

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

IPR2024-00186
Patent 9,637,771

PETITION FOR *INTER PARTES* REVIEW

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MPEP § 2144.05	70

PETITIONER’S EXHIBIT LIST

Ex.	Description
1001	U.S. Patent No. 7,534,584 B2 (“the ’584 Patent”) to Samadpour, titled “Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents” and U.S. Patent No. 7,534,584 C1 (“Reexamination Certificate”)
1002	U.S. Patent No. 8,822,143 (“the ’143 Patent”) to Samadpour, titled “Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents”
1003	U.S. Patent No. 9,637,771 (“the ’771 patent”) to Samadpour, titled “Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents”
1004	Complaint for Patent Infringement, <i>Inst. for Envtl. Health, Inc. v. Nat’l Beef Packing Co., LLC</i> , No. 1:23-cv-00826 (D. Del. Aug. 1, 2023)
1005	Prosecution History for U.S. Provisional Patent Appl. No. 60/599,473
1006	Prosecution History for U.S. Patent Appl. No. 11/199,871 (Pat. No. 7,534,584)
1007	Prosecution History for Reexamination Control No. 95/001,294 (Six Parts)
1008	U.S. Patent No. 8,389,233 (“the ’233 patent”) to Samadpour, titled “Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents”
1009	Prosecution History for U.S. Patent Appl. No. 12/360,796 (Pat. No. 8,389,233)
1010	Prosecution History for U.S. Patent Appl. No. 13/784,606 (Pat. No. 8,822,143)
1011	Prosecution History for U.S. Patent Appl. No. 14/472,144 (Pat. No. 9,637,771)

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”), (“ICMSF 7), or (“ICMSF”)
1013	“Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications,” Int’l Comm’n on Microbiological Spec’s for Foods, Univ. Toronto Press, Glossary (2nd ed. 1986) (“ICMSF 1986”) or (“ICMSF 2”)
1014	David Gombas et al., “Survey of <i>Listeria monocytogenes</i> in Ready-to-Eat Foods,” J. Food Prot., vol. 66, no. 4, pages 559-569 (Apr. 2003) (“Gombas”)
1015	Denise Hughes et al., “ <i>Salmonella</i> in Foods—A New Enrichment Procedure for Use with the TECRA <i>Salmonella</i> Visual Immunoassay: Collaborative Study,” J. AOAC Int’l, vol. 82, no. 3, pages 634-647 (May/June 1999) (“Hughes 1999”) or (“Hughes”)
1016	Denise Hughes et al., “ <i>Salmonella</i> in Foods: New Enrichment Procedure for TECRA <i>Salmonella</i> Visual Immunoassay Using a Single RV(R10) Only, TT Only, or Dual RV(R10) and TT Selective Enrichment Broths (AOAC Official Method 998.09): Collaborative Study,” J. AOAC Int’l, vol. 86, no. 4, pages 775-790 (July/Aug. 2003) (“Hughes 2003”)
1017	W.R. Price et al., “ <i>Salmonella</i> Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples,” Appl. Microbiol., vol. 23, no. 4, pages 679-682 (Apr. 1972) (“Price”)
1018	Diana Stewart et al., “Comparison of Assurance Gold <i>Salmonella</i> EIA, BAX for Screening/ <i>Salmonella</i> , and GENE-TRAK <i>Salmonella</i> DLP Rapid Assays for Detection of <i>Salmonella</i> in Alfalfa Sprouts and Sprout Irrigation Water,” J. AOAC Int’l, vol. 85, no. 2, pages 395-403 (Mar./Apr. 2002) (“Stewart”)
1019	Pina Fratamico et al., “Rapid isolation of <i>Escherichia coli</i> O157:H7 from enrichment cultures of foods using an immunomagnetic separation method,” Food Microbiol., vol. 9, no. 2, pages 105-113 (June 1992) (“Fratamico”)

1020	Eva D’Haese & Hans Nelis, “Rapid Detection of Single Cell Bacteria as a Novel Approach in Food Microbiology,” J. AOAC Int’l, vol. 85, no. 4, pages 979-983 (July/Aug. 2002) (“D’Haese”)
1021	Jean-Yves D’Aoust, “Update on Preenrichment and Selective Enrichment Conditions for Detection of <i>Salmonella</i> in Foods,” J. Food Prot., vol. 44, no. 5, pages 369-374, 393 (May 1981) (“D’Aoust”)
1022	U.S. Food & Drug Admin., “Bacteriological Analytical Manual,” Table of Contents, Introduction, About the Bacteriological Analytical Manual, Chapters 1, 5, 10 (June 2003) (“BAM 2003”)
1023	U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), “Microbiological Testing Program and Other Verification Activities for <i>Escherichia coli</i> O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components,” Directive 10.010.1, Rev. 1 (Mar. 31, 2004) (“FSIS Directive”)
1024	Thaddeus Midura & Raymond Bryant, “Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis,” Chapter 2 in Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association, pages 13-23 (4th ed. 2001) (“Midura”)
1025	J.H. Silliker & D.A. Gabis, “ICMSF methods studies. I. Comparison of analytical schemes for detection of <i>Salmonella</i> in dried foods,” Can. J. Microbiol., vol. 19, no. 4, pages 475-479 (1973) (“Silliker”)
1026	D.A. Gabis & J.H. Silliker, “ICMSF methods studies. II. Comparison of analytical schemes for detection of <i>Salmonella</i> in high-moisture foods,” Can. J. Microbiol., vol. 20, no. 5, pages 663-669 (1974) (“Gabis”)
1027	Basil Jarvis, “Errors Associated with Dilution Count and Presence/Absence Methods,” Chapter 8 in Statistical Aspects of the Microbiological Analysis of Foods, Elsevier Science Publishers, pages 117-146 (1989) (“Jarvis”)
1028	U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), “Microbiology Laboratory Guidebook,” Table of Contents, Cover, Foreword, General Considerations, Chapters 4.02, 5.03, 8.03 (July 2003) (“MLG 2003”) or (“MLG”)

1029	U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), “Microbiology Laboratory Guidebook,” Chapter 8 (3rd ed. 1998) (“MLG 1998”)
1030	Madhu Badoni et al., “Development and testing of a prototype automatic trim sampler,” Food Control, vol. 77, pages 82-87 (July 2017) (“Badoni”)
1031	Tommy Wheeler & Terrance Arthur, “Novel Continuous and Manual Sampling Methods for Beef Trim Microbiological Testing,” J. Food Prot., vol. 81, no. 10, pages 1605-1613 (Oct. 2018) (“Wheeler”)
1032	U.S. Food & Drug Admin., “Bacteriological Analytical Manual,” Chapter 10, § 10.04 (January 1969) (“BAM 1969”)
1033	“37. Microbiological Methods,” in Changes in Official Methods of Analysis Made at the Eightieth Annual Meeting, October 10-13, 1966, J. of the A.O.A.C., vol. 50, no. 1, pages 231-239 (Feb. 1967)
1034	Prosecution History for U.S. Patent Appl. No. 15/499,719 (Expressly Abandoned)
1035	Complaint for Declaratory Judgment of Patent Invalidity and Patent Non-Infringement, <i>Primus Grp., Inc. v. Inst. for Env'tl. Health, Inc.</i> , No. 3-18-cv-00005 (N.D. Cal. Jan. 2, 2018)
1036	Patent Local Rule 4-3 Joint Claim Construction and Prehearing Statement, <i>Primus Grp., Inc. v. Inst. for Env'tl. Health, Inc.</i> , No. 3-18-cv-00005 (N.D. Cal. July 31, 2018)
1037	Institute for Environmental Health, Inc.’s Opening Claim Construction Brief, <i>Primus Grp., Inc. v. Inst. for Env'tl. Health, Inc.</i> , No. 3-18-cv-00005 (N.D. Cal. Sept. 14, 2018)
1038	Claim Construction Order, <i>Primus Grp., Inc. v. Inst. for Env'tl. Health, Inc.</i> , No. 3-18-cv-00005 (N.D. Cal. Jan. 22, 2019)
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1041	Expert Declaration of James S. Dickson, Ph.D.
1042	Curriculum Vitae of James S. Dickson, Ph.D.
1043	Expert Declaration of James L. Mullins, Ph.D. (“Mullins Decl.”)
1044	Mullins Decl. Appendix A - Curriculum Vitae of James L. Mullins, Ph.D.
1045	Mullins Decl. Appendices A-1, A-2, A-3, and A-4
1046	Mullins Decl. Appendices B-1, B-2, and B-3
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1058	Mullins Decl. Appendix N-1, N-2, N-3, N-4, and N-5
1059	Mullins Decl. Appendix O-1, O-2, and O-3
1060	Mullins Decl. Appendix P-1, P-2, and P-3

1061	Mullins Decl. Appendix Q-1, Q-2, Q-3, and Q-4
1062	Proposed Scheduling Order, <i>Inst. for Env'tl. Health, Inc. v. Nat'l Beef Packing Co., LLC</i> , No. 1:23-cv-00826 (D. Del. May 16, 2024)
1063	Assurance® GDS Salmonella Tq (2024)

CLAIMS LISTING

Claim 1 of the '771 Patent	
Pre	A method of sampling and testing products for microbes in multiple separate lots, comprising:
(a)	separately collecting multiple independent samples from each of multiple separate lots, wherein each separate lot is separately sampled by taking said multiple independent samples thereof;
(b)	separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited lot samples, wherein each of the separate composited lot samples is attributed to a particular corresponding separate lot;
(c)	enriching each of the separate composited lot samples to provide a set of separate composited lot samples enriched for the target microbe(s);
(d)	removing portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample; and
(e) (1)	testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s),
(e) (2)	wherein when such testing is negative all of said samples that were composited to form the separate composited lot samples are deemed negative for the target microbe(s) and each of the multiple separate lots is validated, and
(e) (3)	wherein when such testing is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is positive for the target microbe(s), wherein the lots corresponding to any negatively testing composited lot samples are validated.

