

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.

IPR2024-00183
Patent 7,534,584 B2

Before JEFFREY N. FREDMAN, ROBERT A. POLLOCK, and
RYAN H. FLAX, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

National Beef Packing Company, LLC (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–6, 10, 11, 13–20, 22, 23, and 26–33 of U.S. Patent No. 7,534,584 B2 (“the ’584 patent,” Ex. 1001). Paper 2 (“Pet.”). Institute for Environmental Health, Inc. (“IEH” or “Patent Owner”) timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

We review the Petition and accompanying evidence under 35 U.S.C. § 314. An *inter partes* review may not be instituted unless “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Further, a decision to institute may not do so on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); 37 C.F.R. § 42.108(a).

After considering the evidence and arguments presented in the Petition, we determine that Petitioner demonstrates a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the ’584 patent is unpatentable. Accordingly, we institute an *inter partes* review as to the challenged claims of the ’584 patent on the grounds of unpatentability set forth in the Petition.

A. Real Parties-in-Interest

Petitioner identifies only itself, National Beef Packing Company, LLC, as the real party-in-interest. Pet. 84. Patent Owner identifies only itself, Institute for Environmental Health, Inc., as the real party-in-interest. Paper 4, 2.

B. Background and Related Proceedings

In addition to the present proceeding involving the '584 patent, Petitioner has challenged US 8,822,143 ("the '143 patent") in IPR2024-00185 and US 9,637,771 ("the '771 patent") in IPR2024-00186. The '584, '143, and '771 patents share a common specification, insofar as they issued from a series of continuation applications first filed on August 8, 2005, as Application No. 11/199,871, and assert benefit of priority to Provisional Application No. 60/599,473, filed on August 6, 2004. *See* Ex. 1003, code (63). The same parties are involved in IPR2024-01156, involving the unrelated patent, US 9,845,486.

We understand that each of the above patents is at issue in *Institute for Environmental Health, Inc. v. National Beef Packing Company, LLC*, 1:23-cv-00826-UNA (D. Del. 2023); that the '584, '143, and '771 patents were at issue in *Institute for Environmental Health, Inc. v. Food Safety Net Services, Ltd.*, 6:21-cv-00176-ADA (W.D. Tex. 2021); and that the '233, '143, and '771 patents were at issue in *Primus Group, Inc. v. Institute for Environmental Health, Inc.*, 5:18-cv-00005-LB (N.D. Cal. 2018), ("the Primus Litigation"). Ex. 1035, 1; Ex. 3002, 2–3; Ex. 3003, 2. Ex. 3004. The parties are advised to update the record if this information is incorrect or incomplete.

C. The '584 Specification

The '584 patent discloses "[t]he present invention provide[s] novel enrichment, testing and detection methods for detection of pathogens or other microbes in, for example, food, water, wastewater, industrial, pharmaceutical, botanical, environmental samples and other types of samples analyzed by detection methods (e.g., enrichment-detection

methods).” Ex. 1001, 3:45–49; *see also id.* at 1:24–25 (disclosing that “[t]he methods are broadly applicable to many product areas”). The ’584 patent states the

testing program involves compositing a number of samples to form a test lot, independent enrichment of each of the components of the composite sample is performed with subsequent formation of a modular (e.g., wet modular) composite sample by combining portions from each independent enrichment, which allows for determining the outcome of the test for each individual subunit of the composite as opposed to generalizing the results of the test sample to all of its [sic] subunits.

Id. at 3:49–58.

The ’584 patent explains that “individual outcome determination is achieved by retesting the individual enrichment samples in the event that the composite enrichment tests positive.” *Id.* at 3:58–61. “When a positive finding is obtained for any individual reportable lot sample (e.g., single-unit production lot sample), that particular reportable lot (e.g., single-unit production lot) is deemed to be positive, and appropriate actions are taken based on the result.” *Id.* at 4:35–40. With respect to the “pathogen/microbial testing for foods,” for example, “the individual positive sublots can be diverted to cooking, disposal, or other acceptably safe endpoint.” *Id.* at 4:35–43. “The rest of the individually enriched test units that test negative are deemed to be negative and will be reported as such.” *Id.* at 4:43–45.

According to the ’584 patent, the operative art promotes “product ‘hold and release’ monitoring efforts compris[ing] various different sampling plans, typically pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA or EPA guidelines, or intuitive sampling plans.” *See generally,*

id. at 1:34–67. “[A] typical plan for microbial pathogen detection calls for taking more than one sample, for instance ten (10) to sixty (60) sample pieces from a given sample lot (combined production lot), to form a composite sample for testing.” *Id.* at 2:3–7.

Typically, once a composite sample is constructed . . . it 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. If the pathogen/microbe is present, then it grows and multiplies under the favorable conditions of enrichment, thereby providing more material which can be detected by subsequent analysis. The composite sample is then tested by one or more available, art recognized methods.

Id. at 2:46–58.

The ’584 patent states that costs associated with testing food are substantial, and consequently manufacturer[]s often resort to increasing the size of the “production lot” to be tested. For instance, the standard size production lot for trim testing for *E. coli* O157 in the U.S. beef industry is five (5) ‘combos’ (each combo weighing approximately 2,000 pounds).

Id. at 2:27–34. “A primary problem associated with the use of large size test lots,” however, “is that a large quantity of products must be downgraded or destroyed when there is a positive finding of a pathogen.” *Id.* at 2:34–37. Moreover, “compositing a large number of samples may result in reduced sensitivity,” and standard methods render it “very difficult to investigate the cause of the failure and pinpoint the source/cause, and remedial measures cannot be effectively taken.” *Id.* at 2:37–45.

Example 1 of the ’584 patent demonstrates how an exemplary method provides “a Substantial Economic Advantage, while Providing for Enhanced Safety, and Implementation of Remedial Measures.” *Id.* at 11:5–10. In

particular, Example 1 of the '584 patent shows an approach to “trim testing for *E. coli* O157 in the beef industry in the USA” using a Modular Wet Composite Sample (MWCS) method for “testing 62,919 MWCS samples, and then retesting the individual single-unit production lot (combo) samples whenever a positive result was obtained from the MWCS sample.” *Id.* at 11:5–12:20. Referencing its Table 1, the '584 patent states

that out of 62,919 MWCS samples, a total of 217 [sic, 271] yielded a positive testing result for *E. coli* O157. Using prior art protocols, all of the single-unit production lots that comprised the 271 positive samples would go to rendering or be downgraded for cooking. As each MWCS represents five single-unit production lots of 2,000 lbs each, this would represent approximately 2,710,000 pounds of product.

Id. at 11:23–30, 12:10–19. According to the '584 patent, “the individual single-unit production lot samples comprising the MWCS were analyzed separately following each positive MWCS result” and “only 391 individual single-unit production lot samples yielded a positive result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a positive result.” *Id.* at 11:31–37.

The '584 patent discloses “the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in sensitivity relative to the MWCS testing) provides substantial additional assurance of the safety of the food products.” *Id.* at 11:50–54. The patent further explains that

Any combo-specific information including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps can be brought to bear in the context of the 391 individual single-unit production lots yielding a

positive sample result, thereby providing an effective means not only to trace contamination, but also to affect remedial measures.

Id. at 11:67–12:7.

The '584 patent discloses another use of the method: “to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply remediative resources more effectively and efficiently.” *Id.* at 13:14–19. Thus, “[f]or example, where a positive result(s) is associated with one or more specific production lines, targeted aggressive sanitation is used to resolve the problem.” *Id.* at 13:19–21.

In addition to embodiments directed to food production or other consumables, the embodiment set forth in Example V is directed to environmental monitoring. *See id.* at 14:52–67.

In the context of environmental monitoring, when several samples (water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids) are composited and subjected to enrichment followed by testing to detect environmental contamination, the current invention allows for pinpointing the test lots (e.g., operationally-linked unit(s)) that are positive for the microbe of concern.

Id. at 14:61–67.

D. Relevant Prosecution History

The claims before us were amended in the course of an *inter partes* reexamination proceeding brought by bioMerieux Inc. that included two Board opinions on appeal (Ex. 1007, 1560–1588 (“First Board Opinion”) and Ex. 1007, 1774–90 (Second Board Opinion)). Patent Owner provides an overview of these proceedings at pages 6–20 of the Preliminary Response, which we need not repeat here.

E. Illustrative Claims

Petitioner challenges claims 1–6, 10, 11, 13–20, 22, 23, and 26–33 in this proceeding, of which claims 1 and 17 are independent. Illustrative claim 1 is reproduced below with additional paragraphing and sub-numbering as added in Petitioner’s Claims Listing.

1. **Pre** A method of sampling, testing and validating a plurality of operationally-linked test lots of beef for release into commerce, comprising:

(a)(1) collecting a plurality of portions from each of a plurality of separate operationally-linked test lots of beef, each to be validated for release into commerce, the test lots each comprising an assemblage of one or more specimens from which the portions are collected,

(a)(2) wherein each test lot is separately sampled to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the test lot into commerce;

(b) combining the collected conforming plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

(c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

(d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

(e)(1) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism,

(e)(2) wherein when such testing is negative all of said separate test lots are validated for release into commerce, and

(e)(3) wherein when such testing is positive, each of the individual separate test lots are validated for release into commerce, according to the statistical based sampling plan, by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result for each test lot,

(e)(4) wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate test lots with no requirement for further enrichment thereof, and with no requirement for further sampling in a).

