 1320 (Fed. Cir. 2019).....	48
<i>Avant Tech., Inc. v. Anza Tech., Inc.</i> , IPR2018-00828, Paper 7 (PTAB Oct. 16, 2018).....	31, 32, 33
<i>Belden Techs. Inc. v. Superior Essex Commc'ns LP</i> , No. CIV. 08-63-SLR, 2010 WL 3522327 (D. Del. Sept. 2, 2010).....	61, 62, 63
<i>Bicon, Inc. v. Straumann Co.</i> , 441 F.3d 945 (Fed. Cir. 2006).....	48
<i>CAO Lighting, Inc. v. Gen. Elec. Co.</i> , No. CV 20-681-GBW, 2022 WL 17752270 (D. Del. Dec. 19, 2022).....	61, 62, 63, 65

<i>Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.</i> , 289 F.3d 801 (Fed. Cir. 2002)	48, 50
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014).....	32, 33
<i>Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.</i> , IPR2020-00122, Paper 15 (May 15, 2020).....	70
<i>Comcast Cable Comm., LLC v. Touchstream Tech., Inc.</i> , IPR2024-00326, Paper 13 (PTAB July 26, 2024)	70
<i>CommScope Techs. LLC v. Dali Wireless, Inc.</i> , IPR2022-01242, Paper 23 (PTAB Feb. 27, 2023).....	71
<i>DeSilva v. DiLeonardi</i> , 181 F.3d 865 (7th Cir. 1999)	33
<i>DirectTV, LLC v. Qurio Holdings, Inc.</i> , IPR2015-02007, Paper 6 (PTAB Apr. 4, 2016)	33
<i>Eli Lilly & Co. v. Teva Pharms. Int’l GmbH</i> , 8 F.4th 1331 (Fed. Cir. 2021)	48
<i>Gerber Garment Tech., Inc. v. Lectra Sys., Inc.</i> , 916 F.2d 683 (Fed. Cir. 1990)	50
<i>Google LLC v. AGIS Software Dev., LLC</i> , IPR2020-00873, Paper 16 (PTAB Nov. 25, 2020).....	68
<i>Hamilton Beach Brands, Inc. v. f’real Foods, LLC</i> , 908 F.3d 1328 (Fed. Cir. 2018)	41, 51
<i>Hamilton Techs. v. Tehrani</i> , IPR2020-01199, Paper 17 (PTAB Mar. 5, 2021)	33
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	58, 59
<i>Huawei Techs., Co. v. Samsung Elecs. Co.</i> , No. 3:16-CV-02787-WHO, 2017 WL 7058419 (N.D. Cal. Aug. 31, 2017).....	39

<i>Innovention Toys, LLC v. MGA Ent., Inc.</i> , 637 F.3d 1314 (Fed. Cir. 2011)	28
<i>In re Jasinski</i> , 508 F. App'x 950 (Fed. Cir. 2013)	49
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	35
<i>In re Magnum Oil Tools Int'l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	35, 36
<i>NHK Spring Co. v. Intri-Plex Techs., Inc.</i> , IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018).....	59
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.</i> , 868 F.3d 1013 (Fed. Cir. 2017)	<i>passim</i>
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	42, 51
<i>Primus Grp., Inc. v. Inst. for Env'tl Health, Inc.</i> , No. 3:18-cv-00005-WHO (N.D. Cal. filed Jan. 2, 2018)	7, 38, 39
<i>RideShare Displays, Inc. v. Lyft, Inc.</i> , No. CV 20-1629-RGA-JLH, 2021 WL 7286931 (D. Del. Dec. 17, 2021).....	62, 64
<i>Samsung Elecs. Co. v. Elm 3DS Innovations, LLC</i> , 925 F.3d 1373 (Fed. Cir. 2019)	46, 47
<i>Samsung Elecs. Co. v. LED Wafer Sols., LLC</i> , IPR2021-01491, Paper 11 (PTAB Oct. 26, 2022).....	36
<i>SharkNinja Operating LLC v. iRobot Corp.</i> , No. 2023-1151, 2024 WL 1132219 (Fed. Cir. Mar. 15, 2024)	41, 42
<i>SightSound Techs., LLC v. Apple Inc.</i> , 809 F.3d 1307 (Fed. Cir. 2015)	46, 47
<i>SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.</i> , 983 F.3d 1367 (Fed. Cir. 2021)	49, 50

<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020)	69, 70
<i>Teoxane S.A. v. Allergan, PLC</i> , IPR2017-01906, Paper 15 (PTAB Mar. 9, 2018)	33
<i>Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.</i> , 200 F.3d 795 (Fed. Cir. 1999)	36
<i>Vizio, Inc. v. ITC</i> , 605 F.3d 1330 (Fed. Cir. 2010)	48, 49

Federal Statutes

35 U.S.C.	
§ 101	63
§ 112	61, 63
§ 314(a)	58, 59
§ 314(b)	66
§ 315(e)	69
§ 316(a)(11)	66

Regulations

37 C.F.R.	
§ 41.77(b)(1)	17
§ 42.6(a)(3)	32, 34
§ 42.100(b) (2019)	39, 41

Other Authorities

Katherine K. Vidal, <i>Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation</i> (June 21, 2022)	69
<i>Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications</i> , University of Toronto Press, 2d ed. (1986)	53, 54

TABLE OF EXHIBITS

No.	Exhibit
2001	Primus Motion for Summary Judgment of Invalidity, <i>Primus Grp., Inc. v. Inst. for Env'tl Health, Inc.</i> , No. 3:18-cv-00005-WHO (N.D. Cal. June 5, 2019), ECF No. 64
2002	Order Denying Primus's Motion for Summary Judgment of Invalidity, <i>Primus Group, Inc. v. Inst. for Env'tl Health, Inc.</i> , No. 3:18-cv-00005-WHO (N.D. Cal. Aug. 19, 2019), ECF No. 90
2003	National Beef's First Amended Answer and Counterclaims, <i>Inst. for Env'tl Health, Inc. v. Nat'l Beef Packing Co.</i> , No. 1:23-cv-00826-JHS (D. Del. July 10, 2024), ECF No. 40
2004	Docket Report, <i>Inst. for Env'tl Health, Inc. v. Nat'l Beef Packing Co.</i> , No. 1:23-cv-00826-JHS (D. Del.)
2005	Int'l Comm'n on Microbiological Spec's for Foods, Microorganisms in Foods 7: Microbiological Testing in Food Safety Management at xi-xiii, 342-346 (Kluwer Academic/Plenum Publishers, 2002) ("ICMS-7")
2006	Lex Machina, Report of Open Cases before JJ. Connolly, Williams, Noreika, Andrews, and Hall Report of the U.S. District Court for the District of Delaware
2007	Lex Machina, Report of Open Cases before J. Slomsky of the U.S. District Court for the Eastern District of Pennsylvania
2008	U.S. District Courts—Combined Civil and Criminal Federal Court Management Statistics at 14, 16 (June, 2024), <i>available at</i> https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2024/06/30-1 (last visited Oct. 22, 2024) (U.S. District Court for the District of Delaware and Eastern District of Pennsylvania)
2009	National Beef's Invalidity contentions

I. INTRODUCTION

The Board should deny this petition for five reasons. *First*, Petitioner presents hundreds of combinations lacking the statutorily required particularity. *Second*, the petition fails to address any motivation to combine specific teachings of any reference with another, apparently relying instead on the volume of combinations presented to the Board. *Third*, Petitioner attempts to circumvent the statutory word limit by incorporating large swaths of its expert declaration by reference. *Fourth*, the Petition cites no reference that teaches the “validation” step all claims require. *Fifth*, the Board should exercise its discretion to deny the petition because the district court litigation will resolve the same issues before the Board’s final written decision.

Petitioner purports to assert ten grounds using eight references, but fails to explain which reference it relies on for any single limitation or how or why the references should be combined. Instead, Petitioner alleges nearly every limitation is met by more than one reference, leaving it to the Board and Patent Owner to wade through the hundreds of combinations. The Board has repeatedly held that this “catch-all” approach fails to present grounds with sufficient particularity.

The petition also fails to provide a discernible motivation to combine the references generally, let alone a concrete rationale to combine specific teachings in a particular way. For example, Petitioner simply concludes that a “POSA would have

been motivated to modify [one reference] based on [another] under the teaching-suggestion-motivation test” without explaining *what* teaching, suggestion, or motivation supports this conclusion. A Petition cannot replace the requirement to articulate a clear motive to combine the references in a particular way by relying on sheer volume of combinations.

Petitioner compounds the problem by evading the statutory word count by relying on arguments found only in a 317-page expert declaration. This practice violates the Board’s long-standing rules against incorporation by reference, which is particularly applicable where, as here, entire sections of the Petition merely refer to dozens of paragraphs of an expert declaration—while maintaining a word count near the statutory limit. That practice has not been tolerated previously and should not be tolerated here.

Petitioner also fails on the merits because none of the cited references teach validation, which all challenged claims require. To avoid this shortcoming, Petitioner asks the Board contradict the specification and prosecution history showing validation requires determining releasability and that determination is entitled to patentable weight.

Finally, in its discretion, the Board should deny institution because, Petitioner waited over a year after becoming aware of its infringement before filing this

petition. Moreover, the district court is poised to resolve all issues asserted in this petition months before the Board's final written decision.

II. BACKGROUND

A. The '584, '143, and '771 Patents

All challenged patents share a common specification and claim priority to U.S. Provisional Application No. 60/599,473 (filed August 6, 2004). At the time, “recent United States Department of Agriculture, Food Safety and Inspection Service (FSIS) directives and guidelines, [forced] many food producers in the United States [to] adopt[] sampling plans that involve testing [food products] ... for *E. coli* O157:H7, ... *Listeria monocytogenes*[,] and/or *Salmonella*.” Ex. 1001 at 2, 1:40-45. These sampling plans were “typically [made] pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA or EPA guidelines,” which shared the “common feature” of defining the number of pieces needed from a “combined production lot” to create a “composite sample” that would meet the sensitivity level needed for subsequent testing. *Id.* at 2, 1:62-2:26. The “composite sample ... is then enriched for the presence of a given pathogen/microbe by addition of appropriate amounts of enrichment media and incubation at an appropriate temperature for a given amount of time. ... [and] tested [for example,] by immunoassay-based tests ... or culturing of the organism of interest[.]” *Id.* at 2, 2:46-58.

In other words, regulations defined a total number of samples that must be taken, combined, enriched, and tested before a “production lot” could be released for human consumption—but did not define the size of the “production lot.” *See id.* at 2, 2:27-45. Because the required enriching and testing was expensive, “manufacturer’s often resort[ed] to increasing the size of the ‘production lot.’” *Id.* at 2, 2:27-29. But because “microbial contaminants are unevenly spread throughout” food, regulations did not allow for re-testing or re-sampling any portion of the “production lot” used to create the “composite sample.” *Id.* at 3:4-16. Hence, once the manufacturer defined the “production lot” the entire lot was either rejected or validated for release into commerce. *Id.* at 2-3, 2:59-3:3. Large “production lots” also complicated the ability for manufactures to determine the source of any contamination. *Id.* at 3:17-33.

The inventor sought a testing procedure that allowed manufacturers to efficiently pinpoint contamination while mitigating the increased cost of additional sampling and testing by enabling products to be released to consumers that otherwise would not have. *Id.* at 3:34-40.

The Patented process begins by collecting and combining the required number of samples to create a composite lot sample. *Id.* at 5:50-56 (defining “compositing”); *see also id.* at 12, 1:25-40. The composite lot sample is then enriched “under conditions suitable to allow levels of a target agent/organism that is present to reach

detectible levels and become uniform or substantially uniform throughout.” *Id.* at 6:7-16.

Realizing that “enrichment obviates the prior art problem of having microbial contaminants that are not uniformly present throughout the product sample,” (meaning regulations would permit further testing), the patented method uses an “inventive modular (e.g., wet modular) compositing method” that allowed multiple lots to be release into commerce using a single test (e.g., using an immunoassay), and allowed validation and release of lots that otherwise would have been rejected. *Id.* at 7:45-56; *see also id.* 7:1-10.

The specification emphasizes the value of the invention through industry examples. *Id.* at 11:5-14:67. For instance, Example I applied the patented method to beef trim testing for *E. coli*. *Id.* at 11:5-12:20. Under the prior art, one “production unit” comprised 10,000 lbs of beef trimmings, from which a composite sample was created, enriched, and tested, resulting in the entire 10,000 lbs being released into commerce or rejected. *Id.* Conversely, under the patented method, five independent composite samples were created (each from 2,000 lbs of beef trim), and enriched. *Id.* Portions of the five enriched samples were then ***combined*** and tested. *Id.* If the test was negative, all 10,000 lbs of beef trim were released into commerce. *Id.* However, if the results were positive, the five corresponding enriched composite samples were tested individually and any that tested negative resulted in 2,000 lbs

of beef trim being “validated and releasable into the chain of commerce” that otherwise would have been rejected. *Id.* at 11:31-44. In this example, using 64,004 assays,¹ the patented method cleared 1,928,000 lbs of beef trim (representing approximately \$2.5 million) for release into commerce that otherwise would have been rejected. *Id.* at 11:5-12:20. Conversely, 314,595 assays² would have been required to achieve the same result under the prior art. *See e.g., id.* at 7:45-59.

B. Prosecution, Reexamination, and Previous District Court Proceedings

On August 8, 2005, Patent Owner filed the first (in a series) of four U.S. Patent Applications. Ex. 1001 at 1, Ex. 1002 at 1, Ex. 1003 at 1, Ex. 1009 at 2. These four applications resulted in the ’584, the ’233, ’143, and ’771 Patents, respectively.