Claims Depending from Claim 1 of the '771 Patent	
2	The method of claim 1, wherein each of the multiple separate lots is selected from the group consisting of an environmental lot comprising multiple operationally-linked environmental specimens, pharmaceutical lot comprising multiple operationally-linked pharmaceutical specimens, single product lot comprising multiple operationally-linked product specimens, and combinations thereof.
3	The method of claim 1, wherein each of the multiple separate lots is a single production lot, comprised of operationally-linked product specimens.
4	The method of claim 3, wherein product specimens are synonymous with product portions.
5	The method of claim 1, further comprising incubating the pooled modular composite sample of d), prior to testing in e).
6	The method of claim 1, wherein each separate composited lot sample in c) comprises incubating each separate composited lot sample with enrichment medium suitable to enrich for the target microbe(s), and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate composited lot sample and combining the removed portions to provide a pooled modular composite sample.
7	The method of claim 6, wherein the enrichment medium comprises a selective agent that will inhibit a competing non-target microbe.
8	The method of claim 1, wherein testing of the pooled modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the target microbe(s).
9	The method of claim 8 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.
10	The method of claim 1, wherein where testing in e) of the pooled modular composite sample is positive, and wherein the separate individual composited lot samples are further tested using a more sensitive protocol.

Claims Depending from Claim 1 of the '771 Patent — cont'd	
11	The method of claim 10, wherein the more sensitive protocol comprises use of a concentration step to concentrate the target microbe(s), in combination with the same test protocol used to test the pooled modular composite sample.
12	The method of claim 1, further comprising, forming an additional pooled modular composite sample from the set of enriched separate composited lot samples of c) and testing the additional pooled modular composite sample, using the same or a different suitable assay, to confirm the testing status.
13	The method of claim 1, further comprising, forming an additional pooled modular composite sample from an additional enriched separate composited lot sample along with any enriched separate composited lot samples of c) that test negative in e), and testing the additional pooled modular composite sample, using the same or a different suitable assay.
14	The method of claim 1, further comprising, where testing of the pooled modular composite sample in e) is negative, forming an additional pooled modular composite sample from the set of enriched separate composited test lot samples of c), and testing the additional pooled modular composite sample, using a different suitable assay, to confirm the negative testing status.
15	The method of claim 1, wherein each of the lots is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
16	The method of claim 1, wherein the number of separate lots is from 3 to 10.
17	The method of claim 1, further comprising, where testing of the pooled modular composite sample is positive, determining which individual separate lots are positive, application of remedial measures to said separate positive lots, and validating by further testing of the respective remediated separate lots and obtaining a negative test result.
18	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate lots comprises separately collecting from each separate lot a number of samples from 5 to 100.

Claims Depending from Claim 1 of the '771 Patent — cont'd	
19	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate lots comprises separately collecting 30 to 60 samples from each separate lot.
20	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate lots comprises separately collecting at least 30 samples from each separate lot.
21	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate lots comprises separately collecting at least 60 samples from each separate lot.
22	The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate composited lot samples.
23	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of <i>Listeria</i> , <i>Salmonella</i> , and <i>Escherichia coli</i> .
24	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of <i>Listeria</i> spp., <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp., <i>Escherichia coli</i> O157:H7, coliforms and fecal coliforms.
25	The method of claim 1, wherein the target microbe(s) comprises a spoilage organism.
26	The method of claim 1, wherein removing portions of each separate enriched composited lot sample comprises removing equal volume portions of each separate enriched composited lot sample.
27	The method of claim 1, wherein testing of the pooled modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.

Claims Depending from Claim 1 of the '771 Patent — cont'd	
28	The method of claim 1, wherein each of the multiple separate lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
29	The method of claim 28, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.
30	The method of claim 28, wherein the meat is that of beef, pork, sheep or bison.
31	The method of claim 30, wherein the meat is that of beef.
32	The method of claim 1, wherein each of the multiple separate lots are separate production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.
33	The method of claim 1, wherein each of the multiple separate lots are separate production lots of a ready-to-eat product.
34	The method of claim 1, further comprising in (e) wherein when such testing of the modular composite sample is negative, nonetheless testing each of the separate composited lot samples for the target microbe(s) to enhance confidence in the negative testing results prior to deeming the lots validated or releasable into the chain of commerce.
35	The method of claim 1, further comprising, in (e) wherein when such testing of the pooled modular composite sample is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is positive for the target microbe(s), retesting of the separate negatively testing composited lot samples to enhance confidence in the negative testing results prior to deeming the lots corresponding to the negatively testing composited lot samples validated or releasable into the chain of commerce.
36	The method of claim 1, wherein each of the multiple separate lots are production lots of produce, fruits, vegetable, herbs, or spices.

Claim 37 of the '771 Patent	
Pre	A method of sampling and testing products for microbe(s) in multiple separate lots, comprising:
(a)	separately collecting multiple independent samples from each of multiple separate single production lots, wherein each separate single production lot is separately sampled by taking said multiple independent samples thereof;
(b)	separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited single production lot samples, wherein each of the separate composited single production lot samples is attributed to a particular corresponding separate single production lot;
(c)	enriching of the separate composited single production lot samples to provide a set of separate composited single production lot samples enriched for the target microbe(s);
(d)	removing portions of each separate enriched composited single production lot sample, and combining the removed portions to provide a pooled modular composite sample; and
(e)(1)	testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s),
(e)(2)	wherein when such testing is negative all of said samples that were composited to form the separate composited single production lot samples are deemed negative for the target microbe(s) and each of the multiple separate single production lots is validated, and
(e)(3)	wherein when such testing is positive, each of the individual separate composited single production lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited single production lot samples is positive for the target microbe(s), wherein the single production lots corresponding to any negatively testing composited single production lot samples are validated

Claims Depending from Claim 37 of the '771 Patent	
38	The method of claim 37, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate composited single production lot samples.
39	The method of claim 37, further comprising in (e) wherein when such testing of the pooled modular composite sample is negative, nonetheless testing each of the separate composited single production lot samples for the target microbe(s) to enhance confidence in the negative testing results prior to deeming the single production lots validated or releasable for processing or into the chain of commerce.
40	The method of claim 37, further comprising, in (e) wherein when such testing of the modular composite sample is positive, each of the individual separate composited single production lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited single production lot samples is positive for the target microbe(s), retesting of the separate negatively testing composited single production lot samples to enhance confidence in the negative testing results prior to deeming the single production lots corresponding to the negatively testing composited single production lot samples validated or releasable into the chain of commerce.
41	The method of claim 37, wherein each of the multiple separate single production lots are separate single production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
42	The method of claim 41, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.
43	The method of claim 42, wherein the meat is that of beef, pork, sheep, or bison.
44	The method of claim 43, wherein the meat is that of beef.

Claims Depending from Claim 37 of the '771 Patent	
45	The method of claim 37, wherein each of the multiple separate single production lots are separate single production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.
46	The method of claim 37, wherein each of the multiple separate single production lots are separate single production lots of a ready-to-eat product.
47	The method of claim 37, wherein each of the multiple separate single production lots are separate single production lots of produce, fruits, vegetable, herbs, or spices.
48	The method of claim 37, wherein the target microbe(s) comprises at least one selected from the group consisting of <i>Listeria</i> , <i>Salmonella</i> , and <i>Escherichia coli</i> .
49	The method of claim 48, wherein the target microbe(s) comprises at least one selected from the group consisting of <i>Listeria</i> spp., <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp., <i>Escherichia coli</i> O157:H7, coliforms, and fecal coliforms.

I. INTRODUCTION

National Beef Packing Company, LLC (“National Beef” or “Petitioner”) requests *inter partes* review (IPR) of claims 1-11, 15, 16, 18-24, 26-31, 33, 37, 38, 41-44, 46, 48, and 49 (the “Challenged Claims”) of No. 9,637,771 (“the ’771 Patent”) owned by the Institute for Environmental Health, Inc. (“IEH”).

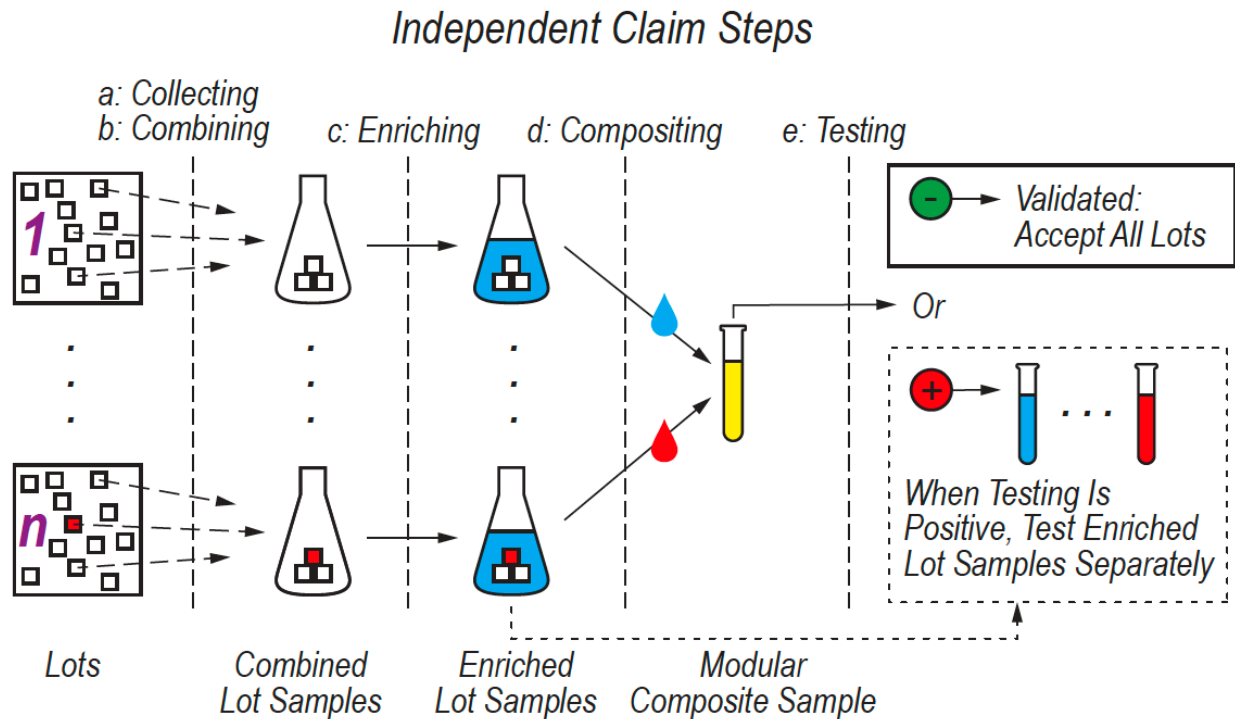
A family tree is provided at § VI *infra*. A declaration from Professor James S. Dickson, Ph.D. (Ex. 1041, “Dickson”) supports this Petition and those of the ’771 Patent’s parent and great-grandparent, as listed below:

IPR	Patent	Exhibit
IPR2024-00183	7,534,584 — ’584 Patent	1001
IPR2024-00185	8,822,143 — ’143 Patent	1002
IPR2024-00186	’771 Patent	1003

The ’143 and ’771 Patents, which claim priority to the ’584 Patent, are referred to herein as the Continuation Patents. The ’584 Patent and the Continuation Patents are collectively referred to as IEH’s Patents.