Pet. xv–xvi.

F. Asserted References

Petitioner bases its challenges to the '584 patent on the following references:

Ex. 1012. “Microorganisms in Foods 7: Microbiological Testing in Food Safety Management,” Int’l Comm’n on Microbiological Spec’s for Foods (ICMSF), Kluwer Academic/Plenum Publishers, Chapters 6, 10, 12, 15–17 (2002) (“ICMSF 2002”).

Ex. 1014. Gombas et al., “Survey of *Listeria monocytogenes* in Ready-to-Eat Foods.” 66(4) J. Food Prot., pages 559–569 (2003) (“Gombas”).

Ex. 1017. Price et al., “*Salmonella* Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples,” 23(4) Appl. Microbiol., pages 679–682 (1972) (“Price”).

Ex. 1015. Hughes et al., “*Salmonella* in Foods—A New Enrichment Procedure for Use with the TECRA *Salmonella*

Visual Immunoassay: Collaborative Study,” 82(3) J. AOAC Int’l, pages 634–647 (1999) (“Hughes”).

Ex. 1018. Stewart et al., “Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water,” 85(2) J. AOAC Int’l, pages 395–403 (2002) (“Stewart”).

Ex. 1019. Fratomico et al., “Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method,” 9(2) Food Microbiol., pages 105–113 (1992) (“Fratamico”).

Ex. 1020. D’Haese and Nelis, “Rapid Detection of Single Cell Bacteria as a Novel Approach in Food Microbiology,” 85(4) J. AOAC Int’l, pages 979–983 (2002) (“D’Haese”).

Ex. 1021. D’Aoust, “Update on Preenrichment and Selective Enrichment Conditions for Detection of *Salmonella* in Foods,” 44(5) J. Food Prot., pages 369–374, 393 (1981) (“D’Aoust”).

G. Asserted Grounds of Unpatentability

Petitioner applies the above references in the following ten grounds of unpatentability, grouped here according to “Base Ground” 1, 2, or 3, shown in bold (Pet. 7):

Ground	Claims	35 U.S.C. §	Reference(s)
1	1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29–33	103¹	ICMSF and Gombas
4	3	103	ICMSF, Gombas, and Stewart

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the ’584 patent issued has an effective filing date of August 8, 2005, the pre-AIA versions of § 103 apply.

Ground	Claims	35 U.S.C. §	Reference(s)
6	5, 6, 29, and 30	103	ICMSF, Gombas, and Fratamico
9	28	103	ICMSF, Gombas, and D’Haese
2	1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29, 31–33	103	ICMSF and Hughes
5	3	103	ICMSF, Hughes, and Stewart
7	5 and 29	103	ICMSF, Hughes, and Fratamico
8	6	103	ICMSF, Hughes, and D’Haese
10	28	103	ICMSF, Hughes, and D’Aoust
3	1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29, 31–33	103	Price, ICMSF, and Hughes

In support of its patentability challenges, Petitioner relies, *inter alia*, on the Declaration of James S. Dickson, PhD. *See* Ex. 1041.

II. ANALYSIS

A. Legal Standards

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This ultimate burden never shifts

to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

Petitioner contends that the challenged claims would have been obvious under § 103. Pet. 6. A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness, if present.² *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But, in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *Id.* at 418.

² Patent Owner has not submitted evidence of secondary considerations with its Preliminary Response. Should Patent Owner elect to rely on such evidence, we will consider its weight in view of the full record adduced at trial.

“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Moreover, a precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *KSR*, 550 U.S. at 418. Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

B. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art at the time of the invention (POSA/POSITA), “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 areas and at least four years of experience with validation methodologies." Pet. 11. (citing Ex. 1041 ¶¶ 22–24). Petitioner further contends that a person of ordinary skill in the art would have had "a working knowledge of microbiology," "would have been involved in developing sampling and testing methodologies for analysis of food products ("validation methodologies")," and "would have been familiar with relevant scientific literature and industry regulations, directives, and guidelines relating to validation methodologies." *Id.*

Petitioner supports its proposed definition with the testimony of Dr. Dickson. *See id.* Dr. Dickson notes that he has a PhD in Food Science and Technology, cites several of the peer reviewed papers he coauthored including "[a] new technique for *Escherichia coli* testing of beef and pork carcasses," and identifies himself as one of at least ordinary skill. Ex. 1041, 8, 14, 24.

Patent Owner does not contest Petitioner's definition for the purpose of institution, but argues that Petitioner overestimates the education level of the POSITA. Prelim. Resp. 27–28. In particular, Patent Owner contends that a person of ordinary skill in the art would have had "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." *Id.*

On the preliminary record before us, we provisionally apply Petitioner's proposed definition, as it is supported by the presently unopposed testimony of Dr. Dickson, and appears to be consistent with the prior art, such as ICMSF (The International Commission on Microbiological

Specifications for Foods). *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355, (Fed. Cir. 2001) (the level of ordinary skill in the art may be reflected in the prior art itself); Ex. 1041 ¶¶ 22–24.

C. Claim Construction

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. *See* 37 C.F.R. § 42.100(b). In construing claims, district courts give claims their ordinary and customary meaning, which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner identifies several claim terms and provides constructions for certain terms, including “lots,” “separately sampled,” “combining/compositing,” “enrichment/enriching,” and “validated.” Pet. 31–35. For clarity, we address each of the terms raised by Petitioner.

Patent Owner responds “Petitioner purports to identify five claim terms for construction . . . 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.” Prelim. Resp. 36. For clarity and completeness, we address each of the terms raised by Petitioner, even if we ultimately determine that no construction of a particular term is necessary.

1. “Lots”

Petitioner contends that the ’584 Specification and claims employ various terms to describe ‘lots’ including test lots, “single production lots,”

and “single-unit production lots.” Pet. 31–32 (citing, *e.g.*, Ex. 1001, 5:21–32, 5:33–36, 7:28–35, claims 1, 17). According to Petitioner,

a lot, such as a test lot or single production lot, should be construed as an assemblage of one or more specimens operationally linked in a manner, such as by proximity, time, process step, etc., whereby information derived about the sampled portions is applicable to all specimens of the assemblage, and thus to the lot.

Id. at 32.

Patent Owner states “Petitioner proposes a definition for the term ‘lots’ but fails to identify any issues that depend on how that term is defined.” Prelim. Resp. 37. Patent Owner states that “[n]onetheless, should the Board decide construction is necessary, it should not use Petitioner’s proposed definition because it contradicts the specification and introduces unnecessary ambiguity.” *Id.*

We agree with Patent Owner that the term “lots” does not require construction because on the current record, there is no controversy over the meaning of the term, and neither Petitioner nor Patent Owner identify any way that claim construction impacts the decision. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

We also agree with Patent Owner that the ’584 patent provides definitions that guide the understanding of the term “lots” including teaching:

The term “test lot” or “reportable lot” as used herein to refer to an assemblage of one or more specimens of a medium or process (e.g. assemblage of specimens of air water, solids or

of products of a production process, etc.) where such assemblage can be sampled by taking portions of the one or more specimens thereof, and where the one or more specimens of the assemblage are operationally linked in a manner (e.g. proximity, time, process step, etc.) whereby information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot. In particular instances, portions are synonymous with specimens.

Ex. 1001, 5:21–31. The Specification similarly provides definitions for “product portion,” “test lot sample,” and “single-unit production lot” that provide significant guidance and clarity as to the meaning of these terms.

Ex. 1001, 5:39–49, 5:57–66, 5:33–38.

2. “*Separately Sampled*”

Petitioner asserts “[s]ampling is not specifically defined but the specification indicates ‘the number and selection of single product portions to be combined conform to statistical-based sampling plans which seek to form a typical or average sample that is representative of the test lot (e.g., single production unit) being sampled.’” Pet. 33 (quoting Ex. 1001, 5:52–56).

Petitioner asserts that, in the related litigation, Patent Owner asserted “the inherent meaning of a ‘sample’ implies a collection of elements that would be *representative* of the lot being sampled.” *Id.* (quoting Ex. 1037, 7). Petitioner “proposes that a lot is ‘separately sampled’ when portions are collected from each lot so the resulting lot sample is representative of the lot being sampled.” *Id.* Petitioner also states that “varying the physical location (*i.e.*, proximity) yields representative samples because a POSA would not collect portions/samples from the same exact same location of a meat lot. . . . because ““microbial contaminants are unevenly spread throughout the

products.” *Id.* at 33–34 (citing, e.g., Ex. 1001, 3:5–6, 11:5–12:19). Petitioner further asserts that “the technique for obtaining representative samples depends on the type of product being collected. The relevant variable(s), such as ‘proximity, time, process step, etc.’ are selected by a POSA ‘whereby information derived about sampled portions is applicable to all specimens of the assemblage, and thus to the test lot.’” *Id.* (quoting Ex. 1001, 5:28–30).

According to Patent Owner, “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 32–34. Because Petitioner has failed to show a need for construction, the Board need not construe this term.” Prelim. Resp. 38.