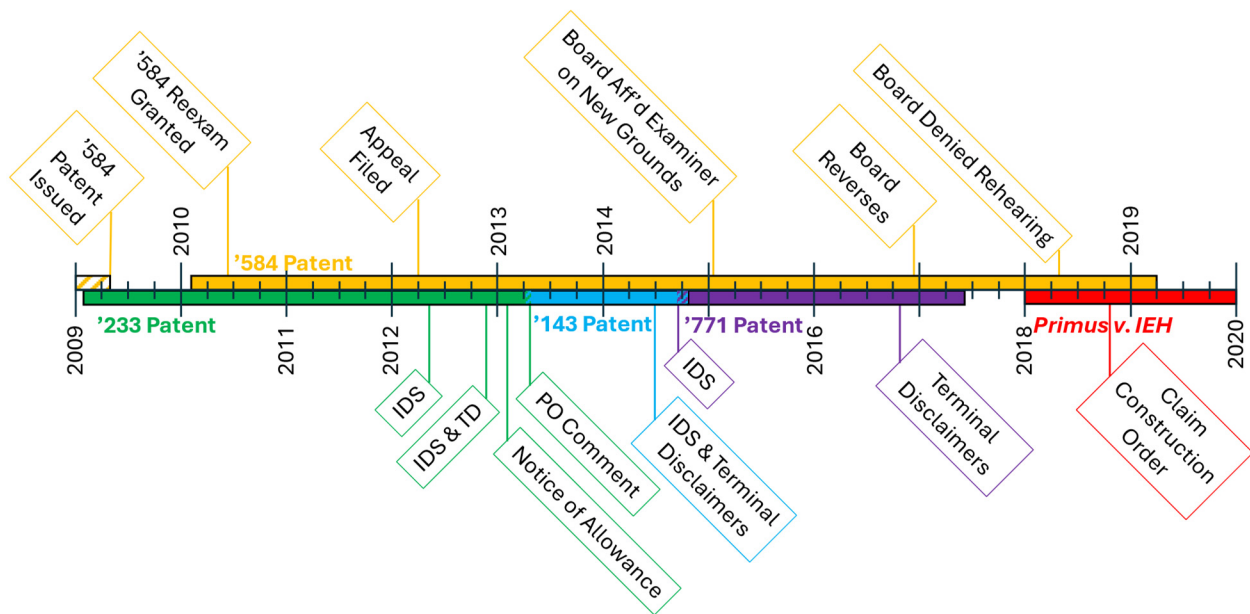
Shortly after the Patent Office issued the ’584 Patent, bioMérieux Inc. filed an *inter partes* reexamination application against the ’584 Patent. The ’584 *inter partes* reexamination lasted nine years and was pending during the prosecution of the ’233,

¹ Example I performed an assay on all 62,919 Modular Wet Composite Samples (“MWCS”), and then tested 1,085 individual enriched composite samples (corresponding to the 217 MWCS testing positive), resulting in 64,004 assays.

² Each MCWS in Example I represented five combos. Therefore, 314,595 assays would be required to assay the 62,919 MCWS.

'143, and '771 Patents and a related District Court case. *See Primus Grp., Inc. v. Inst. for Env'tl Health, Inc.*, No. 3:18-cv-00005-WHO (N.D. Cal. filed Jan. 2, 2018) (the "Primus Litigation").

The following timeline illustrates the overlapping activities related to the '584 Patent and its family. Yellow indicates the '584 Patent, green the '233 Patent, blue the '143 Patent, purple the '771 Patent, and red the Primus Litigation.

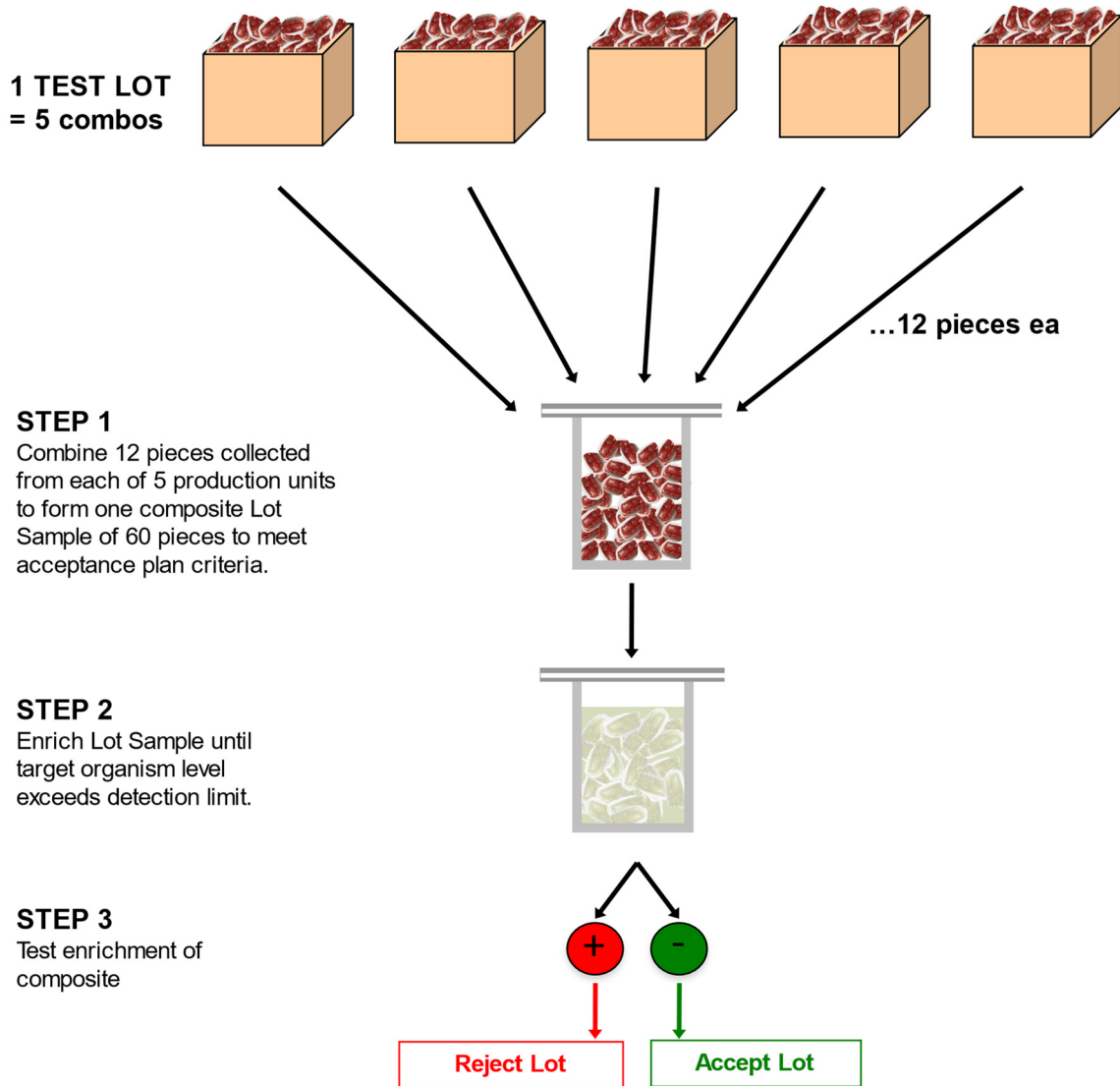


1. Original Prosecution of the '584 Patent

The '584 Patent issued on May 19, 2009, from an application (No. 11/199,871) (the "'584 Patent Application") filed on August 8, 2005. Ex. 1001 at 1. Patent Owner submitted, and the Examiner considered, *Price* and *Silliker*. Ex. 1006 at 278-79, 305-06.

In an interview with the Examiner, Patent Owner presented two figures (recreated below) summarizing the industry art and the invention, leading the Examiner to propose non-substantive revisions clarifying the requirement of multiple levels of combining *separate* objects. Ex. 1006 at 320 (Examiner's interview summary noting the "inventive step" over the prior art), 327 (Examiner's proposed amendment adding "separate" thirteen times to one claim).

PRESENT INDUSTRY ART



CURRENT INVENTION

1 TEST LOT = 1 combo

5 Lots tested simultaneously
(invention has no limit, # of
lots = 1 to ∞).

STEP 1

Collect 60 portions from each
Lot to form individual composite
Lot Samples and meet
acceptance sampling plan
criteria.

STEP 2

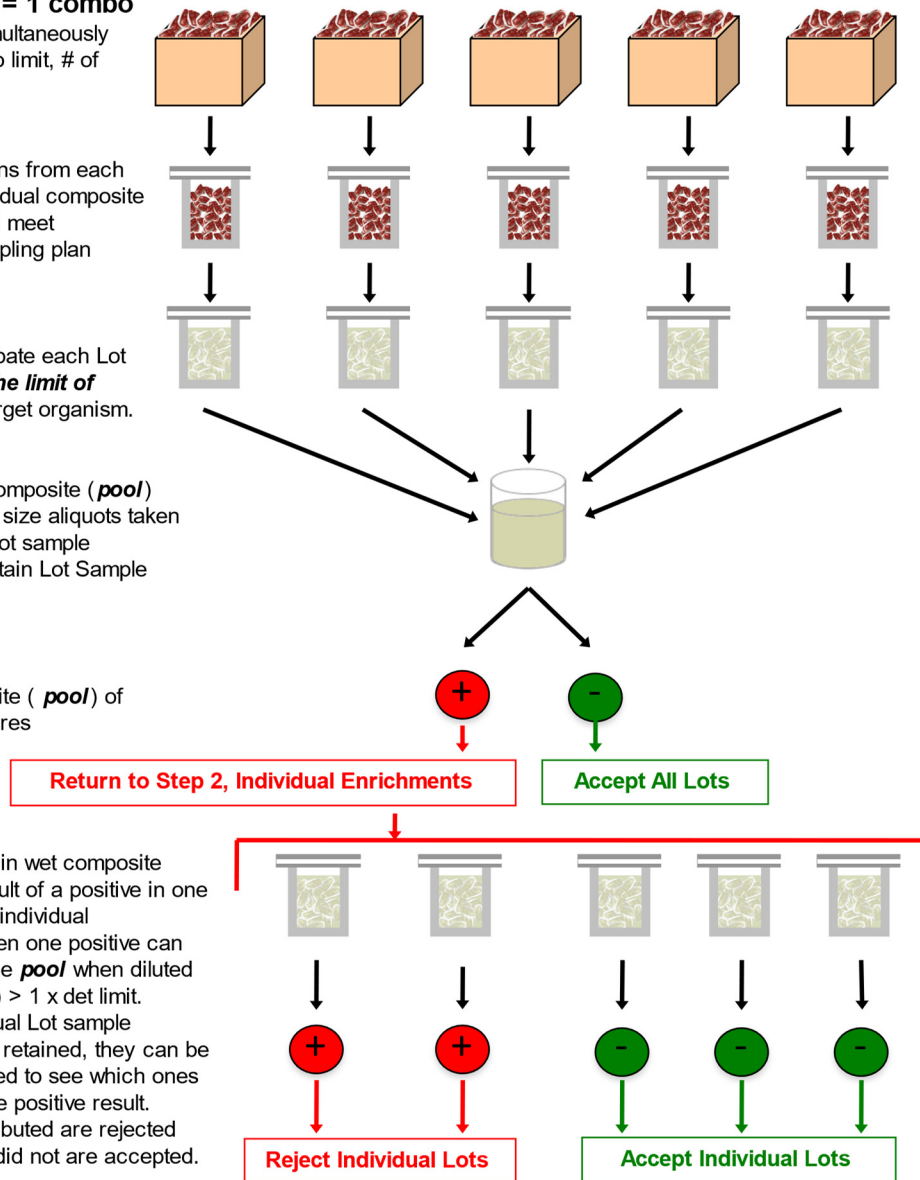
Enrich and incubate each Lot
Sample to $N \times$ the **limit of
detection** for target organism.

STEP 3

Prepare a wet composite (**pool**)
from $N - 1$ equal size aliquots taken
from individual Lot sample
enrichments. Retain Lot Sample
enrichments.

STEP 4

Test wet composite (**pool**) of
enrichment cultures



Ex. 1006 at 322-23 (recreated in color).

After incorporating the Examiner's proposed, clarifying amendments, the Examiner issued a notice of allowance. Ex. 1006 at 335-36 (amendments), 354 (notice of allowance).

2. Further Prosecution of the '584 Patent via *Inter Partes* Reexamination

On April 5, 2010, bioMérieux Inc. effectively filed³ an *inter partes* reexamination application (No. 95/001,294 or “reexamination”) against the '584 Patent. Ex. 1007 at 1, 146. Using fourteen references, including *Price*, *Silliker*, and an ICMSF publication,⁴ the Petition alleged 80 Substantial New Questions of Patentability (“SNQ”) against all claims of the '584 Patent. Ex. 1007 at 150-58. The Board granted the reexamination, determining that all fourteen references raised

³ An incomplete application was filed on January 13, 2010, and the deficiencies were rectified on April 5, 2010.

⁴ Ex. 1007 at 151 ¶ 9 (citing “ICMSF, *Indicator microorganisms*, pp. 1-11; *Important considerations for the analyst*, pp. 91-102; *Preparation and dilution of the food homogenate*, pp. 107-111; *Enumeration of mesophilic aerobes: the agar plate methods*, pp. 113-123; *Coliform bacteria*, pp. 125-139; *Enterobacteriaceae*, pp. 141-143; *The enterococci*, pp. 144-147; *Hemolytic streptococci*, pp. 149-155; *The enumeration of yeasts and molds*, pp. 157-159; and *Salmonellae*, pp. 160-172, in *Microorganisms in Foods, Their Significance and Methods of Enumeration*, Second Edition, University of Toronto Press (1978)”) (“ICMSF-1”).

SNQ. Ex. 1007 at 148-75. The first non-final action regrouped the Petitioner's SNQ into twenty-six grounds but adopted only fifteen (summarized below).

References	Claims	Ex. 1007 at
Jarvis/FSIS Midura	1-4, 8, 10, 11, 13, 17-19, 22, 24, 26, 27, 31 and 32	185-89
Price/FSIS Midura	1-4, 6-18, 20, 22, 24-26, and 31	189-92
Jarvis	1 and 17	192-95
Price/Andrews Midura	1 and 17	196-98
Price/Silliker Midura	1 and 17	198-201
Price/Gabis Midura	1 and 17	201-03
Jarvis, BAM	1 and 17	204-06
Price/BAM, Davies	1 and 17	206-09
Jarvis/FSIS, Midura, Entis	5, 6, 23, 29, and 30	212-14
Price/FSIS, Midura, Entis	5, 6, 23, 29, and 30	214-16
Javis/FSIS, Midura, Cousin	21	219-20
Price/FSIS, Midura, Cousin	21	221-22
Jarvis/FSIS, Midura, Price	23	222-23
Price/FSIS, Midura, Gabis	24, 28, 32, and 33	223-25

References	Claims	Ex. 1007 at
FSIS, Midura, Andrews	28	225-26

Ex. 1007 at 185-227.

In response, Patent Owner added clarifying language to the independent claims. Ex. 1007 at 233-37 (claim amendments), 251 (“Applicant, to further emphasize this distinction (which is already implicit in the claims), has nonetheless amended ... claims 1 and 17”). Patent Owner also submitted four Exhibits in support of its arguments. Ex. 1007 at 296-99. The first two were the same figures (reproduced above) shown to the Examiner during prosecution (summarizing the industry art and current invention). Ex. 1007 at 296-97.⁵ The second two exhibits (reproduced below) used similar figures to summarize *Price* and *Silliker*. Ex. 1007 at 298-99.

⁵ The second exhibit differed from the figure shown during prosecution by adding “inter-lot” to steps 3-5.