Because the scope of the independent claims of the Continuation Patents are either the same as or broader than the original independent claims of the ’584 Patent prior to reexamination and the claims of the ’584 Patent were not significantly altered in reexamination, the grounds in each Petition are the same. See § XIII-B-2 *infra*.

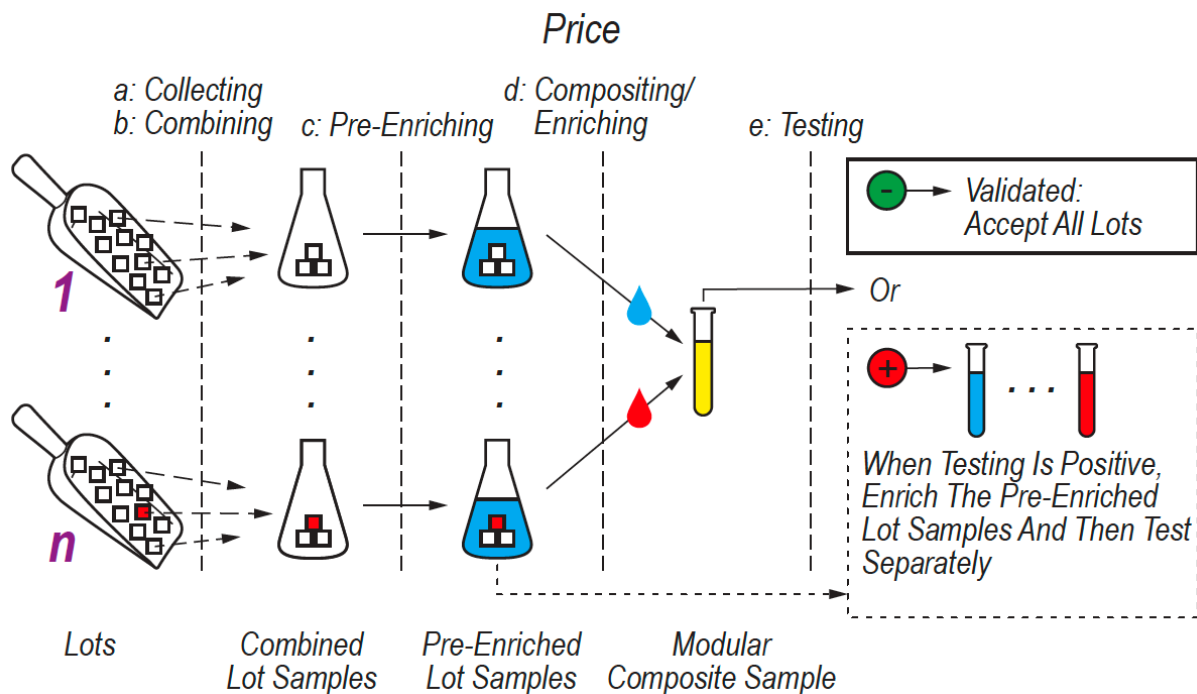
IEH's Patents relate to sampling lots, such as meat lots, testing for microbial contamination, and validating the lots for release. Ex. 1003, 1:39-52. Their independent claims recite steps (a)-(e), as depicted below:



Dickson ¶¶ 64-73.

These five steps cover two-stage compositing. The first stage includes step (a), collecting samples from lots, and step (b), combining/compositing the samples. In the second stage, the combined lot samples are enriched in step (c), then, in step (d), portions of each enriched lot sample are composited into one composite sample. In step (e), the enriched composite sample is tested and the method is complete after a negative test. If the test is positive, portions of each enriched lot sample that were retained, are separately tested to identify contaminated lots. *Id.*

Two-stage compositing minimizes testing volume and reduces waste by not destroying or disposing of uncontaminated lots after a positive test, thereby decreasing costs and improving efficiencies. Yet, two-stage compositing was well known before the priority date. For example, Price discloses two-stage compositing as shown below:

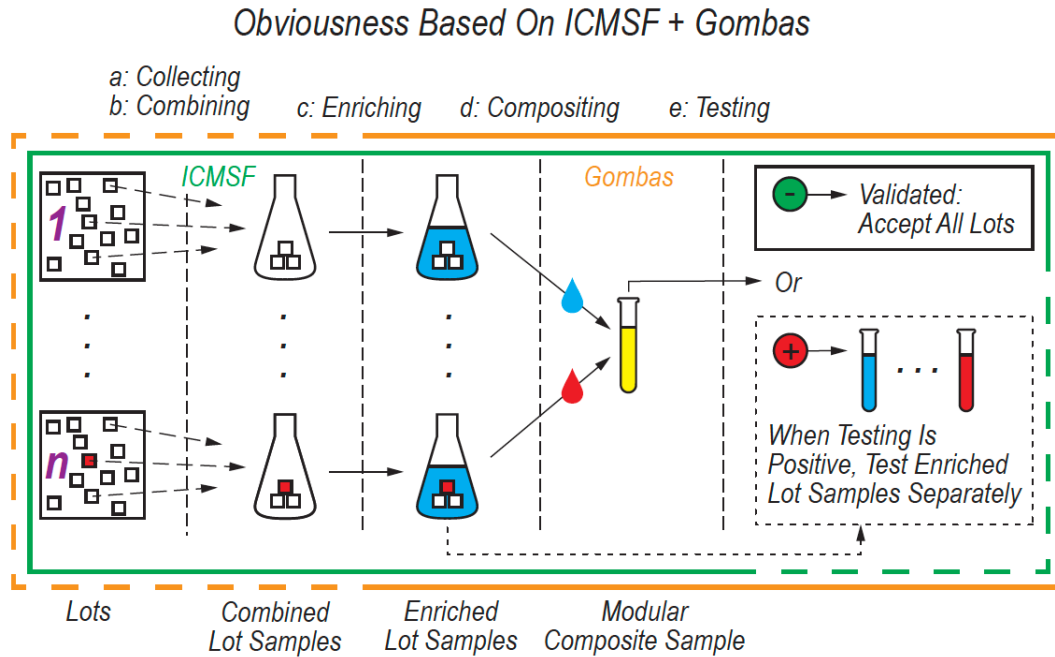


Id. ¶¶ 261-70.

Instead of retaining enriched samples, Price retains pre-enriched samples. Enrichment ranges from rehabilitating microorganisms via non-selective enrichment (pre-enrichment) to facilitating growth of targeted microorganisms via selective enrichment. *Id.* Price was substantively considered during reexamination of the '584 Patent. Because the distinction between non-selective and selective

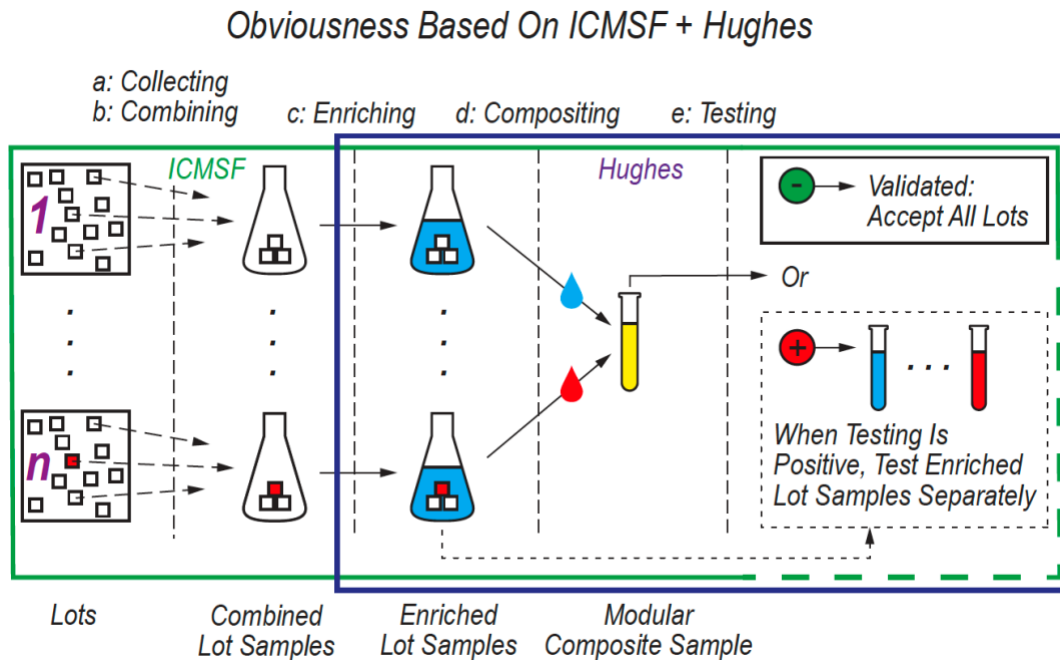
enrichments is nominal for two-stage compositing, the claims were repeatedly rejected in reexamination. *See* § VIII-B *infra*. However, in a second appeal, the Board accepted IEH's arguments about purported secondary considerations after IEH limited the independent claims to specific meats. *See* § VIII-C-3 *infra*. IEH's assertions were only supported by declarations from IEH's employees with no corroborating evidence and no consideration of countervailing evidence. *Id.* Price was also substantively considered during prosecution of the grandparent of the '771 Patent but the Examiner expressed a critical misunderstanding of Price that was not corrected during prosecution of the Continuation Patents. *See* §§ IX-A to IX-C *infra*.

Unlike the reexamination and prosecution of the continuations of the '584 Patent, grounds in this Petition rely on references—including ICMSF, Gombas, and Hughes—disclosing retention of portions of each selectively enriched separate lot sample. ICMSF is included in each ground. ICMSF teaches steps (a)-(d) and most of step (e). In a first ground, ICMSF is combined with Gombas, which teaches at least steps (c)-(e), as depicted below:



Dickson ¶¶ 356-420.

In a second ground, ICMSF is combined with Hughes, which teaches steps (c)-(e), as depicted below:



Id. ¶¶ 421-41.

In this Petition, a third ground relies on Price as modified by ICMSF and Hughes. *Id.* ¶¶ 442-80. Because ICMSF, Gombas, and Hughes have not been considered by the Office relative to the Challenged Claims, each ground presents new art and new arguments. *See* § XIII-B-1 *infra*.