Patent Owner asserts that “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.]’” *Id.* (quoting Ex. 1038, 6). Patent Owner asserts the District Court held 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.” *Id.* at 39 (quoting Ex. 1038, 5).

We agree with Patent Owner that the term “separately sampled” does not require construction; on the current record, there is no controversy over the meaning of the term and neither Petitioner nor Patent Owner identify any way that claim construction may impact our decision. *See Wellman*, 642 F.3d at 1361.

3. “Combining”/“Compositing”

Petitioner notes that the Specification expressly “defines ‘compositing’ as ‘combining a number of single product portions to form one larger sample.’” Pet. 34 (citing Ex. 1001, 5:50–52). According to Petitioner, “[b]ecause the meaning for the synonyms ‘compositing’ and ‘combining’ is clear, construction is unnecessary.” *Id.* (citing Ex. 1041 ¶¶ 350–351. Patent Owner similarly takes the position that “the terms ‘combining’ and ‘compositing’ do not require construction.

We agree with both parties that the terms “combining”/“compositing” do not require construction; we discern no present controversy over the meaning of the term and neither Petitioner nor Patent Owner identify any way that claim construction may impact our decision. *See Wellman*, 642 F.3d at 1361.

4. “Enrichment”/“Enriching”

Petitioner asserts that they agree with Patent Owner’s position in the *Primus* litigation that “‘enriching’ means ‘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.’” Pet. 35 (quoting Ex. 1036, 2). Patent Owner responds that we need not construe these terms because “Petitioner proposes construction for the term(s) ‘enrichment’/‘enriching’ without any showing that construction is needed.” Prelim. Resp. 40.

We agree with both parties that the terms “combining”/“compositing” do not require construction; there is no controversy over the meaning of the terms and neither Petitioner nor Patent Owner identify any way that claim construction may impact our decision. *See Wellman*, 642 F.3d at 1361.

5. “Validated”

Petitioner contends that the Specification defines “[v]alidation” . . . as ‘determining that a particular sample tests negative using the detection assay.’” Pet. 35 (quoting Ex. 1001, 7:1–3; citing 1041 ¶¶ 353–354).

Petitioner also points to the Parties’ joint claim construction statement in the Primus litigation, wherein, in the context of the related ’143 and ’771 patents, Patent Owner agreed that “validate” means “to ‘determine that a particular sample tests negative using the detection assay.’” *See id.* (quoting Ex. 1036, 2).

Patent Owner asserts that the “[c]onstruction 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.” Prelim. Resp. 41. Patent Owner asserts that the instant claims “expressly state that validation requires determining a lot is cleared for release into commerce.” *Id.* at 42. According to Patent Owner, “the specification expressly defines ‘validation’ as including clearing lots ‘for release’ into commerce.” *Id.* (citing Ex. 1001, 7:1–10, 4:22–25, 5:1–3). Patent Owner also asserts the “working examples in the specification reiterate that efficiently determining releasability is a key benefit over the prior art.” *Id.* at 43 (citing Ex. 1001, 11:46–54, 13:6–10, 14:8–14).

Patent Owner further asserts that “validation without determining releasability serves no purpose.” *Id.* at 44. Patent Owner also asserts that “Patent Owner amended the claims to clarify this distinction, including adding ‘for release into commerce.’ . . . When doing so, the Patent Owner explained this was an inherent part of validation.” *Id.* at 45 (citing Ex. 1007, 232–40, 478, 251, 487, 867). Moreover, “[t]he Examiner acknowledged that

these amendments “merely clarify and do not significantly change the scope of the claims.” *Id.* (citing Ex. 1007, 867).

We find that Petitioner has the better position on the current record, as we explain further below.

We first turn to the Specification, which is, “[i]n most cases, the best source for discerning the proper context of claim terms.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004). The Specification of the ’584 patent provides a definition of “validation,” stating

[t]he term “validation” 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, 7:1–10.

This definition requires that a “validation” determines that “a particular sample tests negative.” The initial definition sentence makes no mention of “cleared for release” as necessary for “validation.” Rather, the definition only refers to “cleared for release” in the more limited situation where a particular composite sample “tests negative all single-unit production lot samples,” and even then, the “cleared for release” is a separate step that occurs after the samples are “validated.”

We also disagree with Patent Owner’s assertion that “validation without determining releasability serves no purpose.” Prelim. Resp. 44.

Although that might arguably be correct if the Specification was limited to just one disclosed particular embodiments, the statement is not applicable to the broader scope encompassed by the claims of the related '143 and '771 patents and the Specification shared with the '584 patent challenged here. In particular, while the Specification certainly discusses microbial screening for food safety, the Specification also states:

The methods are broadly applicable to many product areas including, but not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish and other seafood, produce, juices, dairy products, dry goods (cereals nuts, etc.), fruits and vegetables, herbs and spices, and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, air samples taken by impingers and filtration, etc.), pharmaceuticals and other type of samples to be analyzed using microorganism enrichment-detection protocols.

Ex. 1001, 1:24–33. The patent envisions performing the claimed method on environmental samples such as wastewater, soil, or air samples, along with other samples that would simply be used to determine the safety of waste water, soil, or air. The Specification therefore clearly contemplates application of the method, including “validation,” to samples that would not be “cleared for release” into commerce.

We also are unpersuaded by Patent Owner’s focus on Example I (relating to beef processing) of the '584 patent to the exclusion of Examples II and V (directed to Ready-to-Eat food stuffs and environmental monitoring, respectively). *See* Prelim. Resp. 42–44. Example V states:

In the context of environmental monitoring, when several samples (water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids) are composited and subjected to enrichment, followed by testing to detect environmental contamination, the current invention allows for

pinpointing the test lots (e.g., operationally-linked unit(s)) that are positive for the microbe of concern.

Ex. 1001, 14:53–67. Example II of the ’771 patent explains a situation “where a positive result(s) is associated with one or more specific production lines, targeted aggressive sanitation is used to resolve the problem.”

Ex. 1001, 13:19–26.

Thus, whether a sample is ground beef intended for sale at a butcher shop or wastewater to ensure that filtration systems are properly functioning to exclude contamination, “validation” indicates that samples test negative and positive, and that validated samples may be used to identify dangerous environmental conditions or production lines in need of cleaning. The ’584 patent simply does not equate “validation” with a requirement that the product be “cleared for release” into commerce. Indeed, passages relied on by Patent Owner make clear that validation and release are separate and distinct concepts. Patent Owner points to, for example, the Specification’s teachings that “[i]f a negative result is obtained . . . then all of the individual single-unit production lots are *validated and releasable*,” that lots “yield[ing] a negative result are thereby *validated and are releasable* into commerce,” and that a negative result may permit “[t]he *release of the validated* 1,928,000 lbs of beef trim into commerce.” See Prelim Resp. 43–44 (citing Ex. 1001, 5:1–3, 13:6–10, 14:8–14). At best, we read Patent Owner’s citations as indicating that validation may be a prerequisite to designating a product as appropriate for release into commerce; we do not read the two terms as co-extensive.

This interpretation of “validated” as not requiring “cleared for release” is also consistent with the claim construction order in the Primus Litigation, which states: “As an initial matter, the parties agree to the

following constructions, with respect to terms used in the ‘143 and ‘771 patents: To ‘validate’ means to ‘determine that a particular sample tests negative using the detection assay.’” Ex. 1038, 4. Thus, in the context of the district court litigation, Patent Owner agreed to a definition of “validate” that did not include a further requirement of “cleared for release.”

We therefore preliminarily adopt a definition of “validation” based on the ‘584 patent’s express definition that the “term ‘validation’ as used herein with respect to production lots refers to determining that a particular sample tests negative using the detection assay.” Ex. 1001, 7:1–10.

6. *“for release into commerce”*

Unlike the claims at issue in the related ‘143 and ‘771 patents, the independent claims at issue here repeatedly recite that test lots are validated “for release into commerce”—e.g., claim 1’s recitation that “when such testing is negative all of said separate single-unit production lot samples are validated for release into commerce.” Petitioner takes the position—as did the Board in the First Board Opinion—that “‘for release into commerce’ is not limiting because it encompasses a mental step that is not translated into a physical act.” Pet. 35 (citing Ex. 1007, 1568–69). The First Board Opinion explained that “[a]ppreciating that such samples may be released into commerce does not change how the claim is carried out and is thus not considered to limit the claim.” Ex. 1007, 1569 (citing, *e.g.*, *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999)).

Patent Owner urges that we disregard the Board’s finding because it is based on the broadest reasonable interpretation (BRI) claim construction standard, and is superseded by the Second Board Opinion, which, according to Patent Owner, “repeatedly rel[ies] on the distinction between verification

and validation to overcome the prior art and to show industry skepticism.” Prelim. Resp. 51 (referencing Ex. 1007, 1774–90).