Figure 3. CITED PRIOR ART (Price et al, 1972)

**MULTIPLE SAMPLES
from one lot (e.g.,
three bins)**

STEP 1

Take individual portions (N=1)
from each Sample.

STEP 2

Pre-enrich each portion (N=1) to
revive target organism, but to
levels ***below the limit of
detection.***

STEP 3

Prepare a pool (N up to 10 as practical limit)
by placing
equal size aliquots taken from the individual portion
pre-enrichments into a single culture vessel along with
addition of enrichment broth.

STEP 4

Incubation of the pooled pre-enrichment culture of
STEP 3 to increase (enrich) levels of target
organism to above the limit of detection.

STEP 5

Test secondary enrichment. A positive signal in the
pool is the result of a positive in one or more
original individual pre-enrichments.

Return to Step 2, Individual Portion Pre-Enrichments

Return to Step 2...

STEP 6

Select pre-enrichments associated with
positive result.

STEP 7

*Since the organism levels in the pre -
enrichments are below the limit of
detection, they must again undergo
secondary enrichment with its
associated time delay and cost .*

STEP 8

Test new secondary enrichments to verify
testing results, but negative still not
validated.

Reject Individual Samples

Verifies negative, but yet
does not validate for
acceptance

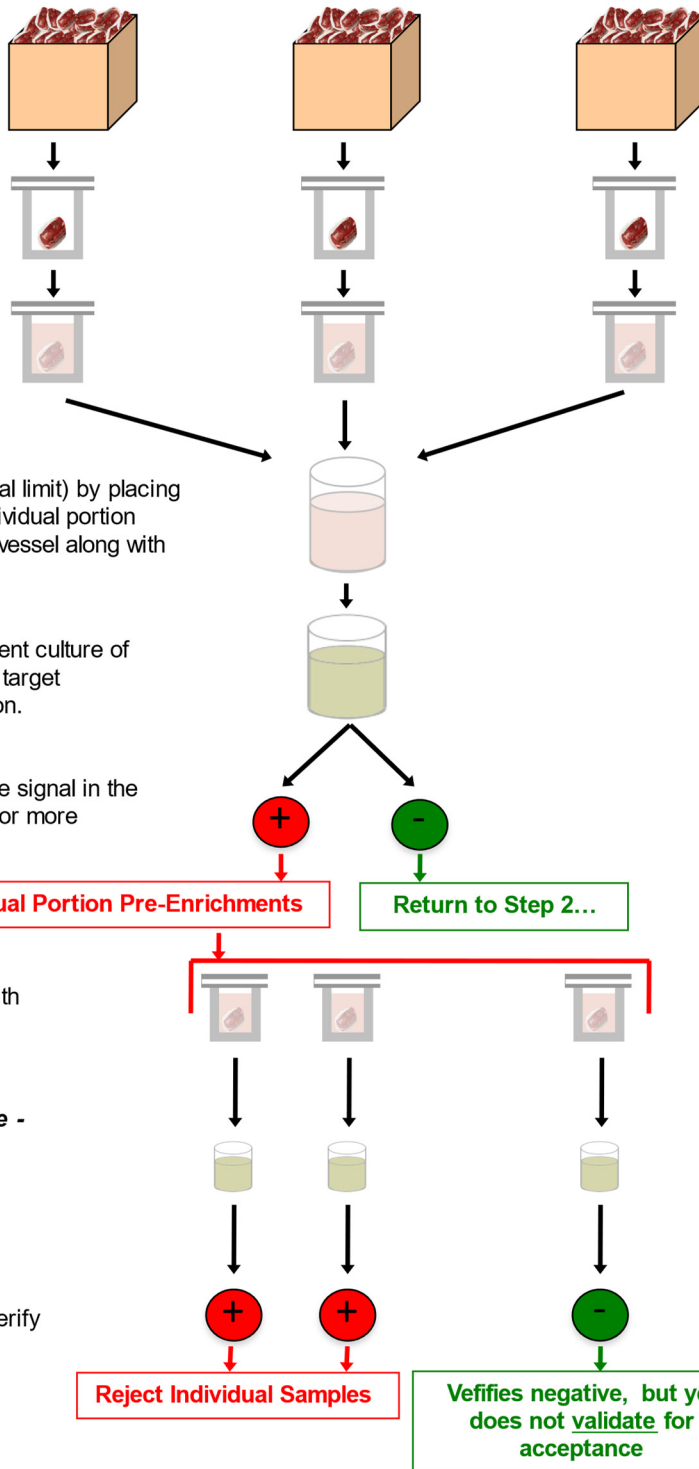
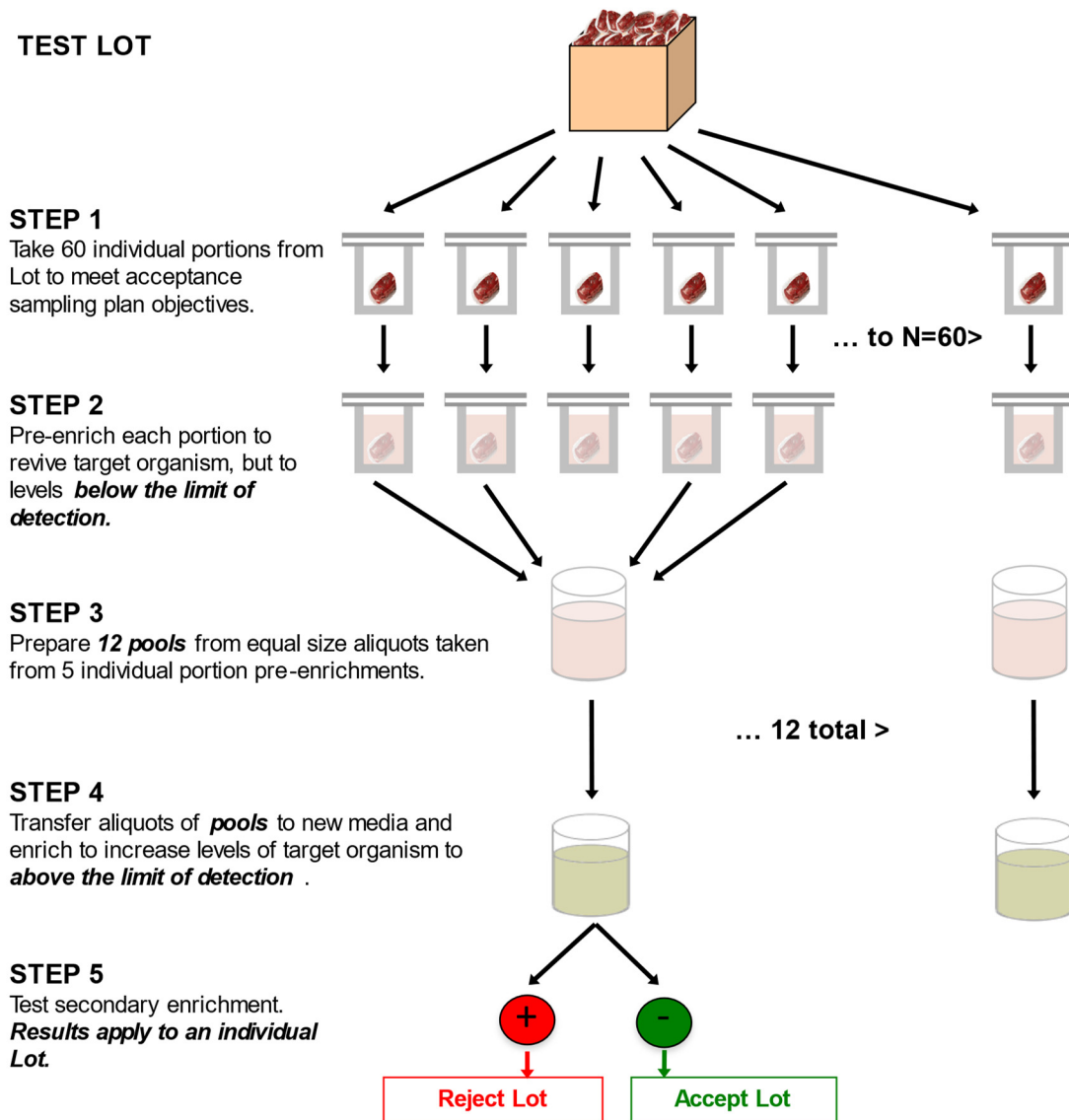


Figure 4. CITED PRIOR ART (Silliker et al, 1972)



Ex. 1007 at 298-99 (recreated in color). Finally, Patent Owner also submitted two declarations in support. Ex. 1007, at 300-04 (Dr. Samadpour); 310-14 (Dr. Koohmaraie).

The Examiner issued an Action Closing Prosecution on July 26, 2010, rejecting all claims. Ex. 1007 at 410. Examiner rejected most of Patent Owner's arguments as "arguing features which are not part of the claims." *See e.g., id.* at 421. The Examiner did withdraw one rejection based on Patent Owner's arguments concerning the distinction between enrichment and pre-enrichment. *Id.* at 425.

Although Patent Owner disagreed with the Examiner's characterization of its arguments, Patent Owner proposed further clarifying amendments to address the Examiner's concerns. *Id.* at 478-84 (amended claims), 487 ("Patentee further contends that the present claim amendments ... were necessitated based on what Patentee respectfully contends is continued misunderstanding of Patentee's invention by the Examiner."). Patent Owner also submitted four declarations in support of its arguments. *Id.* at 485-87. Because the Examiner agreed that the amendments "merely clarify and do not significantly change the scope of the claims" the Examiner entered the amendments but maintained all rejections and issued a right of appeal notice. *Id.* at 865-67.

3. Appeal of the '584 Patent *Inter Partes* Reexamination

Patent Owner filed an appeal, including (again) the two figures summarizing the industry art and current invention. *Id.* at 939, 993-94. The Board held that, contrary to the Examiner's findings, the independent claims required enrichment and not merely "pre-enrichment," which only resuscitates the target organism for

subsequent ... enrichment.” *Id.* at 1565-69. The Board nonetheless affirmed the Examiner, but did so on four new grounds (summarized below) noting that “no portion of the decision [was] final.” *Id.* at 1585-86. The Board also condensed its analysis by noting *Jarvis* and *Price* contained similar teachings. *Id.* at 1562-63.

Ground No.	References	Claims
1	Jarvis/Price FSIS Midura	1-4, 6-20, 22, 24-27, 31, and 32
2	Jarvis/Price FSIS Midura Entis	5, 6, 23, 29, and 30
3	Jarvis/Price FSIS Midura Cousin	21
4	Jarvis/Price FSIS Midura Gabis	24, 28, 32, and 33

Pursuant to (then operative) 37 C.F.R. § 41.77(b)(1), Patent Owner filed a request to reopen prosecution of the reexamination. Ex. 1007 at 1635. On remand to the Examiner, Patent Owner amended the claims again to clarify the claimed lots were “operationally-linked”; and limited them to beef, meat and/or poultry “for procedural expediency and to facilitate prosecution of the present matter.” *Id.* at 1656, 1637-42. The Examiner maintained the Board’s new grounds for rejection. But when the decision returned to the Board, “[u]pon reconsideration of the totality

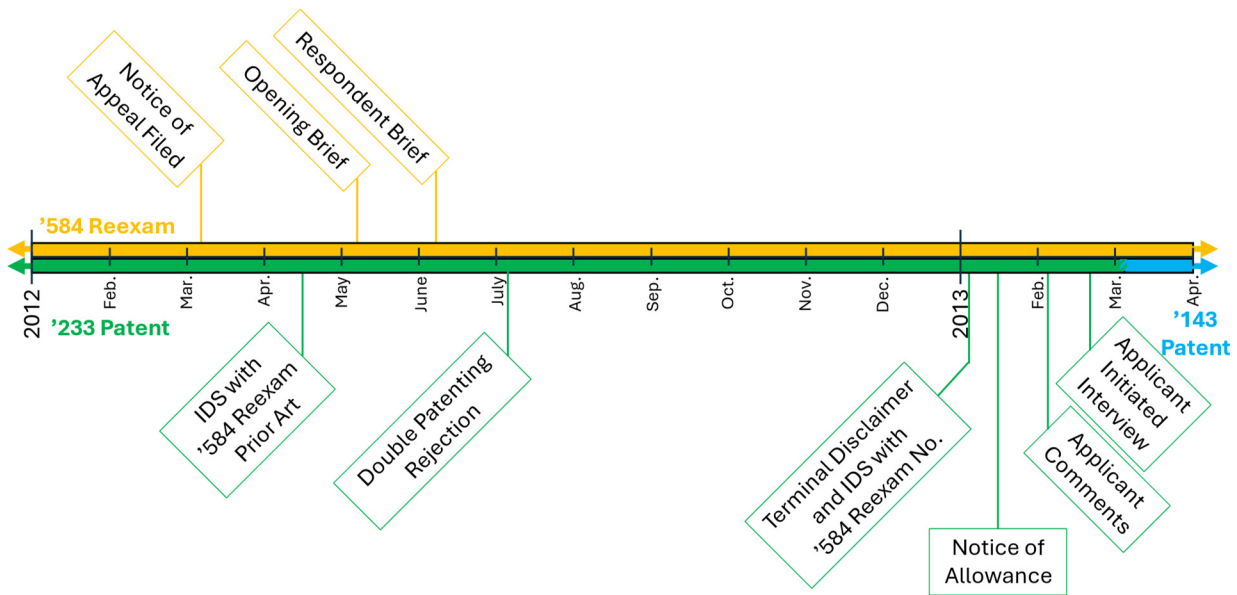
of the evidence, including the evidence of obviousness based on the cited prior art rejections, [the Board] **reverse[d]** all the rejections.” *Id.* at 1778-79. BioMérieux requested a rehearing of this decision. *Id.* at 1791.

The Board denied the request for rehearing, explaining that it had “overlooked” information in its initial decision that “contained the information [the Board] had believed to be deficient in the record.” *Id.* at 1857. The information that had been overlooked were the same two figures shown to the Examiner during the original prosecution of the ’584 patent and to the Examiner and Board in the reexamination. *Id.* at 1857.

4. Prosecution of the ’233 Patent⁶

U.S. Patent No. 8,389,233 (“the ’233 Patent”) issued on March 5, 2013, from a continuing application (No. 12/360,796) (the “’233 Patent Application”) filed on January 27, 2009. The below timeline shows important milestones in both the ’233 Patent’s prosecution and the concurrent reexamination.

⁶ Although the ’233 Patent is not challenged, its prosecution history provides helpful context for the rest of the patent family.