II. IPR REQUIREMENTS

A. Standing

Petitioner is not barred or estopped from requesting IPR of the Challenged Claims on the grounds identified herein and certifies the '771 Patent is available for IPR.

B. Identification of Challenges under 37 C.F.R. § 42.104(b)

Petitioner requests IPR of the Challenged Claims and cancellation of the same as unpatentable.

C. Art Relied on for Challenges

The publications relied upon for unpatentability grounds include:

Reference	Exhibit	Published
ICMSF	1012	2002
Gombas	1014	2003
Hughes	1015	1999
Price	1017	1972
Stewart	1018	2002
Fratamico	1019	1992

D’Haese	1020	2002
D’Aoust	1021	1981

Each publication was prior art when the invention was made (before the priority date of August 6, 2004) under 35 U.S.C. § 102(b) (pre-AIA). Public availability of these references is established by the declaration of James L. Mullins, Ph.D. (Ex. 1042).

D. Statutory Grounds for Challenges

This Petition requests cancellation of the Challenged Claims as unpatentable under 35 U.S.C. § 103 based on the following grounds:

Ground	References	Indep. Claims	Dependent Claims
1	ICMSF and Gombas	1 and 37	2-4, 6, 8-11, 15, 16, 18-24, 26-31, 33, 38, 41-44, 46, 48 and 49
2	ICMSF and Hughes		Same as ground 1 excluding claim 11
3	Price, ICMSF, and Hughes		

Ground	Base Ground	Additional Reference	Dep. Claims
4	1	Stewart	5
5	2		
6	1	Fratamico	8-11
7	2		8 and 9
8	2	D’Haese	10
9	1	D’Aoust	7
10	2		

Each ground is based on a combination by a POSA before the priority date.

III. TECHNOLOGY BACKGROUND

Professor Dickson summarizes developments leading to efficient and effective two-stage compositing for testing meat lots and current state of the art practices. Dickson ¶¶ 39-63, 287-329; *see also* Badoni (Ex. 1030) , Wheeler (Ex. 1031), and Assurance® GDS Salmonella Tq (Ex. 1063).

IV. THE '771 PATENT

A. Independent Claims

The independent claims recite steps (a)-(e) as depicted in the diagram above. Dickson ¶¶ 64-73. In step (a), the **collecting** step, samples are collected from separate lots.

In step (b), the **combining** step, the samples from each separate lot are combined into a lot sample yielding a set of separate combined lot samples, each corresponding to a particular lot. Such combining is also referred to as dry compositing or lumping.

In step (c), the **enriching** step, each separate combined lot sample is separately enriched thereby yielding a set of separate enriched lot samples retained for additional testing as needed in step (e).

Step (d), the **compositing** step, equates to removing portions of each separate enriched lot sample, and combining the removed portions to provide a modular composite sample. Such compositing is also referred to as wet compositing or wet pooling.

Step (e), the **testing** step, tests the modular composite sample using a suitable detection assay. If negative, the lots are validated/released. If positive, each separate enriched lot sample from step (c) is individually tested to determine which is positive for the target microbe(s).

B. AAPA

Applicant-admitted prior art (AAPA) sections of the specification are listed below with emphasis added. Dickson ¶¶ 52-63.

AAPA			
#	Cite	Summary	Step
1	1:59-65	Sampling plans are used by food producers to test beef and ready-to-eat (“RTE”) products for microorganisms.	(a)
2	12:63-66	Under FSIS guidelines, producers of RTE “meat and poultry products may adapt an ‘ end product ’ sampling program as verification that their product is free of” <i>L. monocytogenes</i> .	

3	11:37-41	A lot for trim testing for <i>E. coli</i> O157:H7 in the beef industry may consist of five separate ‘combos,’ each combo being a single production unit weighing ~2,000 lbs.	
4	13:10-22	Producers define and produce single-unit lots to maximize information available for investigating failures, e.g., possible definitions of lots include “ all of the product produced by a particular production line in a particular period of time ” or “a volume of product such as a pallet of packed boxes produced on a particular production line, or a production area in the plant, etc.”	
5	12:67-13:9	“ [F]requency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. ” “ [S]amples are collected at random times over a production shift (e.g., from ‘cleanup to cleanup’), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow” microorganisms “to grow and multiply under the favorable conditions of enrichment. ”	(a)- (d)
6	2:15-36	Sampling plans under ICMSF guidelines involve combining several samples representing production lots into a combined production lot prior to sampling. “For example, a typical plan for microbial pathogen detection calls for taking more than one sample, for instance ten (10) to sixty (60) sample	(a) and (d)

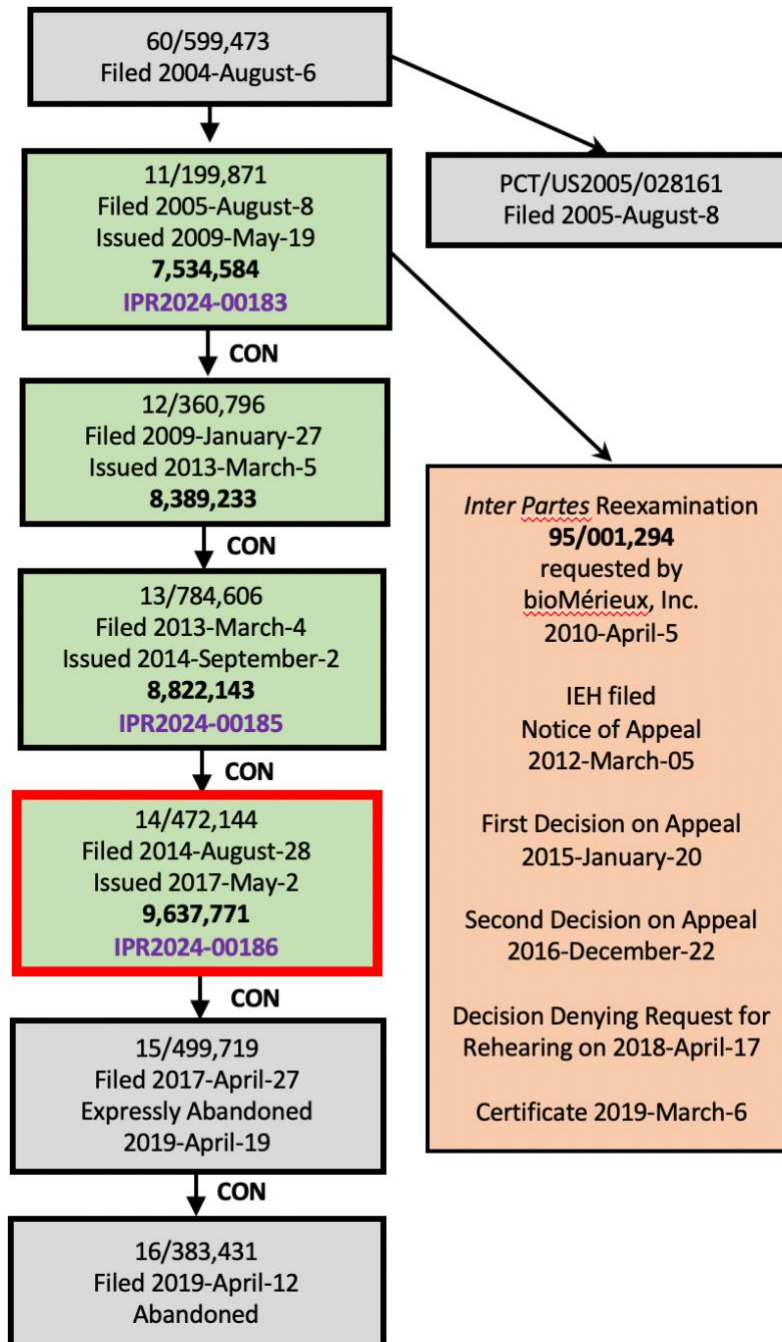
		pieces from a given sample lot (combined production lot) , to form a composite sample for testing. ”	
7	3:1-12	“[O]nce a composite sample is constructed . . . it is then enriched for the presence of a given pathogen/microbe by addition of appropriate amounts of enrichment media” and incubated. Testing is by “art recognized methods” including “immunoassay-based tests or PCR-based methods, or culturing of the organism of interest, or other DNA- or immunochemical-based methods.”	(c)- (e)

V. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”) at the time of invention would have a working knowledge of microbiology and would have been involved in developing sampling and testing methodologies for analysis of food products (“validation methodologies”). The POSA 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. The POSA would have been familiar with relevant scientific literature and industry regulations, directives, and guidelines relating to validation methodologies. Dickson ¶¶ 22-24.

VI. FAMILY TREE

A family tree diagram below depicts the '584 Patent and its continuations, No. 8,389,233 ("the '233 Patent") and the '143 and '771 Patents.



Dickson ¶¶ 87-89. Every application was examined by the same examiner except 15/499,719 (Ex. 1034), which was abandoned. No. 16/383,431 is not publicly accessible.