Patent Owner’s arguments are unavailing on the present record. Patent Owner provides no explanation as to why we should reach a different result under *Phillips*. Nor does Patent Owner make clear why a distinction between verification and validation bears on whether the stated purpose “for release into commerce,” should be read as limiting. Moreover, we understand the Board’s reversal of the obviousness rejections to have been largely based on amendments requiring “test lots to be ‘operationally-linked’”; limiting the independent claims to the testing of beef (claim 1) or meat and poultry (claim 17); and a re-evaluation of the claim steps as compared to the prior art. *See* Ex. 1007, 1787–89 (finding that “a preponderance of the evidence establishes that the claimed modular composite testing is responsible for the commercial success”). Further, the Second Board Decision does not address the claim language “for release into commerce,” and we do not read the Decision as undermining its prior determination that this language does not limit the claim. Accordingly, on the record before us, we find no reason to disturb the finding of the First Board Decision that “for release into commerce” is non-limiting.

The above determinations are preliminary. If the parties believe that further argument on any claim term’s interpretation is needed to resolve any disputed issue, they are encouraged to provide such argument in briefing (in a designated claim construction section, as opposed to merely embedding claim construction positions within argument on the merits) permitted in trial. The parties do not identify any other terms at issue. We therefore find

that there are no other terms that need claim construction at this time. *See Wellman*, 642 F.3d at 1361.

D. Overview of Asserted References³

Petitioner bases its challenge on the following eight references. Patent Owner does not presently contend that any of these references fail to qualify as prior art.

1. Overview of ICMSF (Ex. 1012)

ICMSF is a 2002 publication of the International Commission on Microbiological Specifications for Foods titled “Microorganisms in Foods 7” that discusses microbiological testing in food safety management. Ex. 1012, title page. ICMSF teaches the “particular choice of sampling procedure and the decision criteria make up the *sampling plan*. Proper drawing of samples is essential if the decision making criteria of the sampling plan are to give unbiased results.” *Id.* at 115.

ICMSF teaches “[m]any different types of samples are collected and submitted to the laboratory for analysis. Some are sample units from lots or consignments of food or ingredients for lot acceptance determination.” *Id.* at 225. ICMSF teaches a “sample unit is a small portion of the lot in which the distribution of both numbers and types of microorganisms should be representative of the whole lot.” *Id.* at 225. ICMSF has defined a *lot* as follows:

In the commercial sense, a lot is a quantity of food supposedly produced under identical conditions, all packages of which

³ Petitioner and Dr. Dickson further highlight six “State-of-the-Art” references, which we need not address here. *See* Pet. 29–30; Ex. 1041 ¶¶ 271–329.

would normally bear a lot number that identifies the production during a particular time interval, and usually from a particular line, retort, or other critical processing unit. Statistically, a lot is considered as a collection of units of a product from which a sample is drawn to determine acceptability of the lot.

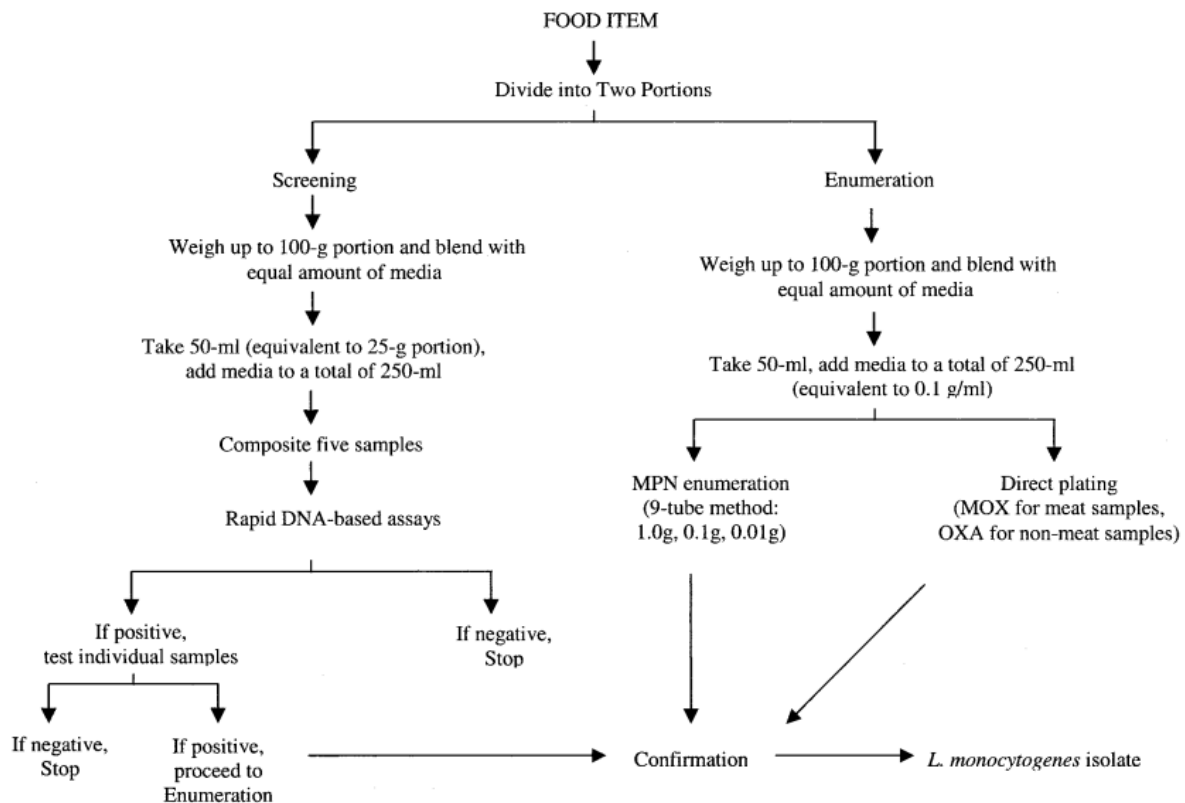
Id. at 327. ICMSF teaches, “[i]f a consignment consisting of a mixture of production batches is treated as one lot, a rejection of an acceptable lot (i.e., the situation the producer’s risk refers to) can have severe consequences, as the whole lot will be affected by this decision, even though only a few of the production batches within the lot may be of poor quality.” *Id.* at 119. ICMSF teaches “[t]reating the individual production batches as lots, and coding appropriately, permits more precise identification of poor quality food and, at the expense of more analyses, can result in the rejection of less units from the whole consignment.” *Id.*

ICMSF teaches that “[t]o 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.” *Id.* at 187. ICMSF teaches 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.” *Id.* ICMSF teaches “[t]here is the very great technical advantage of combining many analytical units for bacteriological examination.” *Id.* at 188.

2. Gombas (Ex. 1014)

Gombas is an article published in the Journal of Food Protection in 2003, titled “Survey of *Listeria monocytogenes* in Ready-to-Eat Foods.” Gombas teaches “to collect 2,500 samples of each of two types of products, luncheon meats and deli salads . . . for a total of 5,000 samples per food type, or 10,000 samples” later doubling “the total number of luncheon meat and deli salad samples collected.” Ex. 1014, 561. Gombas teaches “[s]amples were assigned codes, and the following product information was recorded for the luncheon meats and deli salad samples: sampling location.” *Id.* at 563.

Figure 1 of Gombas is reproduced below:



“FIGURE 1. Detection and enumeration of *L. Monocytogenes* in RTE food samples.” *Id.* at 563. Gombas teaches:

Each sample was divided into two portions for screening and enumeration. For screening, approximately half (up to 100 g) of a sample was aseptically transferred to a sterile stomacher bag and blended with an equal amount of enrichment broth. . . . For northern California samples, demi-Fraser broth was used as the enrichment broth for all products. After blending, 50 g of the homogenate was added to 200 ml of enrichment broth and stomached for 1 min. This procedure resulted in a detection sensitivity equivalent to that of the current regulatory methods (i.e., 1 CFU/25 g). The initial sample-blending step was performed to account for the potential heterogeneous distribution of *L. monocytogenes* in the sample. The 250-ml enrichment was incubated at 35°C for 24 ± h.

Id. at 563. Gombas teaches that a portion of the enriched California sample “was transferred to 10 ml of morpholinepropanesulfonic acid-Listeria enrichment broth and incubated . . . After the secondary enrichment, 1 ml of the broth culture was used for screening with the BAX assay.” *Id.* at 564.

Gombas teaches, “[f]or California samples, five 1-ml samples of secondary enrichment broths were composited, and the 5-ml composite was tested by the BAX assay.” *Id.* Gombas teaches “[i]f a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay.” *Id.*

3. Price (Ex. 1017)

Price is an article published in the Journal of Applied Microbiology in 1972, titled, “*Salmonella* Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples.” Ex. 1017, 679. Price discloses a method “for testing multiple food samples for *Salmonella* without loss in sensitivity.” *Id.* at Abstract. According to Price,

[a]s many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis. The procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found.