As the timeline above shows, Patent Owner submitted, and the Examiner considered,⁷ all prior art at issue in the reexamination before the first substantive response was issued. Ex. 1009 at 113-15, 142 (IDS filed Apr. 16, 2012), 100-02 (Examiner considered on June 15, 2012), 89-94 (first rejection issued on July 5, 2012). Despite the prior art, the Examiner only rejected the claims under the judicially created doctrine of obviousness-type double patenting based on the '584

⁷ The examiner was unable to initially consider seven references due to incomplete citations. Ex. 1009 at 100-02. However, Patent Owner submitted a supplemental IDS with complete citations (*id.* at 80-86), which the examiner considered. *Id.* at 1009 at 55-56.

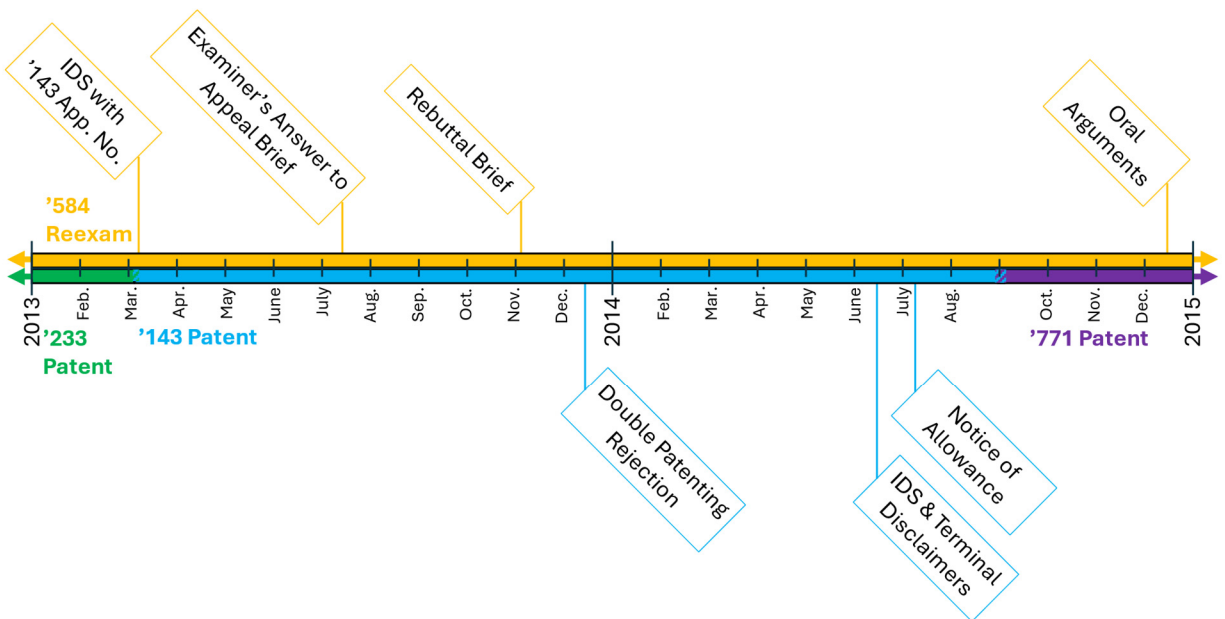
Patent. *Id.* at 90-94. Patent Owner filed a terminal disclaimer against the '584 patent (*id.* at 74-76, 64) and an IDS identifying the reexamination by its Application No. *Id.* at 59, 64 In the '233 Patent's notice of allowance that followed, the Examiner included extensive comments concerning the prior art of the reexamination, including citation to exhibits of record in the reexamination. *Id.* at 20-26.

Patent Owner then submitted its own comments on the Examiner's statements of reason for allowance (*id.* at 11-13) and initiated an interview with the Examiner (*id.* at 4) to (1) more "clearly understand the reasons of allowance" (*id.* at 4), (2) ensure Patent Owner's "arguments of record for patentability in both the underlying parent application ... and in the reexamination proceeding ... are [incorporated as] reasons for allowance" (*id.* at 11-13), and (3) inform the Examiner of Patent Owner's intent to file another continuation application (*id.* at 4). Only then did the Patent Owner pay the issue fee for the '233 patent application. *Id.* at 6-10.

5. Prosecution of the '143 Patent

The '143 Patent issued on September 2, 2014, from a continuing application (No. 13/784,606) (the "'143 Patent Application") filed on March 3, 2013, assigned to the same Examiner as the '233 Patent Application. Ex. 1002 at 1. The Examiner only rejected the claims on obviousness-type double patenting based on the '584 and '233 Patents. Ex. 1010 at 54-55. Patent Owner filed terminal disclaimers against the '584 and '233 Patents (*id.* at 150-52, 157-58) and an IDS identifying the

reexamination by its Application Number and all prior art considered therein. *Id.* at 106-08. The Examiner responded with a notice of allowance. *Id.* at 169. The below timeline overlays these milestones in the '143 patent prosecution alongside the reexamination.



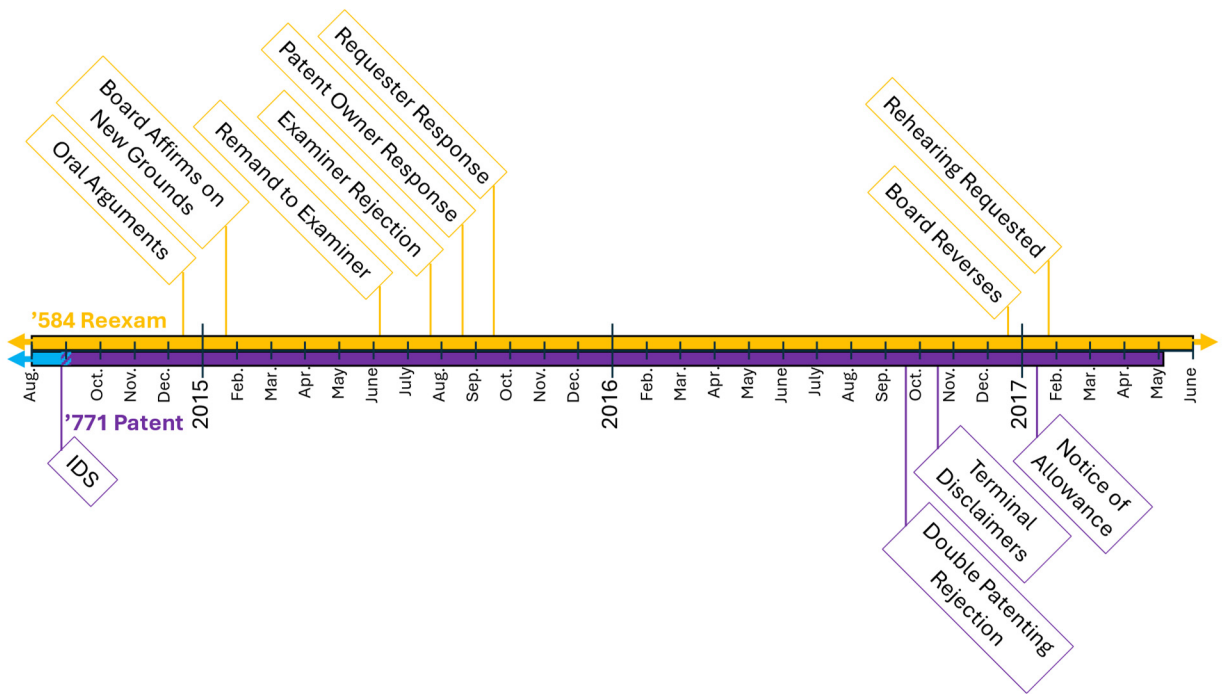
6. Prosecution of the '771 Patent

The '771 Patent issued on May 2, 2017, from a continuing application (No. 14/472,144) (the "'771 Patent Application"), assigned to the same Examiner as the '143 and '233 Patents' Applications. Ex. 1003 at 1. Patent Owner again included an IDS identifying the '584 *inter partes* reexamination by application number and all prior art considered therein. Ex. 1011 at 14-16, 164-66. The Examiner issued an obviousness-type double patenting rejection based on the '584, '233, and '143

Patents (*id.* at 134-40), which Patent Owner overcame by filing terminal disclaimers. *Id.* at 169-79 The Examiner issued a notice of allowance that included a detailed discussion of FSIS and *Skov*⁸ (which were at issue in the reexamination). *Id.* at 203-09. As the timeline below shows, when the notice of allowance for the '771 Patent Application issued, the Board had issued its final decision in the reexamination ***affirming*** patentability of the amended claims.⁹ *Compare* Ex. 1007 at 1774-89 (Board affirmed patentability on Dec. 23, 2016) *with* Ex. 1011 at 199 (Notice of Allowance issued on Jan. 13, 2017).

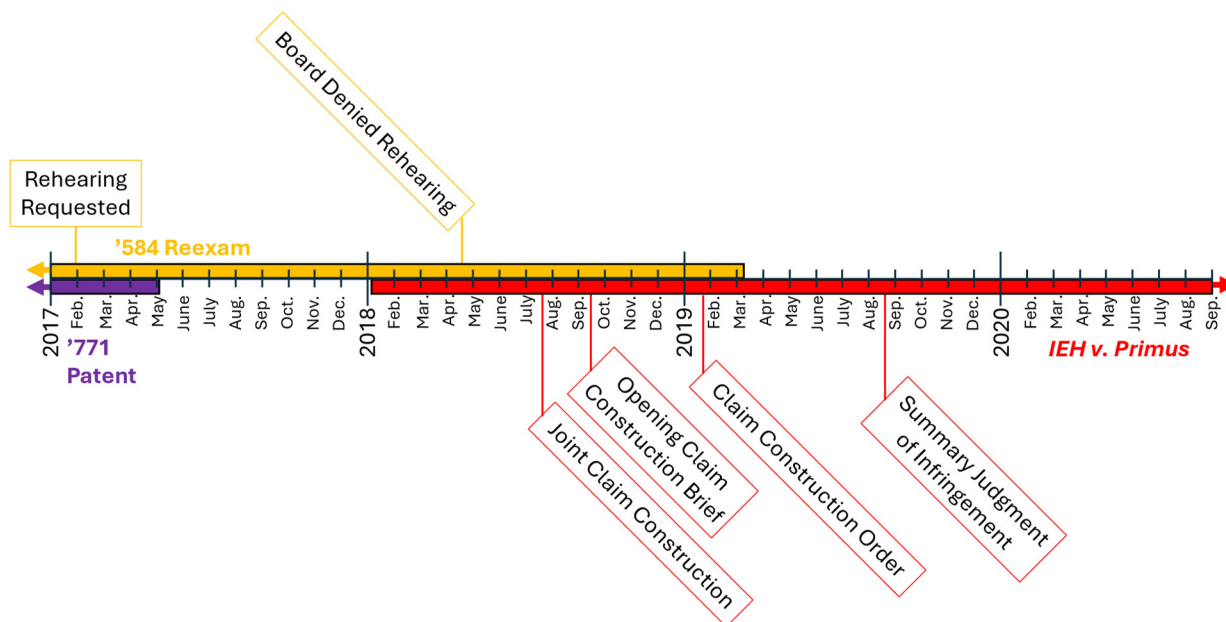
⁸ Ex. 1011 at 206-09 (citing Skov, *et al.*, *Evaluation of Sampling Methods for the detection of Salmonella in broiler flocks*, J. of Applied Microbiology, Vol. 86, at 695-700 (1999)).

⁹ Although irrelevant to the Board's analysis, Patent Owner disputes petitioner's inference that "when the ['771] issue fee was paid" the operative decision found the '584 Patent claims unpatentable. Pet. at 23; *see also* Ex. 1011 at 297 ('771 issue fee paid on Mar. 23, 2017).



7. *IEH v. Primus* District Court Litigation

On January 2, 2018, Primus Group Inc. (“Primus”) filed a declaratory judgement action in the U.S. District Court for the Northern District of California seeking a declaration of non-infringement and/or invalidity of the ’143 and ’771 Patents. Ex. 1035. As the timeline below shows, this was after the Board had affirmed the patentability of all amended claims of the ’584, but before the ’584 reexamination certificate had issued.



During this lawsuit, the court issued a claim construction order and a summary judgment order addressing infringement and validity. The District Court’s January 22, 2019, claim construction order adopted the following three jointly proposed constructions (Ex. 1038 at 4):

Claim Term	Court’s Construction
“validate”	“determine that a particular sample tests negative using the detection assay”
“Enriching”	“incubating a sample under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform”
“selective agent”	“agent that inhibits competing non-target microbe(s)”

Although the court adopted the parties’ proposed construction of “validate,” it did not expressly address whether that term was limiting.

The court also resolved a dispute regarding the phrase “separately collecting multiple independent samples from each of the multiple separate lots.” *Id.* at 6. The dispute focused on whether this limitation required collecting representative samples, and if so, whether representativeness required collection from non-contiguous locations. The court found that “[i]n the context of the asserted patents, ... [t]he use of unrepresentative samples would be commercially useless because results based on unrepresentative samples have little predictive power to identify the presence of microorganism contaminants.” Ex. 1038 at 5. And, “[i]n order to have a representative sample of a given test lot, the portions of the product that constitute the sample *must be taken from non-contiguous locations* to be effective.” *Id.* (emphasis added). The court therefore found that the claims required collecting from “different, non-contiguous locations.” *Id.* at 6 (“I construe the claim term as ‘Collecting multiple samples from different, non-contiguous locations from each of multiple separate lots.’”).

The court later denied Defendant’s motion for summary judgment of invalidity and granted IEH’s motion for partial summary judgement of infringement. Ex. 2002 at 18, 24. In its motion for summary judgment on invalidity, Primus argued “that [the ’584 Patent] only survived re-examination by the USPTO by a thin distinction between the method claimed and prior art[, which] is filled by [Gombas].” *Id.* at 5. In denying Primus’s motion, the District Court found “two

persuasive arguments ... show[ed] that the undisputed evidence does not support this factual contention.” *Id.* at 15. Specifically, the court found that combining *Gombas* with other references was not obvious due to the uncertain nature of pathogen testing and because of industry concerns about the accuracy of pooling post-enrichment samples. *Id.* at 15-18.

C. Current District Court Litigation Paralleling Current Petition

On August 1, 2023, Patent Owner filed a complaint in the U.S. District Court for the District of Delaware accusing Petitioner of infringing four patents: the ’584, ’143, and ’771 Patents and U.S. Patent No. 9,845,486. Ex. 1004. Petitioner filed an opposed motion to dismiss for improper venue or transfer to the U.S. District Court for the District of Kansas. Ex. 2004 at 6. On January 11, 2024, the case was assigned to Judge Slomsky of the U.S. District Court for the Eastern District of Pennsylvania, sitting by designation in the District of Delaware. *Id.* at 7. The parties had a scheduling conference on April 26, 2024, and entered a joint proposed Scheduling Order on May 16, 2024. Ex. 1062. Judge Slomsky denied Petitioners motion to dismiss or transfer the same day the parties filed their proposed scheduling order. *Id.*

Petitioner thereafter filed an answer, including counterclaims against Patent Owner. Ex. 2004 at 8. Patent Owner filed a partial motion to dismiss Petitioner’s counterclaims and strike affirmative defenses, which Petitioner responded to by amending its counterclaims. *Id.* Patent Owner again filed a partial motion to dismiss

Petitioner's amended counterclaims and affirmative defenses. *Id.* Briefing for the Patent Owner's second motion to dismiss concluded on August 14, 2024, and the District Court has scheduling a hearing on that motion for November 20, 2024. *Id.* at 9-10.