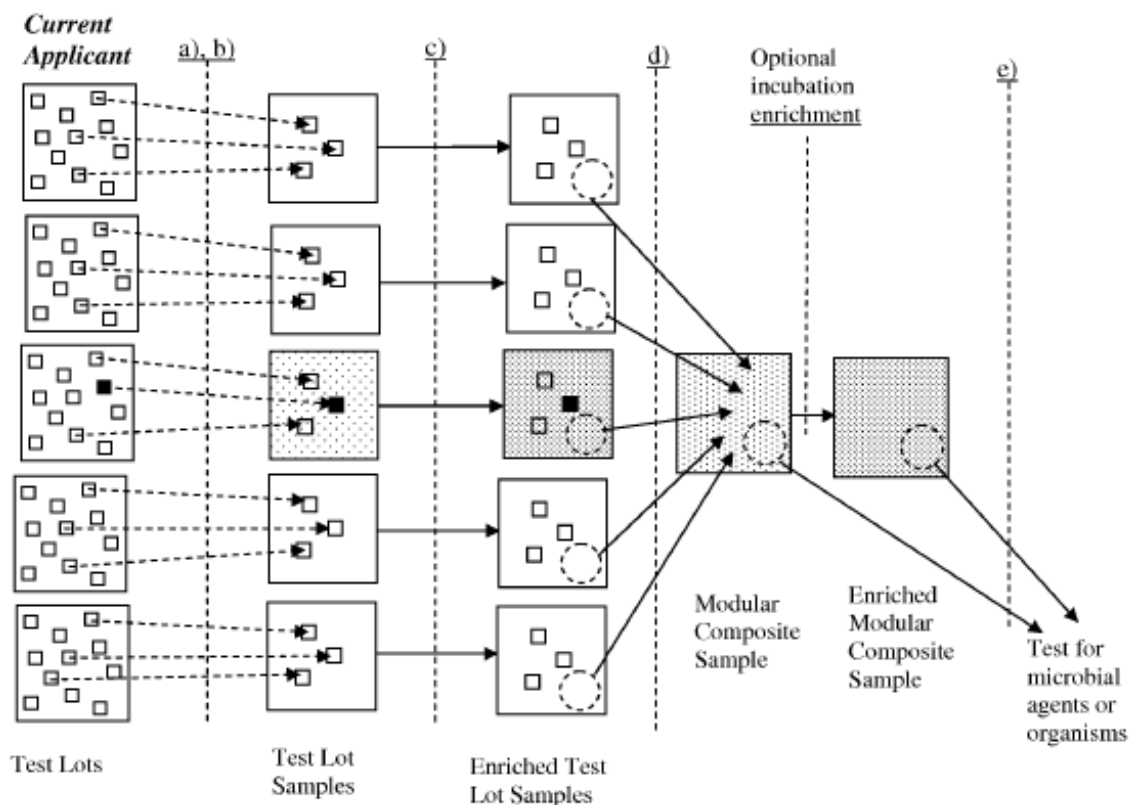
VII. PROSECUTION HISTORY OF '584 PATENT

A. Provisional Application No. 60/599,473

IEH's Patents claim priority to Provisional Application No. 60/599,473, which was filed on August 6, 2004. Ex. 1005 at 1; Dickson ¶ 91.

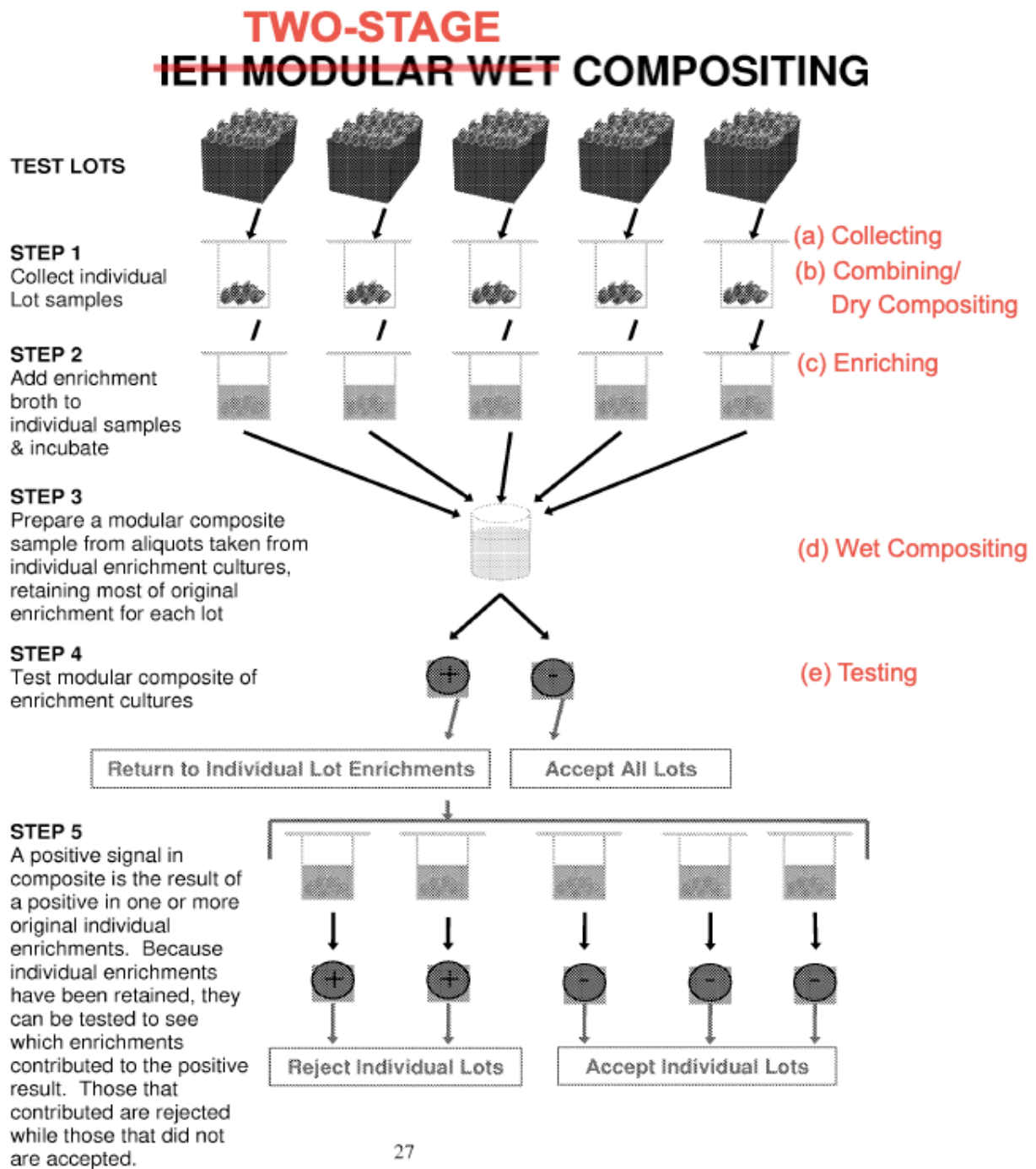
B. Responses to Office Action

In response to an Office Action in No. 11/199,871, IEH depicted independent claim steps (a)-(e) in a diagram, reproduced below. Ex. 1006, 155-87.



Id., 187. Dickson ¶¶ 92-97.

In another response, IEH depicted the independent claim steps with a second diagram, provided below.



Id., 270 (Petitioner’s annotations in red); Dickson ¶¶ 98-101. After minor amendments, the claims were allowed. Ex. 1006, 329, 332, 333, 354-357. Dickson ¶¶ 102-07.

VIII. REEXAMINATION OF ’584 PATENT

A. Summary

In an *inter partes* reexamination, No. 95/001,294, requested by bioMérieux, Inc., the claims of the ’584 Patent were repeatedly rejected by the Central Reexamination Unit (CRU). In an appeal, the Board initially affirmed but then reversed itself. Dickson ¶¶ 108-10.

B. Prosecution Phase

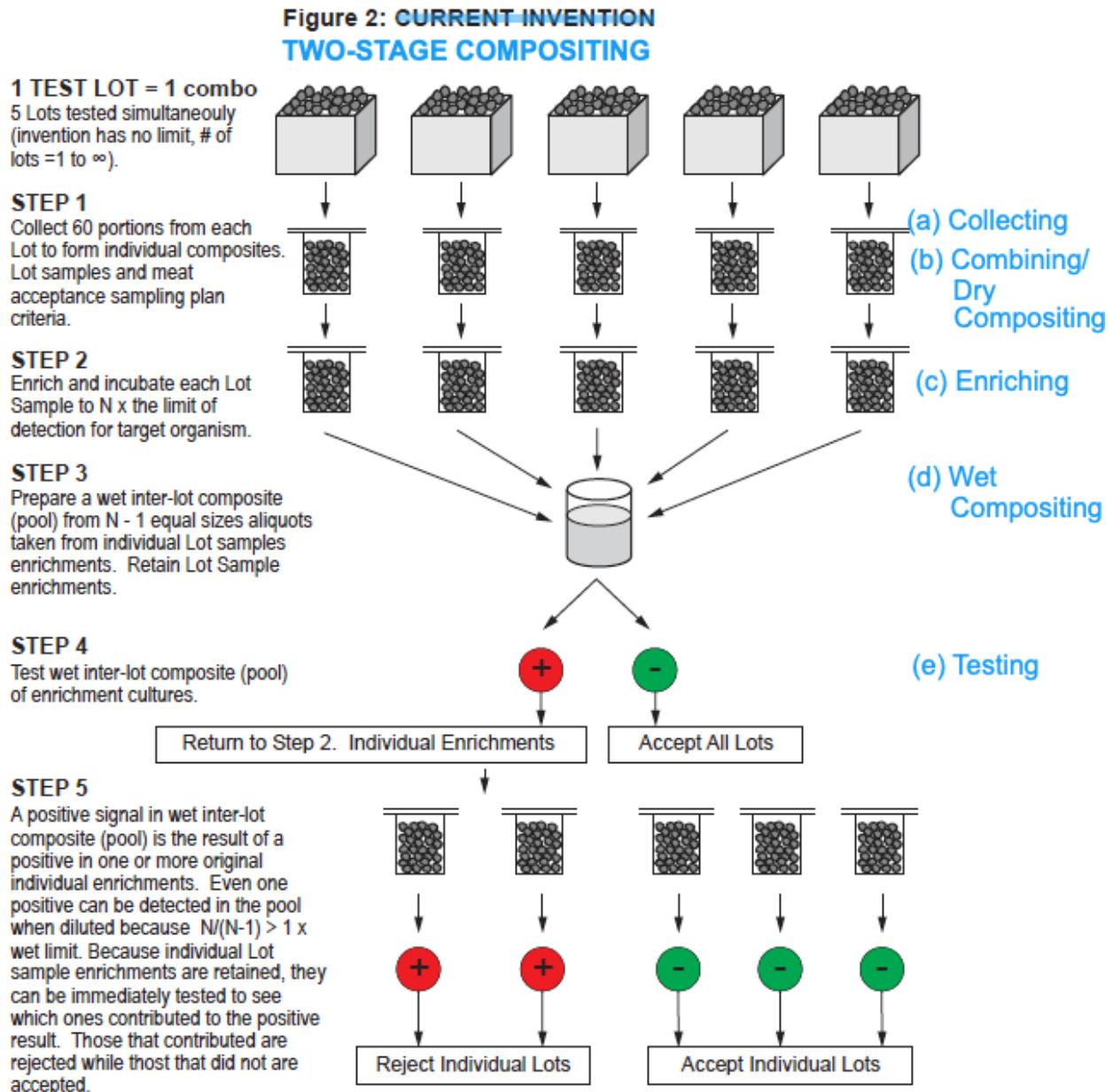
1. Request, Order, and Office Action

References cited in the Request include Chapter 1 of BAM 2003 (Ex. 1022), FSIS Directive (Ex. 1023), and Midura (Ex. 1024). Ex. 1007, 150-52; Dickson ¶¶ 111, 287-95; *see* § X-C *infra*. Additionally, references were cited disclosing retention of pre-enriched samples instead of enriched samples, including Price, Silliker (Ex. 1025), Gabis (Ex. 1026), and Jarvis (Ex. 1027). Ex. 1007, 150-152; Dickson ¶¶ 107, 296-329; *see* § X-D *infra*.