Id. According to Price, “*Salmonella* testing of pooled pre-enrichment broths provides increased consumer protection for a given amount of analytical effort as compared to individual sample analysis” *Id.*

4. Hughes (Ex. 1015)

Hughes is an article published in the Journal of AOAC International in 1999, titled “*Salmonella* in Foods—A New Enrichment Procedure for Use with the TECRA *Salmonella* Visual Immunoassay: Collaborative Study.” Ex. 1015, 634. Hughes discloses the results of a study of a new enrichment procedure (TECRA method) for *Salmonella* testing of various foods including milk chocolate, dried egg, and raw turkey, which was “adopted First Action by AOAC INTERNATIONAL.” *Id.* at Abstract. Hughes’s “Preparation of Sample” section sets forth a four-phase method, including the steps of (a) pre-enrichment “in noninhibitory broth to initiate growth of *Salmonella*,” (b) selective enrichment in two selective broths, (c) post-enrichment to “[r]emove selective broths,” and (d) preparation of sample for enzyme immunoassay (“EIA”), which includes combining aliquots from each of the two selective broth samples. *Id.* at 636–37.

5. Stewart (Ex. 1018)

Stewart is an article published in the Journal of AOAC International in 2002, titled “Comparison of Assurance Gold *Salmonella* EIA, BAX for

Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water.” Ex. 1018, 395.

Stewart teaches the “large number of foodborne illnesses linked to raw vegetable sprouts led . . . [to recommendations for] testing of every sprout production batch for the presence of *Salmonella* and *Escherichia coli* O157:H7, the 2 primary infective agents associated with sprout consumption.” Ex. 1018, 395. Stewart teaches samples of “[s]prouts (25 g) and irrigation water (25 mL) samples were added to 225 mL appropriate enrichment broth.” *Id.* at 398. Stewart teaches that in one assay, the samples were subjected to

selective enrichment by transfer of 0.1 mL BPW + n pre-enrichment to 10 mL Rappaport-Vassiliadis (RV) broth and 1.0 mL pre-enrichment to 10 mL tetrathionate (TT) broth, with incubation at 42°C for 5–8 h; and post-enrichment by transfer and combination of 0.5 mL RV and 1 mL TT into a single tube containing 10 mL prewarmed trypticase soy broth supplemented with novobiocin (TSB + n) at 10 µg/mL with incubation for 16–20 h at 42°C.

Id.

6. Fratamico (Ex. 1019)

Fratamico is an article published in the journal Food Microbiology in 1992, titled “Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method.” Ex. 1019, 105.

Fratamico teaches “[s]everal methods have been developed for the detection of *E. coli* O157:H7 in foods and other samples.” *Id.* Fratamico teaches magnetic beads coated with rabbit antiserum against *E. coli* O157,

the combination named DB-0157. *Id.*, 106. Fratafico teaches “that immunomagnetic separation is a simple and rapid technique and can be used for the selective recovery of *E. coli* O157:H7 from foods.” *Id.* at 109.

7. D’Haese (Ex. 1020)

D’Haese is an article published in the Journal of AOAC International in 2002, titled “Rapid Detection of Single Cell Bacteria as a Novel Approach in Food Microbiology.” Ex. 1020, 979.

D’Haese teaches that “Pathogens, spoilage organisms, or indicator bacteria can be detected in food by various methodologies. Conventional culturing still remains the gold standard, as the demonstration or enumeration of target bacteria in a liquid broth or on solid agar media is unmistakable proof of their viability.” *Id.*

8. D’Aoust (Ex. 1021)

D’Aoust is an article published in the Journal of Food Protection in 1981, titled “Update on Preenrichment and Selective Enrichment Conditions for Detection of *Salmonella* in Foods.” Ex. 1021, 369.

D’Aoust teaches:

Standard cultural procedures for isolation of *Salmonella* in foods are time-consuming and require a minimum of 4-5 days to obtain presumptive evidence of *Salmonella* contamination. These procedures generally include preenrichment of food samples in a non-selective broth medium, enrichment in a selective broth medium, isolation of presumptive colonies on differential plating media, biochemical screening and serological confirmation of presumptive isolates.

Id. (references omitted). D’Aoust teaches “[s]elective enrichment inhibits growth of non-salmonellae and facilitates isolation of *Salmonella* on differential plating media.” *Id.*

E. Petitioner's Obviousness Contentions

Petitioner challenges the '548 patent's claims 1–6, 10, 11, 13–20, 22, 23, and 26–33 of on ten Grounds, including three “base” grounds (Grounds 1–3, bolded above in the table at Section I.G), involving combinations of ICMSF, Gombas, Price, and Hughes. *See* Pet. 7. Because Patent Owner does not presently address Petitioner's secondary references, nor any limitation specific to the dependent claims, we focus on the Grounds 1–3 and the challenged independent claims (claims 1 and 17).

1. Ground 1: ICMSF and Gombas

In Ground 1, Petitioner challenges claims 1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29–33 as obvious in view of ICMSF and Gombas. Pet. 7, 36–54. Patent Owner opposes. Prelim. Resp. 28–36, 51–57.

Addressing independent claims 1 and 17, Petitioner contends that “ICMSF discloses steps (a)-(d) and most of step (e) and Gombas is relied on primarily for disclosing steps (c)-(e).” Pet. 36. Petitioner refers to steps (a)–(e) as the collecting, combining, enriching, wet compositing, and testing steps, respectively. *See generally*, Pet. 2.

With respect to the “collecting step,” step (a), Petitioner cites ICMSF as teaching

[m]any different types of samples are collected and submitted to the laboratory for analysis. Some are sample units from lots or consignments of foods or ingredients for lot acceptance determination. . . . A sample unit is a small portion of the lot in which the distribution of both numbers and types of microorganisms should be representative of the whole lot.

Pet. 38 (quoting Ex. 1012, 225).⁴ Petitioner further points to ICMSF’s definition of a “lot” as “a quantity of food supposedly produced under identical conditions, all packages of which would normally bear a lot number that identifies the production during a particular time interval, and usually from a particular line, retort, or other critical processing unit.” *Id.* at 39–40 (quoting Ex. 1012, 327). Petitioner further asserts that “ICMSF advocates use of a ‘statistically based sampling plan,’” and “[s]tatistically, a lot is considered as a collection of units of a product from which a sample is drawn to determine acceptability of the lot.” *Id.*

As to the “combining step,” step (b), Petitioner cites ICMSF as teaching 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.” Pet. 41–42 (quoting Ex. 1012, 187). Petitioner also references ICMSF’s teaching that, “[t]here is the very great technical advantage of combining many analytical units for bacteriological examination in systems with $c = 0$, because a single positive decides the outcome.” Pet. 42; Ex. 1012, 188.

Also with respect to step (b), Petitioner contends that the requirement for each separate composited lot sample to be attributed to a particular corresponding separate lot, Petitioner points to ICMSF’s teaching that

It is therefore helpful . . . to give identifiable code numbers to batches (lots) of food produced over short time periods (e.g., a

⁴ We generally omit herein any emphasis the parties have added to direct quotations of the cited art.

day or part of a day) for particular processes. . . . Treating the individual production batches as lots, and coding appropriately, permits more precise identification of poor quality food and, at the expense of more analyses can result in the rejection of less units from the whole consignment.

See Pet. 42–43 (quoting Ex. 1012, 119). Petitioner also cites Gombas as teaching “[s]amples were assigned codes, and the following product information was recorded for the luncheon meats and deli salad samples: sampling location.” Pet. 43; Ex. 1014, 563.

As to the “enriching step,” step (c), Petitioner relies on ICMSF’s teaching that, “[t]o 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.” Pet. 41 (quoting Ex. 1012, 187). Petitioner points to Gombas’ teaching that

a sample was aseptically transferred to a sterile stomacher bag and blended with an equal amount of enrichment broth . . . This procedure resulted in a detection sensitivity equivalent to that of the current regulatory methods (i.e., 1 CFU/25 g). The initial sample-blending step was performed to account for the potential heterogeneous distribution of *L. monocytogenes* in the sample.

Pet. 44–45 (quoting Ex. 1014, 563). According to Petitioner, “Gombas avoids potential heterogenous distribution and ensures the target microorganism is at least substantially uniform in a sample by blending the sample and the enrichment broth in the stomacher bag to yield a homogenate. *Id.* at 45 (citing Ex. 1014, 563).

The “wet compositing step,” step (d), requires combining portions of enriched samples. Pet. 46. With respect to step (d), Petitioner points to ICMSF’s teaching that “[t]o 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,” accordingly, “considerable reductions may be made in the cost of laboratory analyses by compositing (pooling) analytical units.” Pet. 41, 46–47 (quoting Ex. 1012, 187). As further support, Petitioner points to Gombas’ teaching that “[u]p to five like-product samples were composited and screened. . . . For California samples, five 1-ml samples of secondary enrichment broths were composited, and the 5-ml composite was tested by the BAX assay.” Pet. 47 (quoting Ex. 1014, 564).

With respect to the portion of the “testing step” that requires “testing of the modular composite sample, using a suitable detection assay,” step (e)(1), Petitioner cites to Gombas, which teaches that “five 1-ml samples of secondary enrichment broths were composited,” and “the 5-ml composite was tested by the BAX assay according to the manufacturer’s procedures.” Pet. 47–48 (quoting Ex. 1014, 564; citing Ex. 1041 ¶¶ 397–398).