Pursuant to the parties' proposed scheduling order (Ex. 1062), Petitioner has produced core technical documents and the parties have exchanged infringement and invalidity contentions. Ex. 1064. The parties have also been diligently exchanging discovery. Ex. 2004 at 7-10.

III. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") at the time of the invention would have either (i) an associate's degree and at least one year of experience in the field, or (ii) a bachelor's degree in biology, microbiology, or food science (or other closely related subject) and some experience in the field. Petitioner attempts to inflate the level of skill to one that would "most likely have an advanced degree in microbiology, food science, or animal science and at least two years of work experience but may alternatively have a bachelor's degree in those area and at least four years of experience with validation methodologies." Pet. at 11. Nonetheless, because Patent Owner believes institution should be denied even under Petitioner's

proposed extraordinary level skill in the art,¹⁰ for the purposes of this preliminary response, Patent Owner does not separately argue the issue but reserves the right to do so in either the co-pending District Court litigation or in the event the Board institutes the present petition. *See Innovention Toys, LLC v. MGA Ent., Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) (finding no reversible error where “a determination of *non* obviousness [is] based on a finding of the highest possible level of skill in the relevant art”).

IV. THE PETITION FAILS TO SET FORTH THE ASSERTED GROUNDS WITH PARTICULARITY

A. Petition Fails to Delineate Grounds as Argued

Petitioner purports to advance ten specific grounds of invalidity (Pet. at 7), but each ground requires the Board to select which reference to rely on for each

¹⁰ Patent Owner also disputed the level of ordinary skill proposed by the applicant in the '584 *inter partes* reexamination, the Board affirmed patentability without addressing the issue.. Ex. 1007 at 26-27 (a POSITA would have “an advanced scientific degree in microbiology, environmental health and safety, or food science or a Bachelor’s degree and ... several years of experience in developing methodology for the sampling and analysis of food products”); Ex. 1007 at 618 (“Patentee contends ... that the level of skill attributed by the Examiner to a ‘person of ordinary skill in the art’ is too high.”).

limitation. A straightforward analysis of the three independent grounds (grounds 1-3) highlights Petitioner’s failure to provide the required clarity. Each of these grounds divides the independent claims into seven elements labeled (a) through (e)(3). Each ground asserts an obviousness theory based on a combination references connected by “and/or” for each of the elements. The following table summarizes those three grounds.

Limitation	Ground 1 (Pet. at 38-53)	Ground 2 (Pet. at 53-58)	Ground 3 (Pet. at 58-65)
Step (a):	ICMSF-7	ICMSF-7	<i>Price and/or ICMSF</i>
Step (b)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7	<i>Price and/or ICMSF</i>
Step (c)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7 and/or <i>Hughes</i>	<i>Price and/or ICMSF and/or Hughes</i>
Step (d)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7 and/or <i>Hughes</i>	<i>Price and/or ICMSF and/or Hughes</i>
Step (e)(1)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7 and/or <i>Hughes</i>	<i>Price and/or ICMSF and/or Hughes</i>
Step (e)(2)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7 and/or <i>Hughes</i>	<i>Price and/or ICMSF and/or Hughes</i>
Step (e)(3)	ICMSF-7 and/or <i>Gombas</i>	ICMSF-7 and/or <i>Hughes</i>	<i>ICMSF and/or Hughes</i>
Possible Combinations:	729	243	64,827

Each ground's use of "and/or" multiplies the ground into hundreds of possible combinations. For example, ground 1 relies on ICMSF-7 for step (a) and one of three combinations for step (b): (1) ICMSF-7, (2) Gombas, or (3) ICMSF-7 and Gombas. *Id.* at 39-44. Ground 1 further argues that each subsequent limitation is satisfied by ICMSF-7, Gombas, or a combination of both references, thus increasing the possible combination by a factor of three at each step. Ground 1 therefore presents the Board with 729 possible combinations. Similarly, ground 2 presents 243 possible combinations. Ground 3 exacerbates the problem by relying on *Price* "and/or" ICMSF-7 "and/or" *Hughes* for four of the limitations, multiplying the possible combinations by seven at each step; i.e., (1) *Price*; (2) ICMSF-7; (3) *Hughes*; (4) *Price* and ICMSF-7; (5) *Price* and *Hughes*; (6) ICMSF-7 and *Hughes*; or (7) *Price*, ICMSF-7, and *Hughes*. *Id.* at 61-63. Ground 3 therefore includes 64,827 possible combinations. Neither the Board nor patentee have any meaningful opportunity to address even the simplest ground (ground 2) containing over 200 potential combinations, let alone the more than 65,000 potential combinations under all grounds.

Petitioners are expressly forbidden from using a petition as "a repository of all the information that a judge could possibly consider." PTAB Consolidated Trial Practice Guide, 39 (Nov. 2019). The Board therefore routinely denies petitions that do so. For example, in IPR2018-00828, the Board denied institution, explaining that

“[b]ecause the [Petition] asserts that multiple claim elements are described in more than one of the references, there are 576 different ways to combine the prior art [and] it is not clear which particular theory or theories Petitioner actually is asserting.” *See Avant Tech., Inc. v. Anza Tech., Inc.*, IPR2018-00828, Paper 7 at 13-14 (PTAB Oct. 16, 2018). Similarly, in *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019), the Board explained that

Petitioner’s “catch-all” ground attempts to require Patent Owner to address whether each and every claim limitation is taught not only by each of [two references], but by each of these references in combination with one or more of the other references asserted in the proceeding. In this way, Petitioner’s “catch-all” ground is not reasonably bounded in scope and unduly burdensome for both Patent Owner and the Board to address.

Id. at 21-21 (informative). Moreover, the Board explained that even “a total of seventeen possible combinations yields an unduly burdensome number of combinations.” *Id.* at 18-19. Here, each of the Petition’s three grounds include far more combinations than 17 combinations.

Petitioner’s “catch-all” ground based on “the combination of [two references],’ ignore[s] [Petitioner’s] express framing of th[e] obviousness ground[s] and rel[ies] on the teachings of either reference alone, [which the Board] decline[s] to do.” *ADT LLC v. Vivint, Inc.*, IPR2022-00634, Paper 7 at 14 (PTAB Oct. 4,

2022).“Moreover, even if [the Board] were to overlook the above-noted deficiency in [Petitioner’s] mapping ... and institute an IPR proceeding, the lack of clarity in [Petitioner’s] asserted obviousness ground might enable [Petitioner] to deviate from the arguments initially presented in the Petition in a manner that may prejudice [the Patent Owner].” *Id.*; *see also Avant*, IPR2018-00828, Paper 7 at 13 (“[F]ailure to explain the proposed grounds of unpatentability with particularity is procedurally unfair to Patent Owner.”). The Board should therefore deny institution of Petitioner’s “catch-all” assertions of hundreds of combinations.

B. Petitioner Improperly Incorporates by Reference Dr. Dickson’s 317-Page Declaration

Petitioner further compounds its numericity issue through liberal and improper incorporation by reference. In particular, in lieu of substantive analysis, the petition cites to large swaths of Dr. Dickson’s 317-page expert declaration for support.

The Board’s rules state that “[a]rguments *must not be incorporated by reference* from one document into another document.” 37 C.F.R. § 42.6(a)(3). The Board consistently rejects petitions that violate this by relying on citations to an expert’s declaration in lieu of analysis in the petition. For example, in *Cisco*, the Board denied a petition that relied on a 250-page declaration from its expert. *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 10 (PTAB Aug. 29,

2014) (informative). The Board denied the petition because it attempted to “circumvent the page limits imposed on petitions for *inter partes* review” and for “imposing on [the Board’s] time by asking [it] to sift through over 250 pages of [an expert declaration] ... to locate the specific arguments corresponding to the numerous paragraphs cited to support Petitioner’s assertions.” *Id.*; *see also Avant*, IPR2018-00828, Paper 7 at 11-12 (denying institution where Petitioner relied on citations to an expert declaration for substantive analysis); *DirectTV, LLC v. Qurio Holdings, Inc.*, IPR2015-02007, Paper 6 at 14 (PTAB Apr. 4, 2016) (“The Petition’s practice of citing multiple pages of the Dr. Lavian Declaration to support conclusory statements and to expand its thin analysis violates our rules”); *Teoxane S.A. v. Allergan, PLC*, IPR2017-01906, Paper 15 at 25 (PTAB Mar. 9, 2018) (“We will not search the record (including [expert’s] declaration) to ascertain whether any evidence supports that bare argument. Petitioner should not expect the Board to search the record to piece together what may support a challenge.”) (citing *DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999)); *Hamilton Techs. v. Tehrani*, IPR2020-01199, Paper 17 at 5 (PTAB Mar. 5, 2021) (“We did not accept Patent Owner’s invitation to play archeologist with the record, and hunt for any other arguments that may have been contained in the claim charts appended to the Tehrani Declaration.”).

This petition repeatedly violates this rule. For example, in place of analyzing the state of the art, the petition simply states that “Professor Dickson summarizes developments leading to efficient and effective two-stage compositing for testing meat lots and current state of the art practices” and incorporates *sixty-eight* paragraphs of Dr. Dickson’s declaration (and three exhibits) by reference. Pet. at 8. Similarly, in place of analyzing the alleged applicant-admitted prior art, the petition relies solely on a citation that incorporates by reference *twelve* paragraphs of Dr. Dickson’s declaration. *Id.* at 9. In lieu of any analysis of the four secondary references relied on for the dependent claims, the petition incorporates *sixteen* paragraphs of Dr. Dickson’s declaration. *Id.* at 30. Indeed, the petition is replete with conclusory statements incorporating large swaths of Dr. Dickson’s declaration. *See, e.g., id.* at 5 (incorporating *sixty-five* and *twenty-one* paragraphs), 6 (incorporating *thirty-nine* paragraphs), 32 (incorporating *fifteen* paragraphs). Thus, much like the petition in *Cisco*, the petition here should be denied for attempting to subvert the statutory word count and violating the Board’s prohibition against incorporated by reference. 37 C.F.R. § 42.6(a)(3).

C. Petitioner’s Motivations to Combine Are Deficient

Another independent basis for denial is Petitioner’s failure to identify any motivation to combine the references. Each ground provides a single section that generally addresses all of the claims and all of the elements at once. Pet. at 52-53

(ground 1), 57-58 (ground 2), 63-65 (ground 3). In each case, Petitioner vaguely asserts that the two (or three) references “have interrelated teachings” because they allegedly teach certain claim elements. Pet. at 52, 57 (same), 63 (“Price, ICMSF, and Hughes overlap and respectively disclose most of steps (a)-(e), ICMSF teaches steps (a)-(d) and most of step (e), and Hughes teaches steps (c)-(e).”). In addition to being circular, this provides no rationale for why or how a POSITA would modify any reference. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be ***some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness.”) (emphasis added).

Petitioner’s arguments concerning a reasonable expectation of success are just as conclusory. Pet. at 53, 57, 64-65. Every ground summarily concludes the nebulous combination would result in a “reasonable expectation of success for efficient validation.” Pet. at 53, 57(same), 65 (“efficient validation, which is a predictable result”). This does not address the combination of any specific teachings in the prior art, let alone explain why a POSITA would have reasonably expected success from a specific combination. *See, e.g., KSR*, 550 U.S. at 418. “To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The Petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*,

829 F.3d 1364, 1380 (Fed. Cir. 2016). Because “Petitioner’s showing as to motivation to combine is conclusory and inadequate and a reasonable expectation of success in combining the teachings in the prior art [is] not shown,” the petition fails. *Samsung Elecs. Co. v. LED Wafer Sols., LLC*, IPR2021-01491, Paper 11 at 15 (PTAB Oct. 26, 2022).

V. CLAIM CONSTRUCTION

Petitioner purports to identify five claim terms for construction: (1) “lots”; (2) “separately sampled”; (3) “combining”/“compositing”; (4) “enrichment”/“enriching”; and (5) “validated”; but has not identified why construction is necessary, which claims it contends the constructions apply to, and (in some instances) even what it proposes as a construction. Pet. at 33-38. The Board “need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Terms that are immaterial to the obviousness dispute therefore do not require construction. *Id.* Here, just one limitation is material to Petitioner’s obviousness grounds and requires construction: the validation step (i.e., step (e) of all challenged independent claims).

A. The Board Should Not Construe “Lots”

Petitioner proposes a definition for the term “lots” but fails to identify any issues that depend on how that term is defined. Pet. at 33-34. Terms that are immaterial to obviousness do not require construction. *Nidec*, 868 F.3d at 1017. Thus, Petitioner’s failure to annunciate a need for construction should end the analysis. *Id.*

Nonetheless, should the Board decide construction is necessary, it should not use Petitioner’s proposed definition because it contradicts the specification and introduces unnecessary ambiguity. Petitioner acknowledges that the specification includes separate definitions for “test lots” and “single-unit production lots.” Pet. at 33-34. Specifically, the specification first defines “test lot.” Ex. 1001 at 5:21-32. It then states that a “‘single-unit production lot’ as used herein *is a form of test lot.*” Ex. 1002 at 5:20-49. Meaning, a “single-unit production lot” is a species of “test lot.” Petitioner proposes that the Board steamroll the patent’s express definitions and the distinctions drawn by them by construing the term “lots” using the patents’ definition for “test lots.” *Compare* Ex. 1001 at 5:21-31 (definition of “test lot”) *with* Pet. at 34 (proposed construction of “lots”). Petitioner provides no explanation, let alone authority, as to why the Board should do this.

B. The Board Need Not Construe “Separately Sampled”

Petitioner proposes the term “separately sampled” requires construction, but fails to provide a construction, let alone identify any issues that depend on the terms meaning. Pet. at 35-37. Because Petitioner has failed to show a need for construction, the Board need not construe this term. *Nidec*, 868 F.3d at 1017.

Nonetheless, for the reasons below, should the Board decide construction is necessary, it should adopt the Northern District of California’s construction in the *Primus* Litigation: “[c]ollecting multiple samples from different, non-contiguous locations from each of multiple separate [test lots/single unit production lots/etc.]” Ex. 1038 at 6.