Reexamination was ordered. Ex. 1007, 145-78; Dickson ¶¶ 113-14. The claims were rejected. Ex. 1007, 179-231; Dickson ¶ 115.

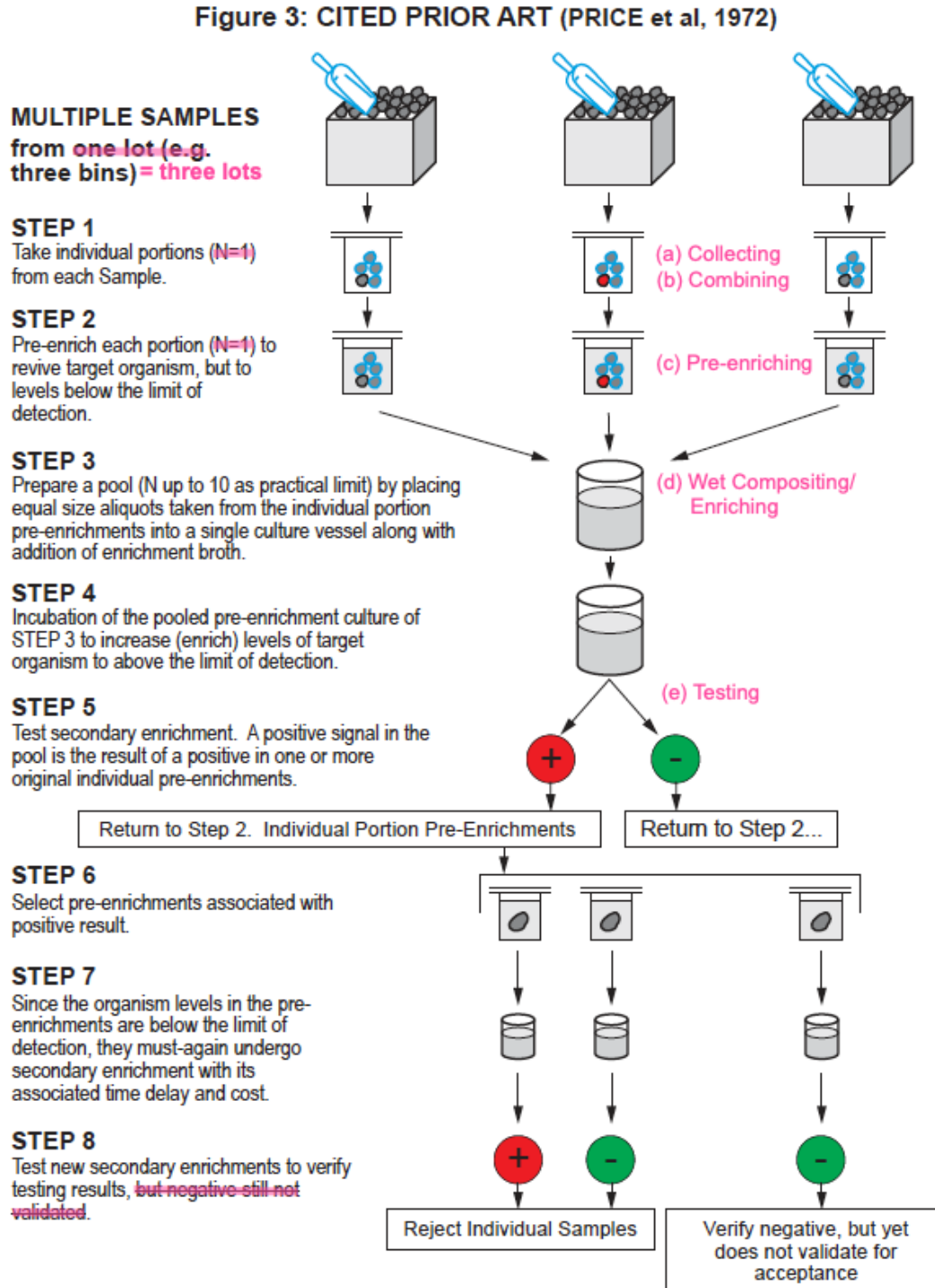
2. Response, Comments, and ACP

IEH responded and included a third diagram of its alleged invention, which has been recreated due to the poor clarity of the original. Ex. 1007, 232-99; Dickson ¶¶ 116-21.



Ex. 1007, 297 (Petitioner's annotations in color).

IEH's diagram of Price has also been recreated by Petitioner due to the original's clarity:



Id., 298 (Petitioner's annotations in color).

Price was characterized in bioMérieux’s Comments. *Id.*, 357-408; Dickson ¶ 122. The Examiner concluded the claims were not patentable in the Action Closing Prosecution (ACP). Ex. 1007, 409-76; Dickson ¶¶ 123-26.

3. Comments and RAN

The parties filed Comments. Ex. 1007, 477-624, 810-61; Dickson ¶¶ 127-34. In the Right of Appeal Notice (RAN), IEH’s arguments were rejected. Ex. 1007, 885-893; Dickson ¶¶ 135-38.

C. Appeal Phase

1. Briefs and First Decision

The parties filed briefs. Ex. 1007, 941-80, 1504-24; Dickson ¶ 135. After the Examiner’s Answer, the Board affirmed in a First Decision. Ex. 1007, 1525-36, 1559-88; Dickson ¶¶ 139-43. The affirmance included a new ground of rejection based on Jarvis, Price, FSIS Directive, and Midura. Ex. 1007, 1561, 1562. The Board concluded IEH failed to establish a nexus for purported secondary considerations because IEH’s data related to testing beef for *E. coli*. while IEH’s claims were broader. *Id.*, 1579-84; Dickson ¶¶ 144-54.

2. IEH’s Responses, bioMérieux’s Comments, and Examiner’s Answer

IEH responded. Ex. 1007, 1635-59; Dickson ¶¶ 155-58. Claims 1 and 37 were respectively amended to recite “beef” and “meat or poultry.” Ex. 1007, 1637,

1640. bioMérieux filed comments agreeing with the First Decision. *Id.*, 1674-97; Dickson ¶¶ 159-63. The Examiner rejected the claims again and concluded there was not a nexus. Ex. 1007, 1703-22; Dickson ¶¶ 164-72. IEH's responded. Ex. 1007, 1723-54; Dickson ¶¶ 173, 174. Then, bioMérieux filed comments. Ex. 1007, 1755-71; Dickson ¶¶ 175-80.

3. Second Decision

The Board's Second Decision reversed the Examiner. Ex. 1007, 1773-81; Dickson ¶¶ 181-90. The Board concluded the art taught wet pooling after non-selective enrichment not selective enrichment. *Id.*, 1780. The Board also relied on declarations from IEH employees (*id.*, 300-04, 310-15, 625-46, 759-84, 793-809, 1660-73) citing no corroborating evidence to support asserted secondary considerations. Ex. 1007, 1781-89; Dickson ¶ 191. Countervailing evidence from bioMérieux was submitted too late in the process to be considered. Ex. 1007, 1807-17; Dickson ¶¶ 192, 193.

Rehearing was requested by bioMérieux. Ex. 1007, 1791-1806; Dickson ¶¶ 192-95. IEH opposed. Ex. 1007, 1818-33; Dickson ¶¶ 196-98. The Board denied rehearing. Ex. 1007, 1854-72; Dickson ¶¶ 199-201. The reexamination concluded. Ex. 1007, 1873-75; Dickson ¶¶ 202, 203.

IX. PROSECUTION HISTORY OF CONTINUATION PATENTS

A. Prosecution History of '233 Patent

The '233 Patent issued from No. 12/360,796. Ex. 1008, 1. Like IEH's other patents, the independent claims of the '233 Patent recite in step (e) further testing of the enriched lot samples after an initial positive test result. However, the independent claims of the '233 Patent recite an additional limitation in step (e) requiring individual testing of each of the enriched separate test lot samples in addition to the composite sample. Ex. 1008, 15:33-38, 17:15-21; Dickson ¶¶ 204-207.

IDSs were filed to identify the reexamination's control number and to submit references from the reexamination. Ex. 1009, 77, 81-82, 113-15; Dickson ¶¶ 207-11. However, no reexamination documents were submitted from the USPTO, IEH, or bioMérieux. Dickson ¶¶ 209, 213, 214.

The claims were only rejected based on double patenting with respect to the '584 Patent. Ex. 1009, 92, 93; Dickson ¶ 208. IEH filed a terminal disclaimer. Ex. 1009, 66-76; Dickson ¶ 210.

The Examiner provided Reasons for Allowance in which Price was incorrectly characterized as not teaching "re-testing of each of the three original pre-enrichment bottles (if that is to be considered as the equivalent of the composite

sample lots . . . of the instantly claimed invention).” Ex. 1009, 24; Dickson ¶ 211. This **mischaracterization** contradicts Price’s Figure 1, which is reproduced below. Figure 1 shows pre-enriched, retained samples being subjected to individual testing after a positive test. Dickson ¶ 212.