As to the portion of step (e) that requires “when such testing is negative all of said separate [test lots/single-unit production lot samples] are validated for release into commerce” (step (e)(2)), Petitioner argues that the language “for release into commerce” is non-limiting. Pet. 49. Petitioner also references sampling plans described in the ICMSF

that include the requirement is $c = 0$, which indicates the testing is negative. [Ex. 1012] at 118, 183-90, 309, 325, 326. A negative test result (*id.*, 113-15, 325, 326) is the expected and desired outcome to determine meat is not contaminated and is safe for consumption (*id.*, 184-89) such that a lot is validated and it is “commercially possible to market” (*id.*, 185) the meat.

Pet. 49. ICMSF teaches, for example, that

[s]ince cooking will kill *E. coli* O157:H7, this suggests that a sampling plan of $n = 15$, $c = 0$ (case 13) would be appropriate. However, approximately 20% of consumers continue to consume rare ground beef. While it would be expected that partial cooking may reduce the number of *E. coli* O157:H7, cooking to a rare state cannot be depended on to eliminate the hazard. This leads to a sampling plan of $n = 30$, $c = 0$ (case 14) as being appropriate for rare ground beef.

Ex. 1012, 326.

Petitioner also cites to Gombas, which states “[i]f a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually.” Pet. 50–51 (quoting Ex. 1014, 564; citing Ex. 1041 ¶¶ 403–404).

As to the portion of step (e) that requires further testing individual lots after a positive test result (step (e)(3)), Petitioner relies on ICMSF, Gombas, and the Dickson Declaration. Pet 50–52 (citing Ex. 1012, 119, 191; Ex. 1014, 564). Summarizing the asserted art, Dr. Dickson states:

ICMSF discloses validating for release into commerce (Ex. 1012 at 113–15 (§§ 6.2–6.6), 118–19 (§§ 6.9–6.10), 184–85 (§ 10.2), 325–27 (§§ 17.5.3–17.5.3.4); *see also id.* at 186–89 (§ 10.4–10.6)) according to a statistically-based sampling plan (*id.* at 113 (§ 6.1); *see also id.* at 115–18 (§§ 6.4–6.8), 184 (§ 10.2), 319–21 (§§ 17.2.3.3–17.2.3.4), 326–30 (§§ 17.5.3.1–17.6), as described regarding steps (a) and (e)(2). Reading ICMSF and Gombas, a POSA would understand that after the composited samples test positive, then the individual samples used to form the composited sample are individually tested with the same or a more sensitive protocol to determine which of the separate composited lot samples is positive for the target microbe(s).

Ex. 1041 ¶ 410. Dr. Dickson further states “a POSA would also recognize that any lots corresponding to any negatively testing composited lot samples are then considered to be validated.” *Id.* ¶ 411.

The “No Requirement” element, step (e)(4), requires that “the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate [test lots/single-unit production lots] with no requirement for further enrichment thereof, and with no requirement for further sampling in a).” According to Petitioner, “ICMSF and Gombas disclose selective enrichment so there is no requirement for further enrichment,” moreover, “Gombas explicitly indicates portions of the enrichment cultures are retained for further testing; thus, there is no need for further sampling in Gombas.” Pet. 52. Relying on the testimony of Dr. Dickson, Petitioner contends that “the negative limitation of step (e)(4) is disclosed by and is obvious based on the combination of ICMSF and Gombas.” *Id.* at 52–53 (citing Ex. 1041 ¶¶ 412–415).

Petitioner contends a “POSA would have been motivated to modify ICMSF based on Gombas under the teaching-suggestion-motivation test^[5] so portions of the enriched, retained samples are further tested after a positive test of a composite sample by the same protocol, with a reasonable expectation of success for efficient validation.” Pet. 53–54 (citing Ex. 1041 ¶¶ 417–419). “Moreover,” Petitioner contends,

⁵ In accord with *KSR*, “[t]he TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence . . . aris[ing] before the time of the invention” and “remains the primary guarantor against a non-statutory hindsight analysis.” *Ortho-McNeil Pharm., Inc. v. Mylan Lab’ys, Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008).

a POSA would have improved ICMSF with the similar methods of Gombas to yield efficient validation, which is a predictable result. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). A POSA would have simply substituted steps of ICMSF, as described above, with those of Gombas so portions of the enrichment cultures are retained and are further tested after a positive test of a composite sample by the same protocol for predictably efficient validation. MPEP § 2143(I)(B); Dickson ¶ 420.

Id. at 54.

2. Ground 2: ICMSF and Hughes

In Ground 2, Petitioner challenges claims 1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29, 31–33. Pet. 54–60. Patent Owner opposes. Prelim. Resp. 28–36, 51–55, 57.

According to Petitioner, “ICMSF discloses steps (a)-(d) and most of step (e) while Hughes discloses steps (c)-(e).” Pet. 54–55. Petitioner relies on its earlier discussion of ICMSF, in whole or in part, for steps (a)-(d). Pet. 55–58.

Further regarding to step (c), Petitioner contends that “Hughes instructs that, after pre-enrichment, portions of the ‘incubated pre-enrichment mixtures’ should be transferred to two separate selective enrichment broths . . . and incubated for 16-20 hours at 41°-43°C.” Pet. 56 (citing Ex. 1015, 636; Ex. 1041 ¶¶ 426–428). Relying on the testimony of Dr. Dickson, Petitioner states that Hughes’ “long incubation at an elevated temperature and mixing ensures the target microbial agent or organism reaches detectable levels and becomes substantially uniform throughout the separate lot samples.” *Id.* (citing Ex. 1041 ¶¶ 426–428).

With respect to step (d), Petitioner points to Hughes’ teaching “to ‘[c]ombine equal volumes (0.5-1 mL) from each M broth tube in a clean

screw-cap tube.” *Id.* at 56. (citing Ex. 1015, 638). Thus, Petitioner contends, “Hughes instructs combining removed portions of enrichments to provide a modular composite sample.” *Id.* at 56–57 (citing Ex. 1015, 638; Ex. 1041 ¶¶ 429–430).

With respect to the “testing” aspect of step (e)(1), Petitioner contends “Hughes states testing of the composite sample is ‘by an enzyme immunoassay (EIA) method.’” Pet. 57 (citing Ex. 1015, 635, 638; Ex. 1041 ¶¶ 431–432).

Addressing the “Tested Negative” aspect of step (e)(2), Petitioner contends that “[b]ecause Hughes explains the steps to be taken when testing is positive (*see* § XII-B-1-h *infra* [(referring to the Petition)]), a POSA would also expect negative testing results,” moreover, “determining meat is safe for consumption so it may be released into commerce is the well-understood point of testing meat.” Pet. 56 (citing Ex. 1015, 638; Ex. 1041 ¶ 434).

Regarding the “further testing after positive test” aspect of step (e)(3), Petitioner contends that Hughes “explicitly teaches retention of the enriched lot samples for further testing after a positive result. Hughes provides instructions to refrigerate the “remaining M broth and TT and Rappaport-Vassiliadis R10 tubes [that were enriched] for culture confirmation of any EIA-positive samples.” Ex. 1015, 638.” Pet. 58. Petitioner also contends “Hughes indicates ‘[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must be streaked on selective media.’” *Id.* (citing Ex. 1015, 635). Culture confirmation using streaking is more sensitive than the EIA method, as was commonly understood and

confirmed by the teachings of D’Haese.” *Id.* (citing Ex. 1018, 979; Ex. 1041 ¶ 436).

With further respect to the “No Requirement” aspect of step (e)(4), Petitioner contends that, as with Gombas, “Hughes explicitly indicates portions of the enrichment cultures are retained for further testing; thus Hughes has no need for further sampling.” Pet. 58 (citing Ex. 1041 ¶ 437).

Petitioner further contends that a person of ordinary skill in the art would have been motivated to modify ICMSF based on Hughes under the teaching-suggestion-motivation test. ICMSF extols the efficiency benefits of traceability (*see* § XII-A-1-c *supra*) and Hughes would have motivated a POSA to modify ICMSF so portions of the enrichment cultures are retained (*see* §§ XII-B-1-c and XII-B-1-d *supra*) and are further tested after a positive test of a composite sample by a more sensitive protocol (*see* XII-B-1-h *supra*) with a reasonable expectation of success for efficient validation. Dickson ¶ 438. Additionally, because ICMSF and Hughes disclose selectively enriching prior to removing portions, a POSA would have considered the enrichment sufficient to enable validation of the lots without further enrichment or sampling. *See* XII-B-1-i *supra*. Ex. 1041 ¶¶ 439-40.

Pet. 59. Citing *KSR*, Petitioner further argues that the skilled artisan would have predictably “substituted steps of ICMSF, as described above, with those of Hughes so portions of the enrichment cultures are retained and are further tested after a positive test of a composite sample by a more sensitive protocol for predictably efficient validation.” *Id.* at 59–60 (citing Ex. 1041 ¶ 441).

3. Ground 3: Price, ICMSF, and Hughes

In Ground 3, Petitioner challenges claims 1, 2, 4–6, 10, 11, 13–20, 22, 23, 26, 27, and 29, 31–33. Pet. 60–75. Patent Owner opposes. Prelim. Resp. 28–36, 51–57.

Petitioner relies on its earlier discussions of ICMSF and Hughes, in whole or in part, for steps (a)–(e). Pet. 60–68. In addition, Petitioner relies on Price as “disclos[ing] most of steps (a)–(e) except it is not related to meat and involves the pooling of pre-enrichments, not enrichments.” *Id.* at 60.