The term “separately sampled” appears within a “wherein” clause of the collection step (i.e., step (a)), which the *Primus* Court already construed. Ex. 1001 at 12, 1:30 (claim 1), 2:15-16 (claim 17); Ex. 1002 at 15:10-11 (claim 1), 17:53-54 (claim 35); Ex. 1003 at 15:33-34 (claim 1), 18:12-13 (claim 37). Relying on the meaning of the “separately sampled” wherein clause, the *Primus* Court defined the collection step as “[c]ollecting multiple samples from different, non-contiguous locations from each of multiple separate lots.” Ex. 1038 at 4-6. Without identifying any error in the District Court’s ruling, Petitioner now asks the Board to abandon the *Primus* Court’s construction for a broader one that includes samples taken from the same location at different times. *See* Pet. at 35-36 (“Representative samples may be

obtained via randomness of a single variable, time”). But the *Primus* Court already found this argument is “flawed,” holding that “[i]n order to have a representative sample of a given test lot, the portions of the product that constitute the sample ***must be*** taken from non-contiguous locations to be effective.” Ex. 1038 at 5; *see also id.* at 6 (“this construction is the only way ‘to capture the scope of the actual invention rather than ... allow the claim language to become divorced from what the specification conveys is the invention.’”) (quoting *Huawei Techs., Co. v. Samsung Elecs. Co.*, No. 3:16-CV-02787-WHO, 2017 WL 7058419, at *8 (N.D. Cal. Aug. 31, 2017)); Pet. at 35 (“National Beef agrees ... the resulting lot sample is representative of the lot being sampled”).

Because Petitioner concedes the collection step requires representativeness and because the Board uses the same claim construction standard as District Courts, should the Board choose to construe any portion of the collection step, including the term “separately sampled,” it should construe it as “[c]ollecting multiple samples from different, non-contiguous locations from each of multiple separate [test lots/single unit production lots/etc.]” Ex. 1038 at 6; *see also* 37 C.F.R. § 42.100(b) (2019); Pet. at 35 (“National Beef agrees ... a lot is ‘separately sampled’ when ... resulting lot sample is representative of the lot[.]”).

C. The Board Need Not Construe “Combining/Compositing”

Petitioner concedes “construction is unnecessary” for the terms “Combining” and “Compositing” but asks the Board to declare they are synonyms. Pet. at 37. For the purposes of this preliminary response, Patent Owner agrees the terms “combining” and “compositing” do not require construction. Because the Board should not construe terms the parties agree need no construction, the analysis should end there. *Nidec*, 868 F.3d at 1017. Should the Board nonetheless construe those terms, it should not construe them as synonyms because the specification expressly defines “compositing” as a particular type of combining. Ex. 1001 at 5:50-52 (“The term ‘compositing’ as used herein refers to combining a number of single product portions to form one larger sample”).

D. The Board Need Not Construe “Enrichment/Enriching”

Again, Petitioner proposes construction for the term(s) “enrichment”/“enriching” without any showing that construction is needed. Pet. at 37. The Board therefore need not construe this term. *Nidec*, 868 F.3d at 1017.

Should the Board decide construction is necessary, the Board should use the specification’s express definition, which Petitioner’s proposal truncates without explanation: “‘enrichment’ as used herein refers to incubating a test lot sample (e.g., single-unit production lot sample) under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform

or substantially uniform throughout the enriched test lot sample (e.g., single-unit production lot sample).” Ex. 1001 at 6:7-16 (emphasis added to terms omitted by Petitioner’s construction); *see also* Pet. at 37.

E. Validation/Determining Releasability Limits the Claims

The only term relevant to Petitioner’s obviousness analysis is its construction of the claimed validation step—or “step (e).” Patent Owner therefore agrees the Board should construe this term. *Nidec*, 868 F.3d at 1017. Construction of this term presents two issues. First, whether the term “validate” means determining a lot is releasable into commerce. Second, whether validation limits the claims.

1. “Validate” means “determining a lot is releasable”

The Board interprets a claim “using the same claim construction standard that would be used to construe the claim in a civil action.” 37 CFR § 42.100(b) (2019). Namely, claims are construed “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*¹¹ Because “the claims of a patent

¹¹ The claim construction standard for PTAB proceedings change on November 13, 2018, from the “broadest reasonable interpretation” standard to the “ordinary and customary meaning.” *Hamilton Beach Brands, Inc. v. f’real Foods, LLC*, 908 F.3d 1328, 1339 n.3 (Fed. Cir. 2018).

define the invention,” construction “begin[s] with the language of the claims.” *SharkNinja Operating LLC v. iRobot Corp.*, No. 2023-1151, 2024 WL 1132219, at *2 (Fed. Cir. Mar. 15, 2024) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc)).

The claims of the ’584 patent expressly state that validation requires determining a lot is cleared for release into commerce. For example, the preambles of the ’584 independent claims state that the claimed invention is “[a] method of ... validating ... test lots ... for release into commerce.” Ex. 1001 at 12, 1:22-59, 2:7-8 (cleaned up). Likewise, the body of the claims requires collecting “a number of portions ... to provide for validation and release into commerce.” *Id.* at 12, 1:33-35, 2:19-21 (cleaned up). The body of the claims further states that “wherein such testing is negative all of said separate test ... lots are validated for release into commerce.” *Id.* at 12, 1:54-56 (cleaned up), 2:45-46. The claims of the ’584 Patent make clear that validation means determining that test lots are fit “for release into commerce.”

The specification confirms this by using validation and releasability interchangeably. For example, the specification expressly defines “validation” as including clearing lots “for release” into commerce:

“[V]alidation” as used herein with respect to production lots refers to determining that a particular sample tests negative using the detection assay. Where a modular composite sample tests negative, all single-unit production lot samples comprising the composite sample ***are validated***

along with the respective single-unit production lots, which are ***thus cleared for release***. Where a modular composite sample tests positive, individual single unit production lots may nonetheless yet be validated if particular respective single-unit production lot samples test negative.

Ex. 1001 at 7:1-10 (emphasis added). The specification then explains, after a negative test result, lots are “released” or “validated and releasable” into commerce; thus, reinforcing that validation requires determining samples are releasable. *See* Ex. 1001 at 4:22-25 (“If a negative result is obtained from the MWCS, then all of the individual single unit production lots are ***released***.”) (emphasis added), 5:1-3 (“If a negative result is obtained from the MWCS, then all of the individual single-unit production lots are ***validated and releasable***.”) (emphasis added).

The working examples in the specification reiterate that efficiently determining releasability is a key benefit over the prior art. Ex. 1001 at 11:46-54 (“The ***release of the validated*** 19,280,000 lbs of beef trim into commerce using the present invention ... ***represents a cost savings*** to the producer of about \$2,500,000, relative to prior art methods.”) (emphasis added); *id.* at 13:6-10 (“Individual single-unit production lots ... [that] yields a ***negative result are released into commerce*** ... represent[ing] a direct cost savings to the producer relative to a prior art approaches[.]”) (emphasis added); *id.* at 14:8-14 (“Individual single-unit production lots ... [that] yields a negative result are thereby ***validated and are releasable*** into

commerce ... represent[ing] a direct cost savings to the producer relative to prior art approaches[.]” (emphasis added). Stated differently, validation without determining releasability serves no purpose.

This distinction, between an accurate test result and a test result with the necessary sensitivity to certify products as safe for consumption and releasable, confuses two similar terms that were at issue during the reexamination—“verification,” which determines a test result is correct, and “validation,” which determines products are releasable into commerce. The request for reexamination cited prior art that described verification. The Patent Owner responded to institution by explaining that the claimed **validation** is “fundamentally different” than the “**verification**” taught in the prior art. Ex. 1007 at 245 (explaining that, at best, the prior art “allow[ed] for **verification of positive** samples by retesting ... [but] would not provide for the fundamentally different statistical ‘**validation**’ ... in the context of prior art assays”), 248 (“verification of positive samples is fundamentally different tha[n] validation of negative samples”). Patent Owner reiterated that validation as opposed to mere verification is critical to all steps of the invention:

the number of samples ... (e.g., 5, as in Jarvis method (3)) is **insufficient to validate/certify the lot for release** even if such were possible. Significantly, however, in the Jarvis method (3), for example ... **any positive** from the composite pre-enrichment pool **must, by**

regulation, invalidate the lot, and accordingly there is no value, aside from curiosity ... to go back and verify a positive.

Ex. 1007 at 246 (some emphasis added); *id.* at 250 (“validation in step e) of a negative test lot sample ... requires that the number of portions/samples lumped in step a), must be large enough to statistically provide for Lot validation according to step e)”), 258-59 (discussing *Price* “while verification of positive testing or negative testing may be afforded, no validation of the original single lot is afforded by verification of a negatively testing individual pre-enrichment cultures.”) (emphasis omitted); *see also* 274-75.

Twice, the Patent Owner amended the claims to clarify this distinction, including adding “for release into commerce.” *Id.* at 232-40 (first clarifying amendments), 478 (second clarifying amendment adding “for release into commerce”). When doing so, the Patent Owner explained this was an inherent part of validation. *See id.* at 251 (explaining that the first amendment was “to further emphasize ... [what] is already implicit in the claims”), 487 (explaining that the second amendment was required to address the Examiner’s “continued misunderstanding and/or error ... in interpreting [the] Patentee’s claim elements”). The Examiner acknowledged that these amendments “merely clarify and do not significantly change the scope of the claims.” *Id.* at 867.

On Appeal, the Patent Owner also presented evidence of industry skepticism that the method could be used to validate food for release into commerce because of a belief that the method would result in false negatives, leading to contaminated food reaching consumers. *Id.* at 1785. The Patent Owner also presented evidence of his commercial success once he overcame the skepticism that his method could validate samples for release—and not just verify them. *Id.* at 1788. In response, the Board reversed its original decision and affirmed patentability of all amended claims. *Id.* at 1789. The Board likewise reiterated the importance of the distinction between verification and validation in its decision denying rehearing, stating an IEH Customer “explained that he had to carry out detailed testing ***to be convinced that the method had the requisite sensitivity to be used for meat testing***” before release into commerce. *Id.* at 1867 (emphasis added); *see also id.* at 1785 (“a meat producer [testified] that he carried out detailed testing using the method ... [to address concerns] that it was sensitive enough to meet the requirements [of his company]. ... [And] identified major customers[,] ... such as Tyson Company, that had ‘initially refused to accept product that was tested using [the patented] methods,’ but were later convinced that Patent Owner’s method worked.”).

“Where multiple patents derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents.” *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373 (Fed.

Cir. 2019) (quoting *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1316 (Fed. Cir. 2015)). The prosecution history of the later patents in this family further confirms the distinction between validation and verification, and that it applies equally to all patents in the family. For example, the '233 Patent included claims that all required validation, but did not expressly state that validation meant for release into commerce. The Examiner was aware of, and considered, the same verification prior art and the reexamination itself. Ex. 1009 at 100-02 (Signed IDS), 55-56 (same), 59, 64. In fact, the Examiner included extensive comments concerning the verification prior art considered in the reexamination—including citation to exhibits of record in the reexamination—in its notice of allowance for the '233 Patent. *Id.* at 20-26. The Patent Owner also submitted additional comments on the notice of allowance (*Id.* at 11-13) and initiated an interview with the Examiner to ensure it “clearly underst[oo]d the reasons of allowance” (*Id.* at 4) as including the “arguments of record for patentability in both the underlying parent application ... and in the reexamination proceeding.” *Id.* at 11-13. The Examiner then allowed the '233 Patent to issue over the verification-but-not-validation prior art. *Id.* at 2. The same Examiner also examined the '143 and '771 Patents' Applications and allowed them to issue over the verification-but-not-validation prior art. Ex. 1010 at 169 (the '143 Patent); Ex. 1011 at 199 (the '771 Patent). This prosecution history confirms

that “validation” requires determining releasability into commerce, and not mere verification.

2. Validation/Determining Releasability Limits the Claims

Validation is an essential—and limiting—part of the claims. There is no “litmus test” for determining whether claim language concerning an intended use is limiting. *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). Instead, whether to treat disputed language as limiting turns “on the facts of each case in light of the claim as a whole and the invention described in the patent.” *Id.* In general, disputed language is regarded as limiting if it recites essential elements of the invention or is necessary to give life and meaning to the claim. *Id.*; *see also Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1340-41 (Fed. Cir. 2021); *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1329 (Fed. Cir. 2019). Additionally, “clear reliance on the [disputed language] during prosecution to distinguish the claimed invention from the prior art transforms the [language] into a claim limitation because such reliance indicates use of the [language] to define, in part, the claimed invention.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

The Federal Circuit’s decision in *Vizio, Inc. v. International Trade Commission*, 605 F.3d 1330 (Fed. Cir. 2010) is instructive. In *Vizio*, the Federal Circuit considered whether the phrase “for decoding” limited claims for devices that

identified and assembled specific “channel map” information in order to decode a digital television user’s selected program. *Id.* at 1340-41. Although the “for decoding” phrase was drafted in the preamble, the Federal Circuit recognized “the ‘for decoding’ language ... is properly construed as a claim limitation, and not merely a statement of purpose or intended use for the invention, because ‘decoding’ is the essence or a fundamental characteristic of the claimed invention.” *Id.* at 1341. The claim “would have little meaning without the intended objective of decoding.” *Id.* Thus, “[t]he decoding requirement of the preamble does not ‘only add an intended use,’ but rather, states an essential limitation to the claims.” *Id.*

The Federal Circuit’s decision in *In re Jasinski*, 508 F. App’x 950 (Fed. Cir. 2013), is likewise instructive. In *Jasinski*, the Court considered whether the preamble phrase for “verifying the accuracy” and body limitation “to verify the accuracy” limited the claims. *Id.* at 952. The Federal Circuit found that “[n]ot only does the ‘to verify/verifying’ language refer to the ‘essence of the invention,’ it also provides the criteria by which the ... limitation is analyzed.” *Id.*

These principles confirm validation is limiting. *First*, just as in *Jasinski*, the validation language here is found in the body of the claims, not just the preamble, where statements of intended use are more commonly found. Thus, given its placement, there is at least a presumption that the language is limiting. *See SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1375

(Fed. Cir. 2021) (“language ... [that] is part of the body of the claim ... **place[s] its limiting character beyond dispute**”) (emphasis added); *Catalina*, 289 F.3d at 811 (“By virtue of its inclusion in the body ... this phrase limits [the claim]”); *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 689 (Fed. Cir. 1990) (finding the term “the cutting blade” was entitled to patentable weight because it “is referenced repeatedly in the body of the claim”).

Second, validation is “necessary to give life, meaning, and vitality” to the claim. *See Catalina*, 289 F.3d at 808. As discussed above, the specification explains the entire benefit of the invention is the ability to efficiently validate lots for release into commerce. *See* § V.E.1 *supra* (citing Ex. 1001 at 11:46-54, *id.* at 13:6-10, and *id.* at 14:8-14).