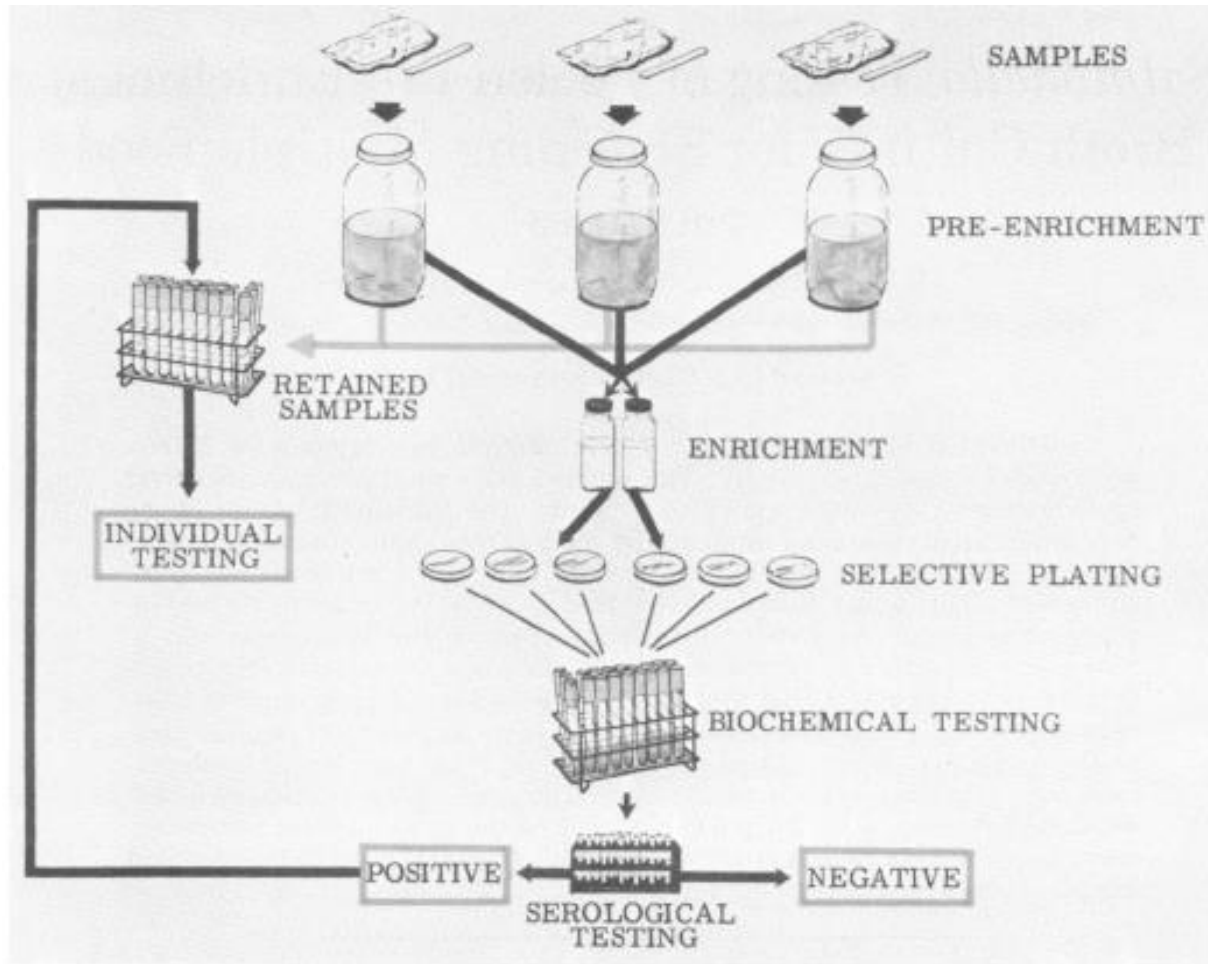


FIG. 1. *Salmonella* testing of pooled pre-enrichment broths.

Ex. 1017 at 680. The mischaracterization also contradicts Price’s clear statements. For example, Price states “[t]he pooling of broth cultures permits small portions of each individual culture to be retained for subsequent analysis if a positive test is detected following enrichment, thus maintaining the individuality of each test

sample.” *Id.*, 681; *see also id.*, 679; Dickson ¶ 212. The Examiner correctly noted in an Interview Summary after a telephone call with IEH’s attorney that Price was the “closest reference of record” and “does not teach to re-assess the sample constituting the composite.” Ex. 1009, 4; Dickson ¶¶ 215-216. However, the Examiner’s misunderstanding regarding further testing of portions of the enriched lot samples was **not corrected** on the record and there is no reason to conclude that the Examiner’s misunderstanding was ever corrected in the prosecution of the applications that yielded the Continuation Patents. Dickson ¶ 217; *see* § XIII-B-2 *infra*.

B. Prosecution History of ’143 Patent

The ’143 Patent issued from No. 13/784,606. Ex. 1002, 1. The claims were only rejected based on double patenting with respect to the ’584 and ’233 Patents. Ex. 1010, 52-58, 83-96; Dickson ¶¶ 218-20. An IDS was filed to submit references from the reexamination, however, no reexamination documents were included from the CRU, the Board, IEH, or bioMérieux, such as Office Actions, Responses, or Third-Party Comments. Ex. 1010, 106-108; Dickson ¶ 221. Also, the interview summaries from three interviews do not indicate that any documents or references from the reexamination were considered. Dickson ¶¶ 222-24. When the issue fee was paid, the appeal from the reexamination was proceeding and teams at the CRU had concluded multiple times that the claims of the ’584 Patent were not patentable,

the same claims that the Examiner had concluded were not patentably distinct from those that issued in the '143 Patent. Dickson ¶ 225.

C. Prosecution History of '771 Patent

The '771 Patent issued from No. 14/472,144. Ex. 1003, 1; Dickson ¶ 226. The claims were only rejected based on double patenting with respect to the '584, '233, and '143 Patents. Ex. 1011, 136-39; Dickson ¶¶ 229-30. An IDS was filed to submit references from the reexamination, however, no reexamination documents were included from the CRU, the Board, IEH, or bioMérieux, such as Office Actions, Responses, or Third-Party Comments. Ex. 1011, 14-16; Dickson ¶ 227. Also, the interview summary from an interview does not indicate that any documents from the reexamination were considered. Dickson ¶ 231.

When the issue fee was paid, the Board had issued its First Decision in the reexamination concluding that the claims of the '584 Patent were not patentable and the CRU Examiner had reached the same conclusion based on the Board's new ground in the reexamination. Dickson ¶ 232. Based on the record, it appears the Examiner was not informed about these adverse findings regarding claims he considered not patentably distinct from those in No. 14/472,144. *Id.* No longer concerned by Price, the Examiner indicated that he considered the FSIS Directive and Skov to be "[t]he closest art." Ex. 1011, 205-07; Dickson ¶¶ 233, 234. The Examiner faulted the FSIS Directive for not teaching "**re-testing individually each**

of the original specimens constituting any of the composites.” Ex. 1011, 205 (emphasis in original). While the FSIS Directive is relevant, it is primarily focused on sampling. Ex. 1023; Dickson ¶ 233. Skov relates to sampling methods for fecal samples. Ex. 1006, 227.

X. PRIOR ART

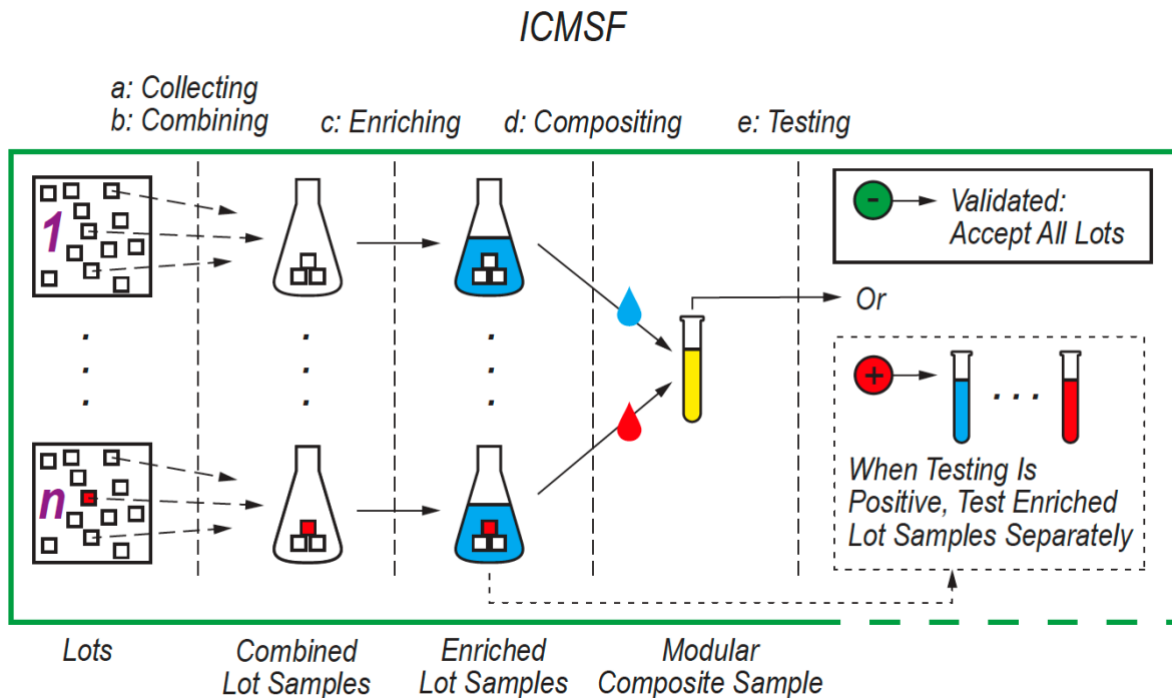
A. Ground References

1. ICMSF

The International Commission on Microbiological Specifications for Foods publishes a series of books titled “Microorganisms in Foods,” referred to in the industry as the ICMSF guidelines or more specifically by their series number such as ICMSF 7. Exhibit 1012, which includes Chapters 6, 10, 12, and 15-17 of ICMSF 7, is referred to herein as ICMSF.