Petitioner states, for example, that

Price’s teachings relevant to step (a) are based on standard practices as described in BAM 1969 (Ex. 1032, 1 (§ 10.04), which cites to JAOAC 1967 (Ex. 1033, 234). Ex. 1017, 679, 682; Dickson ¶¶ 445–52. IEH’s diagram of Price (reproduced below) shows step 1 corresponds to IEH’s step (a), with instructions to “[t]ake individual portions . . . from each Sample.” Ex. 1007, 298.

Pet. 61–63.

With respect to step (b), Petitioner states “[w]hile Price does not explicitly disclose step (b), a POSA would have understood Price to implicitly disclose this step based on the inherent mixing involved with dry food materials.” *Id.* at 63 (citing Ex. 1041 ¶¶ 454–456).

With respect to step (c), Petitioner points to Price’s teaching that “[i]n the multiple pooling of pre-enrichment broth cultures . . . , 1-ml quantities of cultures were transferred, generally, to a volume of enrichment broth,” and “problems with interfering organisms may warrant the use of direct selective enrichments.” *Id.* at 63 (citing Ex. 1017, 682; Ex. 1041 ¶¶ 457–460).

Petitioner further points to Board’s finding in the First Board Opinion that

“there is a suggestion in Price (at 682) . . . of direct enrichment.” *Id.* (citing Ex. 1007, 1576).

Addressing step (d), Petitioner states “Price discloses wet compositing as ‘[s]amples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage.’” *Id.* at 64 (citing Ex. 1017, 679; Ex. 1041 ¶¶ 462–463).

With further respect to the “testing” aspect of step (e)(1), Petitioner contends that Price teaches “[t]esting the composite sample using a detection assay for *Salmonella*.” *Id.* (citing Ex. 1017, 680 (Figure 1), 681; Ex. 1041 ¶ 465).

With respect to the “Tested Negative” aspect of step (e)(2), Petitioner contends that “Price states ‘a test procedure that gives a single negative answer for many negative samples offers an important saving in the analytical effort required for quality control.’” *Id.* at 64 (citing Ex. 1017, 679; Ex. 1041 ¶ 467).

Addressing the “further testing after positive test” aspect of step (e)(3), Petitioner points to Price’s teachings that “a portion of each pre-enrichment is . . . retained . . . for later reference to the individual samples,” and “[i]f the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.” *Id.* at 64 (citing Ex. 1017, 679; Ex. 1041 ¶ 469).

Petitioner contends that reasons to combine the asserted art with a reasonable expectation of success “are plentiful.” *See* Pet. 66–68 (citations omitted). “For example,” Petitioner states,

Price (Ex. 1017, 679) and ICMSF (Ex. 1012, 187) extol pooling samples to increase efficiency while Hughes's implementation has the same benefits. Additionally, Price's framework provided a trajectory leading to industry acceptance of two-stage compositing for testing meat in ICMSF. Ex. 1012, 187, 188. A POSA would have also been motivated to pool enrichments as taught by ICMSF and Hughes instead of Price's pre-enrichments to eliminate the need to wait for the selective enrichment process when retesting after a positive test.

Id. at 67 (further citing Ex. 1041 ¶¶ 475–479).

F. Analysis

Patent Owner contends that we should deny the Petition based on the reasons discussed below.

1. Delineation of the Asserted Grounds

Patent Owner contends

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 eight elements labeled (a) through (e)(4). Each ground asserts an obviousness theory based on a combination references connected by "and/or" for each of the elements.

Prelim. Resp. 29. Patent Owner contends "[e]ach ground's use of 'and/or' multiplies the ground into hundreds of possible combinations" *Id.* at 30.

Patent Owner contends "[n]either the Board nor patentee have any meaningful opportunity to address even the simplest ground (ground 2) containing over 700 potential combinations, let alone the more than 200,000 potential combinations under all grounds." *Id.* at 30. Patent Owner contends that in *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019) the Board explained that "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 31 (citing *Adaptics* at 21). Petitioner also cites *Avant* for the proposition that “failure to explain the proposed grounds of unpatentability with particularity is procedurally unfair to Patent Owner.” *Avant Tech., Inc. v. Anza Tech., Inc.*, IPR2018-00828, Paper 7 at 13 (PTAB Oct. 16, 2018).

We do not read the Petition as asserting overly “voluminous and excessive grounds” akin to those which led to the denial of institution in *Adaptics*. See *Adaptics*, Paper 20, 18. Unlike in *Adaptics* where Petitioner’s recurrent “use of ‘and/or’ . . . yield[s] hundreds of possible combinations” among ten references, the instant Petition uses four primary references in three clearly delineated Base Grounds (Grounds 1–3). See *Adaptics* at 19; Pet. 7. Petitioner here addresses independent claims 1 and 17 (as well as all challenged dependent claims except claims 3 and 28) under the three Base Grounds (Grounds 1–3). And, although Petitioner further challenges a subset of dependent claims under the remaining Grounds, each of these are predicated on one of the three Base Grounds. Notably, none of the Petitioner’s grounds employs the “and/or” language criticized in *Adaptics*. As such, we are not persuaded that undue effort would be required to address the asserted combinations.

This difference between the instant Petition that at issue in *Adaptics* is particularly stark where, in *Adaptics*, a ground simply identified alternative teachings from each of the ten recited references without any substantive analysis. See *Adaptics*, Paper 4, 62–63. In contrast, the grounds of the current Petition are sufficiently detailed to place Patent Owner on notice as to the arguments that are at issue. Not surprisingly, Patent Owner has not

pointed to any specific arguments for which it alleges there is confusion regarding the combination of references in play.

2. Incorporation of the Dickson Declaration

Patent Owner argues that we should deny institution because the Petition incorporates “large swaths” of Dr. Dickson’s Declaration in contravention of our rules. *See* Prelim. Resp. 32–34. Patent Owner contends that, “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.” *Id.* at 33–34 (citing Pet. 7). “Similarly,” Patent Owner argues, “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 34 (citing Pet. 9). Accordingly, Patent Owner contends “the petition here should be denied for attempting to subvert the statutory word count and violating the Board’s prohibition against incorporate[ion] by reference.” 37 C.F.R. § 42.6(a)(3).” *Id.*

While we agree with Patent Owner that “it is improper to incorporate by reference arguments from one document into another document,” not every statement made by a declarant needs to be repeated in a brief to avoid incorporation by reference. *See Cisco Sys., Inc. v. C-Cation Tech., LLC*, IPR2014-00454, Paper 12, 10 (PTAB Aug. 29, 2014) (informative) (citing 37 C.F.R. § 42.6(a)(3)); *Sumitomo Elec. Indus., Ltd. v. United Techs. Corp.*, IPR2017-00966, Paper 7, 11 (PTAB Sept. 13, 2017). For the reasons

discussed below, we do not find the Petition contains improper incorporation by reference.

As to Patent Owner's first example regarding the analysis of the state of the art, the relevant paragraph from the Petition states in full: "Professor Dickson summarizes developments leading to efficient and effective two-stage compositing for testing meat lots. Dickson ¶¶ 39-63, 287-329." Pet. 7. Citation to a declaration as support, without repeating the testimony, is not improper.

As evidenced by the excerpt, the portions of Dr. Dickson's Declaration cited by Patent Owner solely relate to explanatory background information that is not relied upon for any of the obviousness grounds. Patent Owner's second example states: "Applicant-admitted prior art (AAPA) sections of the specification are listed below with emphasis added. Dickson ¶¶ 52-63." See Pet. 9-10. Here, the objected-to portions of the Declaration states that the "Examiner cited five statements, which are discussed below, and are listed as AAPA #1-#5. Two additional sections are included and are listed as AAPA #6-#7. IEH's responses are cited below with respect to each AAPA." Ex. 1041 ¶ 52. These numbered paragraphs are relied upon by Petitioner to interpret the prior art, for example when contending that

ICMSF indicates a **consignment** may be "a very large quantity of food" and may be "composed of **several lots**, representing for example, different days of production from the same plant." *Id.*, 119, 120 (emphasis added); *see also* AAPA #3-#5. This corresponds with the specification of IEH's Patents which reflects the common practice of producers defining what constitutes a lot grouped for traceability purposes. Ex. 1003, 3:13-24, 11:37-41 (AAPA #3), and 13:10-22; Dickson ¶ 365.

Thus, ICMSF discloses collecting a plurality of portions from separate lots.

Pet. 93.

In both of the examples cited by Patent Owner, therefore, the paragraphs of the Dickson Declaration cited in the Petition provide appropriate supporting technical details and/or testimony as to the understanding of a person of ordinary skill in the art. They do not offer wholly new arguments not found in the Petition.

Accordingly, we do not find the circumstances here to amount to improper incorporation by reference or an attempt to circumvent our word count limits.

3. Petitioner's Motivations to Combine

Patent Owner contends that we should deny the Petition because Petitioner “fail[s] to identify any motivation to combine the references.” Prelim. Resp. 34–35. According to Patent Owner, “Petitioner vaguely asserts that the two (or three) references ‘have interrelated teachings’ because they allegedly teach certain claim elements. . . . In addition to being circular, this provides no rationale for why or how a POSITA would modify any reference.” *Id.* at 35. In Patent Owner’s view,

[e]very ground summarily concludes the nebulous combination would result in a “reasonable expectation of success for efficient validation.” Pet. at 53, 57(same), 65 68 (“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.