Third, the history of this patent family demonstrates “clear reliance on the [disputed language] during prosecution to distinguish the claimed invention from the prior art.” *Catalina*, 289 F.3d at 808; *see also* § V.E.1 *supra*. Namely, the Patent Owner repeatedly distinguished the prior art **verification** from the claimed **validation**, explaining that the two are “fundamentally different.” Ex. 1007 at 245, 248. In relying on this distinction, the Office allowed all challenged patents’ applications. Much as the Examiner and the Board relied on this difference to distinguish prior art, so to should the Board afford it limiting weight here. *Catalina*, 289 F.3d at 808.

3. Petitioner Has No Support for Its Position That “for Release into Commerce” Is Non-limiting

Petitioner relies solely on an overturned Board decision applying the wrong standard of construction to argue validation is not limiting. ’584 Pet. at 35 (citing Ex. 1007 at 1568-69), 40 (same), 57 (same); *see also* Ex. 1007 at 1559 (opinion issued Jan. 20, 2015); *Hamilton*, 908 F.3d at 1339 n.3 (petitions filed before November 13, 2018, construed claims using the broadest reasonable interpretation standard; petitions filed on or after November 13, 2018, apply the *Phillips* standard). As discussed above, the Board’s subsequent decisions, which supersede the decision cited by Petitioner, repeatedly rely on the distinction between verification and validation to overcome the prior art and to show industry skepticism. *See* § V.E.1 *supra*. Thus, for the reasons discussed above, validation limits the claims.

VI. NONE OF THE CITED PRIOR ART TEACHES THE VALIDATION STEP

All claims include Step (e) and thus require validating samples. Ex. 1001 at 12, 1:30-35; *see also id.* at 12, 1:30 (claim 1), *id.* at 12, 2:15-16 (claim 17); Ex. 1002 at 15:10-11 (claim 1); *see also* 17:53-54 (claim 35); Ex. 1003 at 15:33-34 (claim 1), 18:12-13 (claim 37). Petitioner cites four references it claims each teach validation: *Price*, ICMSF-7, *Gombas*, and/or *Hughes*. Pet. at 48-52 (ICMSF-7 and/or *Gombas*), 56 (ICMSF-7 and/or *Hughes*), 62-63 (*Price*, ICMSF-7, and/or *Hughes*). But Petitioner basis its contentions on the failed claim construction argument discussed

above, which confuses verification for validation and claims it not to be limiting. Because none of the references teach validation, which limits the claims and requires determining releasability, all grounds fail.

A. *Price* Does Not Teach Validation

The Office has already found that *Price* does not teach validation. *Price* was before the Office during prosecution and reexamination of the '584 patent. Ex. 1006 at 306; Ex. 1007 at 151. Before the '584 Patent received a final rejection, the Patent Owner submitted, and the Examiner reviewed, *Price*. Ex. 1006 at 278-79 (submitted), 306 (reviewed). Moreover, during the reexamination, the Examiner adopted nine grounds of invalidity including *Price* (Exhibit 1007 at 185-227) and the Board included *Price* in all four of its grounds. Ex. 1007 at 1562-63. After its extensive review and consideration of *Price*, the Board expressly found that it did not disclose the validation step (e) requires. Ex. 1007 at 1787 (“step e[] was not described in the prior art”), 1862 (“it is our opinion that such steps (particularly steps d and e of claim 1) were not readily available in the prior art”).

The Petition points to no error¹² in the Office’s finding, and instead simply cites the same sections of *Price* that the Office had already reviewed. Pet. at 62-63

¹² Petitioner claims that the Examiner “mischaracterized [*Price*] as not teaching” the validation step and “that the Examiner’s misunderstanding was [never]

(citing Ex. 1017 at 679); Ex. 1007 at 1575-79 (discussing *Price*). Those sections, however, show that *Price* does not teach validation because, as the Office found, the number of “samples” taught in *Price* “is insufficient to validate/certify the lot for release.” Ex. 1007 at 246. In affirming patentability, the Board expressly acknowledged this as one of the “key difference(s) between” the prior art—including *Price*—and the invention. Ex. 1007 at 1780.

B. ICMSF-7 Does Not Teach Validation

The ICMSF is a non-government organization formed in 1962 to collect and evaluate microbiological safety of foods and, where appropriate, propose methods of sampling and examination for microbiological contaminations in food.¹³ ICMSF has published a series of textbooks, the first two being: ICMSF-1¹⁴ and *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and*

corrected.” Pet. at 79. But this amounts to “disagree[ment] regarding the purported treatment of the art or arguments,” which is not an error. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 9 (PTAB Feb. 13, 2020) (precedential).

¹³ <https://www.icmsf.org/about/history/> (last visited Oct. 28, 2024).

¹⁴ *Infra* note 4.

Specific Applications (“ICMSF-2”), University of Toronto Press, 2d ed. (1986).¹⁵ In 2002, Part of ICMSF-2 was revised and reformatted into ICMSF-7.¹⁶

Patent Owner expressly disclosed the ICMSF, its rules, and its publications. *Id.* The specification explains that the industry typically operated “pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products.” Ex. 1001 at 2, 1:62-66. The Office examined ICMSF-1 when BioMeriux included it in its request for *inter partes* reexamination. Ex. 1007 at 226.

Likewise, the Office examined the underlying content of ICMSF-7, which simply summarizes two studies that were directly before the Office. *See* Ex. 1025; Ex. 1026. Dr. Silliker is both a member of ICMSF and a contributor to ICMSF-7. Ex. 2005 at xiii, 342-43, 346. Prior to ICMSF-1 publication, Dr. Silliker published two papers describing laboratory investigations undertaken on behalf of ICMSF. Ex. 1012 at 187, 187. Both *Silliker* publications were considered by the Examiner during the original prosecution of the ’584 Patent. Ex. 1006 at 306 (signed IDS). Moreover, the Examiner adopted three grounds based on one or both of the *Silliker* publications during reexamination (Ex. 1007 at 198-203, 223), and the Board

¹⁵ <https://www.icmsf.org/publications/books/> (last visited Oct. 28, 2024).

¹⁶ *Id.*; *see also* Ex. 2005 at xi-xiii.

included one of the *Silliker* publications in one of its grounds of invalidity. *Id.* at 1563.

The portion of ICMSF-7 that Petitioner relies on for the validation step summarizes those two *Silliker* publications. *See* Pet. at 50-51 (referring to Pet. at 42-48, in turn citing to ICMSF-7, page 187); *see also* Ex. 1012 at 187, 197. Apparently recognizing this problem, Petitioner omits ICMSF-7's citation to *Silliker*'s publications from the quotes it presents to the Board. For example, the Petition repeatedly includes the following block quote from ICMSF-7, but omits the portion now highlighted in yellow, which confirms the cited portions are summarizing the *Silliker* papers:

To reduce laboratory effort while maintaining the stringency of the sampling plan, it would be helpful to combine either groups of analytical units or the enrichment cultures therefrom, using plans in which the presence of a single positive rejects the consignment. A laboratory investigation undertaken for ICMSF (*Silliker & Gabis, 1973*) indicated that different sized analytical units drawn from a single well-mixed sample unit of dried food give very similar results. A subsequent investigation (*Gabis & Silliker, 1974*) using foods of high moisture content (including eggs, poultry meat, meat, and meat products) showed comparable reliability in the use of composite analytical units; for example, examination of three composites of 20 × 25 g analytical units gave the same result as examination of all 60 analytical units individually (the total amount examined being 1500 g in both instances). This finding suggests that considerable reductions may be made in the cost of laboratory analyses by compositing (pooling) analytical units. Such compositing offers the prospect of large increases in the number of analytical units, *n*, with corresponding increase in the stringency of examination, without correspondingly increasing laboratory effort.

Ex. 1012 at 187; *see also* Pet. at 42-43, 45, 47. As detailed above, the Office reviewed both *Silliker* publications and found they did not teach the claimed validation. *See* Ex. 1007 at 1787 (“step e[] was not described in the prior art”), 1862 (“it is our opinion that such steps (particularly steps d and e of claim 1) were not

readily available in the prior art”). Petitioner identifies no error made in reaching this conclusion. Because the Petition relies on a reference that does no more than parrot material already considered by the Office, the Board should maintain its finding that the material in ICMSF-7 does not teach the claimed validation.

C. *Gombas* Does Not Teach Validation

Gombas describes a study seeking to quantify the prevalence of listeria in food already released into commerce. Ex. 1014 at 559-60 (describing the problem as “consumers [being] exposed to detectable levels of *L. monocytogenes* billions of times each year” but “there are almost no data on *L. monocytogenes* levels in foods”). *Gombas* therefore purchased “samples” from two grocery stores, screened them for potential presence of listeria, and enumerated the positive samples. *Id.* at 561-62.

Because *Gombas* was evaluating food already released into commerce, it was not bound by the heavy regulation controlling sensitivity and reliability of testing food *prior* to release into commerce. *See* Ex. 1001 at 2, 1:40-45 (citing FSIS directives), 1:62-67 (citing ICMSF, FDA, USDA, and EPA guidelines). Not surprisingly, *Gombas* makes no suggestion that, after concluding testing, researchers somehow snuck back into the grocery stores and returned the leftover samples to store shelves. Indeed, *Gombas* warns that, despite the regulatory agencies’ “zero tolerance” policies against contamination, it modified the approved “USDA or FDA testing procedures,” and provides no claim that its unapproved test provides any

indication that the samples are fit for release into commerce. Ex. 1014 at 563 (“Methods described in chapter 8 of the revised *Microbiological Laboratory Guide* ... were **adapted** for meat products, and those in the *Bacteriological Analytical Manual* ... were **adapted** for nonmeat products”) (emphasis added); *see also id.* at 559 (“zero tolerance”). The patented invention plays the opposite role and requires validating samples for release into commerce—a task subject to the very “zero tolerance” policies *Gombas* disregarded. Because the samples in *Gombas* were already released into commerce and were never determined to be fit for re-release back into commerce, *Gombas* does not teach the required validation.

D. Hughes Does Not Teach Validation

Hughes describes a study evaluating the efficacy of using a different primary enrichment media for *Salmonella* testing. Ex. 1015 at 634-35. To determine whether the new enrichment procedure would generate more false negatives than a prior procedure, *Hughes* deliberately infected its samples with increasing amounts of *Salmonella* to determine the concentrations the new enrichment procedures could detect. *See Id.* at 634-35. Like *Gombas*, *Hughes* makes no suggestion that its testing method provides any information about whether the samples—which it intentionally infected—were fit for release into commerce. *Id.* at 643-46.

Petitioner claims that “[b]ecause Hughes explains the steps to be taken when testing is positive ... a POSA would also expect negative testing results.” Pet. at 56.

But because *Hughes* was testing infected samples, a POSA would **not** expect negative results. *See* Ex. 1015 at 635. Indeed, any negative results when testing intentionally infected samples would inherently be false negatives. *Id.* In contrast, the patent claims a method designed to **avoid** false negatives and requires validating samples for release into commerce.

VII. INSTITUTION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)

The Board, in its discretion under 35 U.S.C. § 314(a), should deny institution because the District Court will likely reach a decision on the same arguments presented in the Petition before the Board issues its final decision. Petitioner’s threadbare discussion of *Fintiv* relies almost entirely on the assumption that “it would be very unlikely for the trial in the litigation to be reached before issuance of the FWD.” Pet. at 76. But Petitioner makes this assumption using the wrong District Court time-to-trial statistics and concluding—without support—that the proposed case schedule supports its foregone and inaccurate conclusion. *Id.* As discussed below, once this and other errors in Petitioner’s cursory discussion are corrected, the *Fintiv* factors favor the Board exercising its discretion to deny institution under 35 U.S.C. § 314(a).

A. The *Fintiv* Factors

Under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir.

2016). When there is a parallel proceeding, the Board has enumerated six factors (“the *Fintiv* factors”) it considers in determining whether to exercise its discretion to deny institution based on the parallel proceeding:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the Petitioner and the defendant in the parallel proceeding are the same party; and;
6. other circumstances that impact the Board’s exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 15 at 7-8 (PTAB May 13, 2020) (precedential) (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 19–20 (PTAB Sept. 12, 2018) (precedential)). “In evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* at 8.

Discretionary denial is warranted under § 314(a) and *Fintiv* because: (1) there is essentially no likelihood of a stay being granted; (2) trial in the district court will likely occur before the Board’s final written decision; (3) the parties and district

court have already substantially invested significant resources and will invest even more by the time of the Board’s institution decision; (4) the Petition relies on the same prior art and invalidity theories as the district court proceeding; (5) the Petitioner is the defendant in the district court proceeding; and (6) as explained in § VI *supra*, none of Petitioner’s asserted grounds teach validation—required in all challenged claims.

B. The District Court Is More Likely to *Deny* a Stay if the Petition Is Instituted

Because there is evidence that the District Court would be more likely to *deny* a stay if the present petition is instituted, the first *Fintiv* factor favors the Board denying institution.

Petitioner asserts without support that *if* the Board institutes the present petitions the likelihood of a stay would increase. Pet. at 75. But Petitioner has yet to seek a stay in the district court litigation and case law from the District of Delaware indicates that filing a motion for a stay *after* an institution decision decreases rather than increases the likelihood that a stay will be granted. *See 3G Licensing, S.A. v. HTC Corp.*, No. CV 17-83-GBW, 2023 WL 34553, at *5 (D. Del. Jan. 4, 2023) (denying request for stay in part because a “request for reexamination made well after the onset of litigation followed by a subsequent request to stay may lead to an inference that the moving party is seeking an inappropriate tactical advantage”)

(quoting *Belden Techs. Inc. v. Superior Essex Commc'ns LP*, No. CIV. 08-63-SLR, 2010 WL 3522327, at *2 (D. Del. Sept. 2, 2010)).

The District of Delaware generally considers three factors when considering whether to grant a motion to stay pending an *inter partes* review:

- (1) whether granting the stay will simplify the issues for trial;
- (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set;
- (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage.

CAO Lighting, Inc. v. Gen. Elec. Co., No. CV 20-681-GBW, 2022 WL 17752270, at *2 (D. Del. Dec. 19, 2022).¹⁷

Under the first factor, “a stay is not favored when infringement, validity under 35 U.S.C. § 112, or other issues outside the purview of reexamination remain to be tried.” *Belden Techs.*, 2010 WL 3522327, at *2. In addition to whether discovery is

¹⁷ The District Court indicates a fourth factor is “whether a stay, or the denial thereof, will reduce the burden of litigation on the parties and on the court,” but this factor is coextensive with factor two. *CAO Lighting*, 2022 WL 17752270, at *2; *see also id.* at *3 (“for the reasons discussed above in the context of the second factor ... the fourth factor disfavors a stay”).

complete, and a trial date has been set, under the second factor, courts also consider the significance of resources the parties and Court have expended. *See CAO Lighting*, 2022 WL 17752270, at *2 (“The second factor ... weighs strongly against a stay. ... [because] the parties [and Court] have already expended significant resources litigating these actions.”).