Prelim. Resp. 35.

On the current record, we are not persuaded that Petitioner’s motivations to combine are vague and insufficient for obviousness. With respect to Ground 1, for example, Petitioner contends that one of ordinary skill in the art

would have been motivated to modify ICMSF based on Gombas under the teaching-suggestion-motivation test so portions of the enriched, retained samples are further tested after a positive test of a composite sample by the same protocol, with a reasonable expectation of success for efficient validation. *See* § XII-A-1-h *supra* [(referring to the Petition)]; Dickson ¶¶ 417-19.

Pet. 53–54. Petitioner further argues that an ordinarily skilled artisan would have sought to

improve[] ICMSF with the similar methods of Gombas to yield efficient validation, which is a predictable result. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). [In this combination] a POSA would have simply substituted steps of ICMSF, as described above, with those of Gombas so portions of the enrichment cultures are retained and are further tested after a positive test of a composite sample by the same protocol for predictably efficient validation. MPEP § 2143(I)(B); Dickson ¶ 420.

Id. at 54. As such, the Petition provides specific reasons to combine ICMSF and Gombas that are consistent with the flexible test set forth in *KSR*, including the benefit of efficient validation of the test and that the combination is a simple substitution of steps. As *KSR* notes, “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417. Petitioner here has made its reasons to combine explicit. *See* Pet. 53–54, 59–60, 66–68. Patent Owner, on this

record, has not provided reasons or evidence to persuasively rebut Petitioner's position.

On the current record, we are also not persuaded that the evidence shows that Petitioner's recited combinations would have lacked a reasonable expectation of success. The requirement is not an *absolute* expectation of success, but rather a *reasonable* expectation of success based on the teachings of the prior art. *See In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) ("Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success.").

Patent Owner points to no evidence suggesting that there would be a lack of predictability in performing the combinations of steps rendered obvious by the prior art of ICMSF, Gombas, Price, and Hughes as asserted by Petitioner. In contrast, Petitioner relies on Dr. Dickson's testimony that, for example, one of ordinary skill in the art

would have had a reasonable expectation of successfully achieving these objectives by the combination of ICMSF and Gombas. . . . These benefits would be predictable to a POSA because combining ICMSF and Gombas merely involves known methods for assessing the safety of meat. Given ICMSF's recognition of the benefits of tracing a lot to improve efficiency, using Gombas to improve ICMSF with further testing after a positive test just as further testing is used in Gombas, is a slight change or substitution, and the benefits would be entirely predictable to a POSA. Gombas clearly just considered such further testing to be standard practice, not a new innovation.

Ex. 1041 ¶¶ 419–420.

Accordingly, on the current record, we find that the evidence supports Petitioner's assertions regarding reasons to combine and a reasonable expectation of success.

4. The validation step

Patent Owner argues that the Petition is flawed because none of the cited art teaches the validation step. Prelim. Resp. 51–57. According to Patent Owner: “Validation is an essential—and limiting—part of the claims.” Prelim. Resp. 48. With respect to this term, Patent Owner contends that “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.” *Id.* at 48. Patent Owner argues that “validation is ‘necessary to give life, meaning, and vitality’ to the claim. *See Catalina*, 289 F.3d at 808,” and here, “the specification explains the entire benefit of the invention is the ability to efficiently validate lots for release into commerce.” *Id.* at 50. According to Patent Owner, during prosecution it “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.” *Id.*

Patent Owner contends that, “[b]ecause none of the references teach validation, which limits the claims and requires determining releasability, all grounds fail.” Prelim. Resp. 52. As to Ground 1, Patent Owner asserts

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 . . . portions [that] are summarizing the *Siliker* papers . . . the Office reviewed both *Siliker* 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”).

Prelim. Resp. 54–55 (citing Ex. 1012 at 187; *see also* Pet. 42–43, 45, 47). Patent Owner asserts “the Office reviewed both *Silliker* publications and found they did not teach the claimed validation.” *Id.* (citing Ex. 1007, 1787).

Patent Owner also asserts that “[b]ecause *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. *Id.* at 56 (citing Ex. 1001, 2, 1:40–45, 1:62–67).

Patent Owner asserts:

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.

Id. at 56–57.

On the current record, we do not agree with Patent Owner’s proposed interpretation of the term “validation”—and the associated “for release into commerce” language—as discussed in Section II.C.5–6, above. As explained above, we preliminarily adopt the ’584 patent’s express definition that the “term ‘validation’ as used herein with respect to production lots refers to determining that a particular sample tests negative using the detection assay.” Ex. 1001, 7:1–10; *see supra* Section II.C.5 (claim construction). As also explained above, we accord no weight to the intended use language “for release into commerce.” Section II.C.6. In light of these preliminary constructions, we do not agree that the cited references fail to teach “validation,” or that Petitioner incorrectly addressed the prior art.

We also note that the prior art teaches determining negative tests for production lots using detection assays. For example, *Gombas* teaches “[i]f a

composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay.”

Ex. 1014, 564. Similarly, Dr. Dickson testifies that, “a POSA would also recognize that any lots corresponding to any negatively testing composited lot samples are then considered to be validated.” Ex. 1041 ¶ 411. And Price teaches that this “procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found.” Ex. 1017, 679. Accordingly, on this record, we find that Petitioner has demonstrated a reasonable likelihood that the prior art teaches a step of validation as required by the claims of the ’584 patent.

We do not agree with Patent Owner’s assertion that “the Office reviewed both *Silliker* publications and found they did not teach the claimed validation.” Prelim. Resp. 55 (citing Ex. 1007, 1787). Rather, our review of that page of the Second Board Opinion reveals no discussion of the *Silliker* publications. Indeed, that Decision stated that in “the previous Decision, the Board had found that Patent Owner did not persuasively demonstrate that the success of the claimed invention was a result of an inventive and claimed feature, rather than a step that was readily available in the cited prior art.” Ex. 1007, 1787. Patent Owner has not pointed us to a citation supporting this position.

Lastly, on the current record, we are not persuaded by Patent Owner’s statement that Gombas failed to teach validation 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.” Prelim. Resp. 56. Patent Owner presumes a definition of validation that requires validation “for release into commerce.” However, that limitation is not present in the instant claims and, for the reasons given in Section II.C.6 above, we do not read that limitation into the instant claims.

G. Discretionary Denial

Patent Owner contends that we should exercise our discretion to deny institution under 35 U.S.C. § 314(a) in light of the related litigation in the District of Delaware. Prelim. Resp. 58–71. In sum, Patent Owner contends that the factors identified in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”), weigh in favor of exercising discretion to deny institution. *Id.*

On June 21, 2022, the Director of the U.S. Patent and Trademark Office (“USPTO”) issued a Memorandum titled “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation” (“Memorandum”) ⁶, which states, among other things, that “the PTAB will not discretionarily deny institution in view of parallel district court litigation where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB.” Memorandum 3 (citing *Sotera*

⁶ Available at www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_2022_0621_.pdf.

Wireless, Inc. v. Masimo Corp., IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A)).

By email dated November 25, 2024, Petitioner requested leave to file a Reply to Patent Owner’s Preliminary Response to address, *inter alia*, its proposed submission of a *Sotera* stipulation. Ex. 3001. We denied Petitioner’s request for briefing, but granted its request to submit the stipulation. *Id.* The *Sotera* stipulation avers that “if IPR Nos. IPR2024-00183, IPR2024-00185, and IPR2024-00186 are instituted, National Beef will not pursue in the related district court proceeding, *Inst. for Env’tl. Health, Inc. v. Nat’l Beef Packing Co., LLC*, No. 1:23-cv-00826 (D. Del. Aug. 1, 2023), any ground National Beef raised or reasonably could have raised in the aforementioned IPRs,” and that the stipulation “binds National Beef in the related district court proceeding, *Inst. for Env’tl. Health, Inc. v. Nat’l Beef Packing Co., LLC*, No. 1:23-cv-00826 (D. Del. Aug. 1, 2023). Ex. 1064.

Applying the guidance provided in the Memorandum, we decline to exercise our discretion to deny institution in this proceeding under *Fintiv*, because Petitioner submitted a *Sotera* stipulation.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the ’584 Patent is unpatentable. In particular, because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by the asserted combinations of ICMSF, Hughes, and Price, we institute *inter partes* review on all grounds set forth in the Petition.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and inexpensive manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–6, 10, 11, 13–20, 22, 23, and 26–33 of U.S. Patent No. 7,534,584 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '584 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2024-00183
Patent 7,534,584 B2

PETITIONER:

Kevin Laurence
Matthew Phillips
Seth Black
Derek Meeker
klaurence@lpiplaw.com
mphillips@lpiplaw.com
seth@blkip.com
dmeeker@lpiplaw.com

PATENT OWNER:

Benjamin Byer
Gregory Rosenthal
Samantha Hunt
benbyer@dwt.com
gregrosenthal@dwt.com
samhunt@dwt.com