When considering prejudice to the non-moving party under the third factor, the district court further considers “(1) the timing of the request for review; (2) the timing of the request for a stay; (3) the status of the review proceedings; and (4) the relationship of the parties.” *Id.* at *3. Accordingly, “[a] request for reexamination made well after the onset of litigation followed by a subsequent request to stay may lead to an inference that the moving party is seeking an inappropriate tactical advantage.” *Belden Techs.*, 2010 WL 3522327, at *2. Moreover, district courts find the delay caused by a stay “inherently harms a non-moving party by prolonging resolution of the dispute, even if the party is not currently a direct competitor.” *RideShare Displays, Inc. v. Lyft, Inc.*, No. CV 20-1629-RGA-JLH, 2021 WL 7286931, at *2 (D. Del. Dec. 17, 2021).

Here, the District of Delaware would be unlikely to grant a stay because none of the factors favor it. The first factor weighs against a stay because the present petitions concern only some of the patents-in-suit in the parallel district court

litigation¹⁸ and Petitioner asserts invalidity claims and defenses that are outside the purview of *inter partes* review proceedings. Ex. 1004 at 12-17 ¶¶ 51-90 (complaint asserting four counts of infringement); Ex. 2003 at 12-13 (asserting affirmative invalidity defenses under 35 U.S.C. §§ 101 and 112 and inequitable conduct), 16-18 ¶¶ 19-26 (counterclaim for declaratory judgment of invalidity under 35 U.S.C. § 112), 19-21 ¶¶ 36-42 (counterclaim for declaration of unenforceability due to alleged inequitable conduct); *Belden Techs.*, 2010 WL 3522327, at *2 (“a stay is not favored when infringement, validity under 35 U.S.C. § 112, or other issues outside the purview of reexamination remain to be tried”).

The second factor weighs against a stay because the parties have already expended significant resources, exchanging contentions, conducting discovery, resolving a motion to dismiss (or transfer) due to improper venue, and briefing a motion to dismiss defendant’s counterclaim for failing to state a claim upon which relief can be granted. Ex. 2004; *CAO Lighting*, 2022 WL 17752270, at *2 (“The second factor ... weighs strongly against a stay.... [because] the parties have already

¹⁸ Petitioner has filed petitions on all district court patents-in-suit; however, the petition (against a different patent family) was filed later than the present petitions. *Compare* IPR2024-00185 (institution decision expected Jan. 30, 2024), with IPR2024-01156 (institution decision expected Feb. 23, 2024).

expended significant resources litigating these actions and the Court has expended significant resources becoming intimately familiar with them and resolving disputes along the way.”). By the time the Board issues its institution decision, the parties will have conducted an in-person hearing concerning the motion to dismiss Petitioner’s counterclaims, further invested in discovery, attended mediation, exchanged expert reports and conducted expert depositions on claim construction issues, and filed their opening claim construction briefs. Ex. 1062 at 7-8. Hence, this factor weighs heavily against the district court granting a stay after an institution decision.

The third factor also weighs against a stay because the Petitioner waited nearly a full year after the parallel district court litigation commenced before filing the instant petition and plans to wait even longer to request a stay—if at all. Namely, Petitioner states that it will only request a stay if the Board institutes, which would delay trial by months if not years at that point. Ex. 1004 at 18 (complaint filed Aug. 1, 2023); Pet. at 85 (served July 16, 2024), *id.* at 75 (“If this IPR is instituted ... National Beef will seek a stay”); Ex. 1062 at 8 (trial scheduled for approximately seven months after Claim Construction Order, briefing for which concludes Feb. 19, 2025); *RideShare*, 2021 WL 7286931, at *2 (“Even if we picked back up on the day that the [Board’s] decisions come out ... there would not be time to ... maintain the current trial date.... [A] stay [here] would almost certainly cause delay, and the

prejudice accompanying that delay is undue.”). Prejudice increases as time and resources in the district court are expended, hence this factor weighs even more in favor of denying a stay. *CAO Lighting*, 2022 WL 17752270, at *3 (finding prejudice where trial could be delayed until exhaustion of appeals from a final written decision).

Because all three factors weigh in favor of denying a stay, the first *Fintiv* factor weighs in favor of the Board denying institution. *See Fintiv*, IPR2020-00019, Paper 15 at 7 (first factor is “whether ... evidence exists that [a stay] may be granted if a proceeding is instituted”).

C. Trial Will Likely Precede the Board’s Final Written Decision

The second *Fintiv* factor favors the Board exercising its discretion to deny institution because the proper district court statistics indicate any final written decision will come after trial in the parallel district court litigation. *See id.* at 12-13 (finding factor two favors exercising discretionary denial when the trial is likely to occur prior to the Board’s final written decision).

Petitioner claims that, based on the “most recent statistics on median time-to-trial for civil actions in the District of Delaware, any potentially foreseeable court trial date is on October 1, 2026”—but statistics from the District of Delaware are irrelevant because this case has been assigned to a judge sitting by designation in the U.S. District Court for the Eastern District of Pennsylvania. Pet. at 76; Ex. 2004 at

7, Dkt. No. 23 (“designating and assigning the Honorable Joel H. Slomsky of the United States District Court for the Eastern District of Pennsylvania”). Indeed, Judge Slomsky has 63% fewer cases overall and 94% fewer patent cases than the Judges for the U.S. District Court for the District of Delaware. *Compare* Ex. 2006 at 2-3 (showing average case load (for Connolly, Williams, Noreika, Andrews, and Hall) is 340, with approximately 129 being patent cases) *with* Ex. 2007 at 2 (showing Judge Slomsky has 125 open cases (in both E.D. Pa. and D. Del.), only seven of which are patent cases). Statistics for the Eastern District of Pennsylvania, which place the trial three months ahead of the Board’s final written decision, would therefore apply to how this judge is likely to manage this lawsuit. *See* Ex. 1004 (Complaint filed Aug. 1, 2023); Ex. 2008 (showing average time to trial of 27.1 months (i.e., early November 2025); Paper 3 (Patent Owner preliminary response due Oct. 30, 2024); 35 U.S.C. § 314(b) (institution decision due Jan. 30, 2025); 35 U.S.C. § 316(a)(11) (final written decision due Jan. 30, 2026)); *see also 10x Genomics, Inc. v. President & Fellows of Harvard Coll.*, IPR2023-01299, Paper 15 at 16-17 (PTAB Mar. 7, 2024) (finding this factor favors denial where the presiding judge “is a visiting judge with fewer cases than the average District of Delaware judge”). Thus, the second *Fintiv* factor favors the Board denying institution.

D. The Parties and the District Court Have Already Invested Substantial Resources

The third *Fintiv* factor also strongly favors discretionary denial because both the parties and the court have made substantial investments in the parallel district court proceedings.

Petitioner merely reiterates that “it would be very unlikely for trial in the litigation to be reached before issuance of the FWD in January 2026;” but that simply repeats Petitioner’s incorrect analysis of the second *Fintiv* factor. Pet. at 76. The third *Fintiv* factor considers “the level of investment and effort already expended ... in the District Court.” *Fintiv*, IPR2020-00019, Paper 15 at 14. By the time the Board issues its institution decision the parties will have fully briefed two motions to dismiss, be well into fact discovery, exchanged infringement and invalidity contentions, attended mediation, exchanged terms for claim construction, exchanged expert reports, and be within weeks of completing claim construction briefing. Ex. 1062; Ex. 2004. For its part, the district court has already denied Petitioner’s motion to dismiss or transfer for improper venue and will have heard oral arguments for (if not decided) Patent Owner’s motion to dismiss Petitioner’s counter claim for inequitable conduct. Ex. 2004; *see also 10x Genomics*, IPR2023-01299, Paper 15 at 17-19 (“the district court has invested substantial resources in the parallel proceeding” in considering two motions to dismiss and presiding over other

disputes). “Thus, it is clear that Judge [Slomsky] has invested a significant amount of time and resources to the parallel proceeding.” *Id.*

Petitioner’s delay in filing the present petition also weighs in favor of the Board exercising its denial under the third *Fintiv* factor. *See id.* at 18-19. Petitioner waited to file this petition within weeks of its statutory deadline, despite relying almost exclusively on prior art identified in the prosecution history or the prior litigation. *See Google LLC v. AGIS Software Dev., LLC*, IPR2020-00873, Paper 16 at 12 (PTAB Nov. 25, 2020) (“Because the evidence shows that Petitioner had everything it needed to file the Petition much earlier in the parallel district court proceedings and because Petitioner offers no explanation for why the filing was delayed, we find the timing of the Petition weighs heavily toward exercising discretion to deny institution.”). Patent Owner notified Petitioner of infringement no later than April 18, 2023, and filed the Complaint asserting infringement of the Patents-at-issue on August 1, 2023. Ex. 1004 at 10 ¶¶ 37-39. Yet Petitioners waited ***more than a year*** before filing this Petition. Pet. at 85 (served July 16, 2024). “Notably, although Petitioner addresses *Fintiv* in the Petition, Petitioner provides no explanation for the delay. Accordingly, ... this factor weighs in favor of exercising [the Board’s] discretion to deny institution.” *10x Genomics*, IPR2023-01299, Paper 15 at 19; *see also* Pet. at 76.

E. Overlap of Issues

This factor favors denial where (as here) the “petition includes the same (or substantially the same) claims, grounds, arguments, and evidence as presented in the parallel proceeding.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 12 (PTAB Mar. 20, 2020). All grounds asserted in the petition are also asserted in the district court. Pet. at 7; Ex. 2009 at 34-41; *compare id.* at 635-702 (ICMSF-7 and *Gombas*), 703-70 (ICMSF-7 and *Hughes*), and 771-915 (*Price*, ICMSF-7, and *Hughes*) with Pet. at 7 (IPR Grounds).

Although the underlying “concerns of potentially conflicting decisions and duplicative efforts” can be mitigated when “a Petitioner *stipulates* not to pursue ... the same grounds ... or any grounds that could have reasonably been raised in the petition” in the parallel district court proceedings, Petitioner has not done so. Katherine K. Vidal, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* at 7 (June 21, 2022) (“Director Memo”) (emphasis added) (citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 14 (PTAB Dec. 1, 2020) (precedential as to § II.A)). Instead, Petitioner merely acknowledges the existence of statutory estoppel. Pet. at 76. But the estoppel provisions of 35 U.S.C. § 315(e) only attach once the Board issues its final written decision. This leaves Petitioner free to pursue the exact same invalidity grounds in both the district court and patent trial and appeal board proceedings until

the Board issues a final written decision—which (as explained in § VII.C *supra*) will come *after* the trial in the district court. Hence, Petitioner’s “promise” of estoppel does nothing to mitigate the risk of “potentially conflicting decisions and duplicative efforts” which this factor is trying to avoid. Director Memo at 7. Because the art and arguments in the parallel proceeding substantially overlap with the present petition, this factor weighs in favor of the Board denying institution.

F. The Petitioner Is the Defendant in the Parallel Litigation

When, as is the case here, the “Petitioner is the defendant in the related district court case ... [the Board] find[s] that this factor favors denial.” *Comcast Cable Comm., LLC v. Touchstream Tech., Inc.*, IPR2024-00326, Paper 13 at 13 (PTAB July 26, 2024) (citing *Sotera Wireless*, IPR2020-01019, Paper 12) (precedential as to § II.A).¹⁹

¹⁹ Petitioner’s cited reference agrees. *Compare Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, IPR2020-00122, Paper 15 at 10-11 (May 15, 2020) (Repko, A.J.J., *writing for the Board*) (“If the petitioner and the defendant in the parallel proceeding are the same, this factor weighs in favor of discretionary denial.”) *with* Pet. at 77 (“the factor is neutral” (allegedly quoting *Cisco*, IPR2020-00122, Paper 15 at 10) *and Cisco*, IPR2020-00122, Paper 15 at 11 (Crumbley, A.J.J., *dissenting*)).

G. Petitioner Has Not Presented Compelling Evidence of Unpatentability

Because all five *Fintiv* factors weigh in favor of denying institution, the Board may also consider “whether the Petition presents compelling merits that would outweigh those factors and weigh against exercising [its] discretion.” *10x Genomics*, IPR2023-01299, Paper 15 at 21 (citing *CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 (PTAB Feb. 27, 2023) (precedential)). “Compelling, meritorious challenges are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” Director Memo at 4.

As explained more thoroughly in § VI *supra*, none of Petitioner’s asserted grounds teach validation—an element all claims require. Hence, Petitioner has failed to even meet the statutory threshold of a reasonable likelihood of unpatentability on any claim or ground let alone present a compelling case for invalidity that it can overcome the first five *Fintiv* factors.

VIII. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Petition be denied.

Date: October 30, 2024

Respectfully submitted,

s/Benjamin J. Byer

Benjamin J. Byer (Reg. No. 62,106)
DAVIS WRIGHT TREMAINE LLP

920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8105; F: 206-757-7105
BenByer@dwt.com

Gregory B. Rosenthal (Reg. No. 71,111)
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8132; F: 206-757-7132
GregRosenthal@dwt.com

Samantha Hunt (Reg. No. 79,993)
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8563; F: 206-757-7700
SamHunt@dwt.com

Attorneys for Patent Owner

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S PRELIMINARY RESPONSE** specified in 37 C.F.R. § 42.24, excluding the Table of Content, Patent Owner's Exhibit List, Certificate of Compliance and Certificate of Service, is no more than 13,996 words, in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(1).

s/Benjamin J. Byer
Benjamin J. Byer

Benjamin J. Byer (Reg. No. 62,106)
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8105; F: 206-757-7105
BenByer@dwt.com

Gregory B. Rosenthal (Reg. No. 71,111)
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8132; F: 206-757-7132
GregRosenthal@dwt.com

Samantha Hunt (Reg. No. 79,993)
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104
P: 206-757-8563; F: 206-757-7700
SamHunt@dwt.com

Attorneys for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was served on October 30, 2024 via email to the following addresses:

Kevin Laurence
Matthew Phillips
Derek Meeker
Laurence & Phillips IP Law
1050 Connecticut Avenue, N.W., Suite 500
Washington, DC 20036
P: 202-558-6080; F: 202-558-6081
klaurence@lpiplaw.com
mphillips@lpiplaw.com
dmeeker@lpiplaw.com

Seth Black
Black IP, PLLC
370 South 300 East
Salt Lake City, UT 84111
P: 435-513-2664
seth@blkip.com

s/Benjamin J. Byer
Benjamin J. Byer