Chapter 6 discusses lots in a consignment. Ex. 1012, 119. ICMSF 2 defines a consignment as “a quantity, large or small, of food destined, in commerce, to a particular recipient, usually consisting of multiple containers of food from one or more lots.” Ex. 1013, 275. Chapters 6, 10, and 12 describe (a) collecting, according to a sampling plan, sub-samples representative of meat lots in a consignment; (b) combining the sub-samples to yield composited lot samples while maintaining traceability; (c) enriching the composited lot samples to provide a set of enriched, composited lot samples; (d) wet compositing by removing portions of the enriched,

composited lot samples and combining them; and (e) testing to obtain a negative result. Ex. 1012, 113-21, 183-97, 225-36. Thus, ICMSF is depicted below as disclosing every aspect of steps (a)-(d) of the independent claims and most of step (e) too:

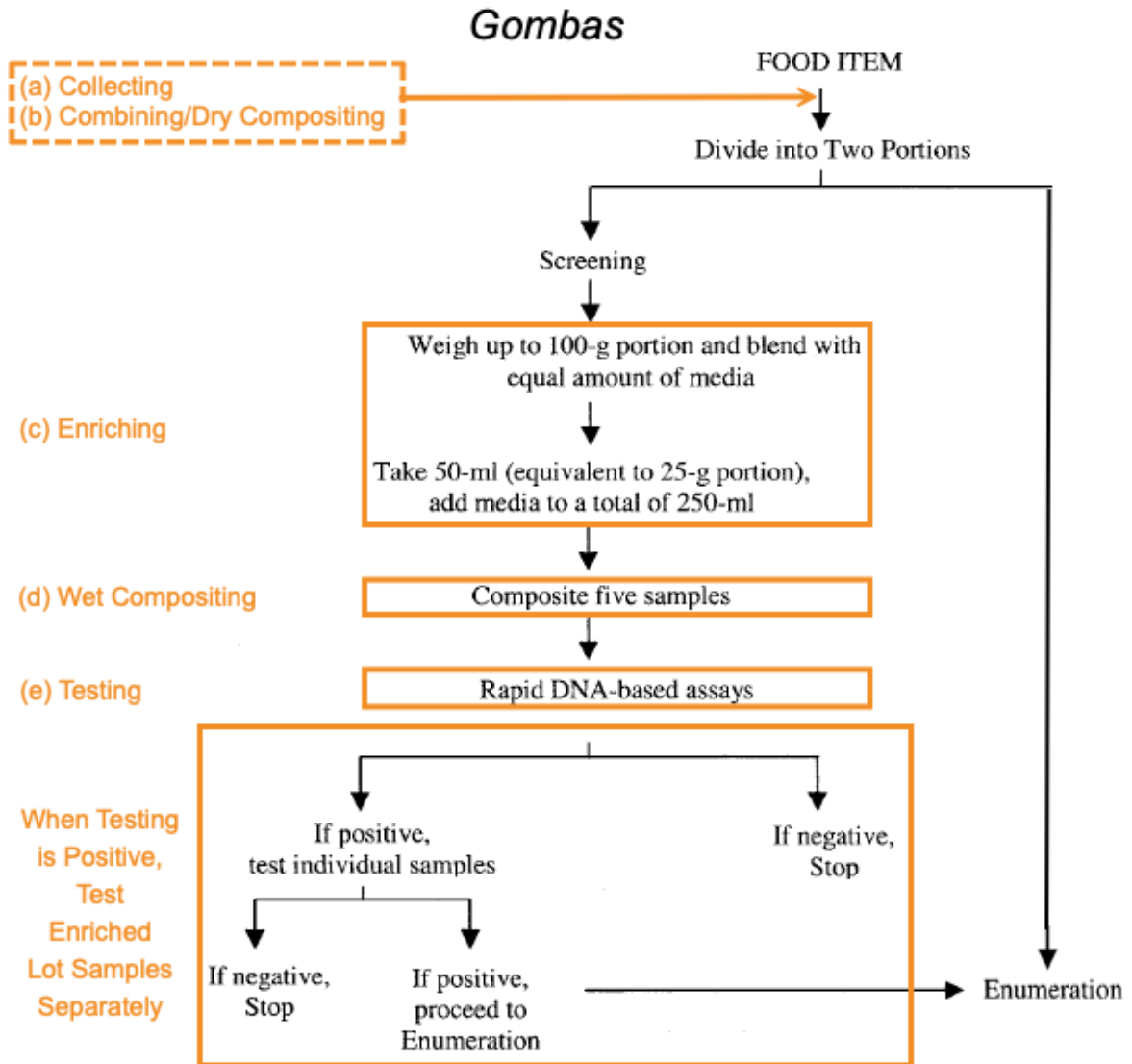


Dickson ¶¶ 235-40. Chapters 15-17 respectively focus on *Salmonella*, *Listeria*, and *E. coli*. *Id.*, 273-332.

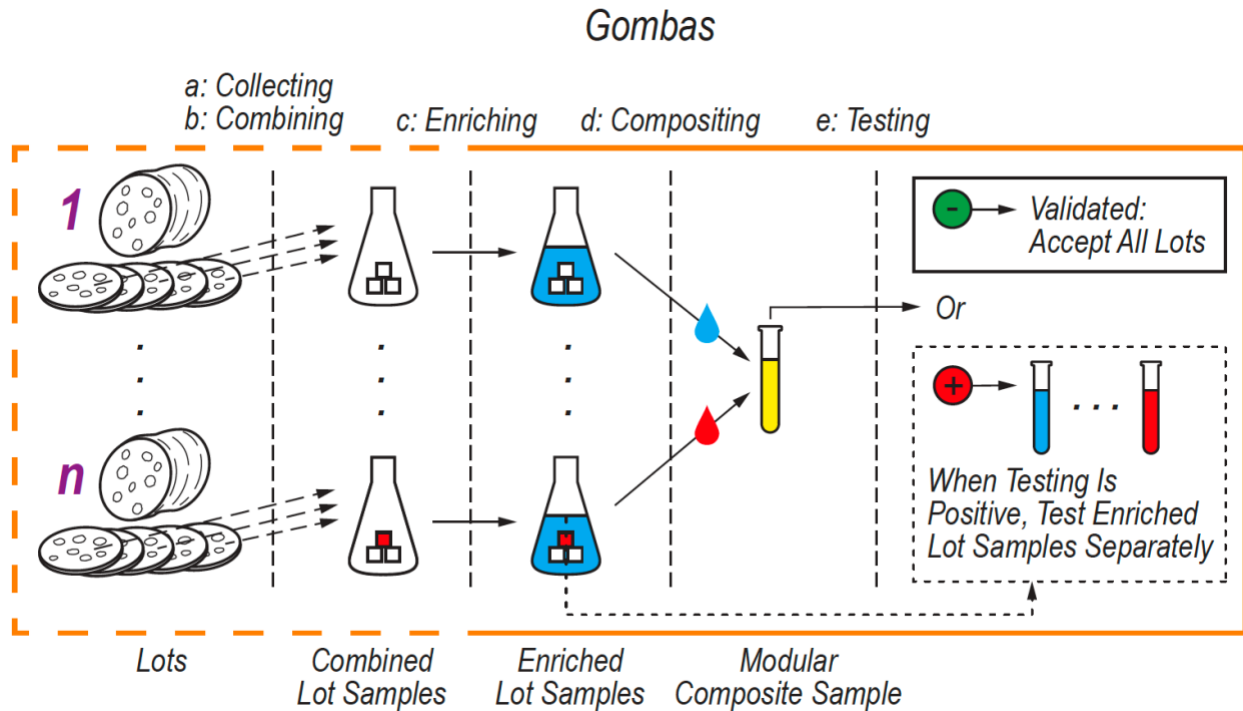
2. Gombas

Gombas is a research article surveying *Listeria* in RTE foods including beef bologna. Ex. 1014, 559, 562. Gombas describes the primary limitations of each independent claim step but is relied on for its teachings regarding steps (c)-(e).

Below is an annotated version of Figure 1 in Gombas correlated to the independent claim steps:



Ex. 1014, 563 (Figure 1 (annotated)). Below is a diagram of Gombas mirroring the information in Figure 1 but styled like the diagram of the independent claim steps:

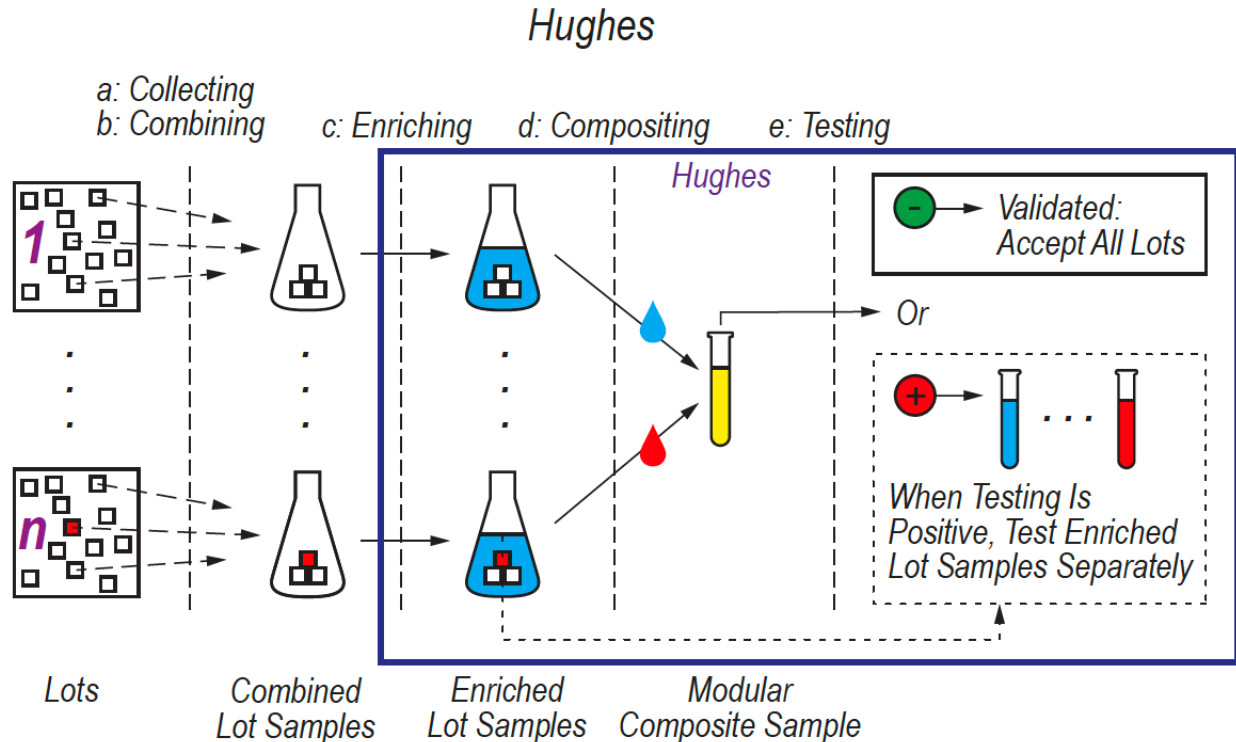


Dickson ¶¶ 241-49. Gombas adapted methods of Chapter 8 of MLG 1998 (Ex. 1029). Ex. 1014, 563; Dickson ¶ 238.

3. Hughes

Hughes is a comparative study of enrichment procedures for *Salmonella* testing of food including raw turkey. Ex. 1015, 634. Its “Preparation of Sample” section identifies four phases including (a) pre-enrichment, (b) selective enrichment, (c) post-enrichment, and (d) preparation of sample for enzyme immunoassay analysis (“EIA”). *Id.*, 636, 638. This section further discloses compositing portions of enriched samples to form a composite sample. *Id.* It also discloses retention of the enriched samples “for culture confirmation of any EIA-positive samples.” *Id.*,

638. The steps described in this section of Hughes correlate to independent claim steps (c)-(e) as depicted below:

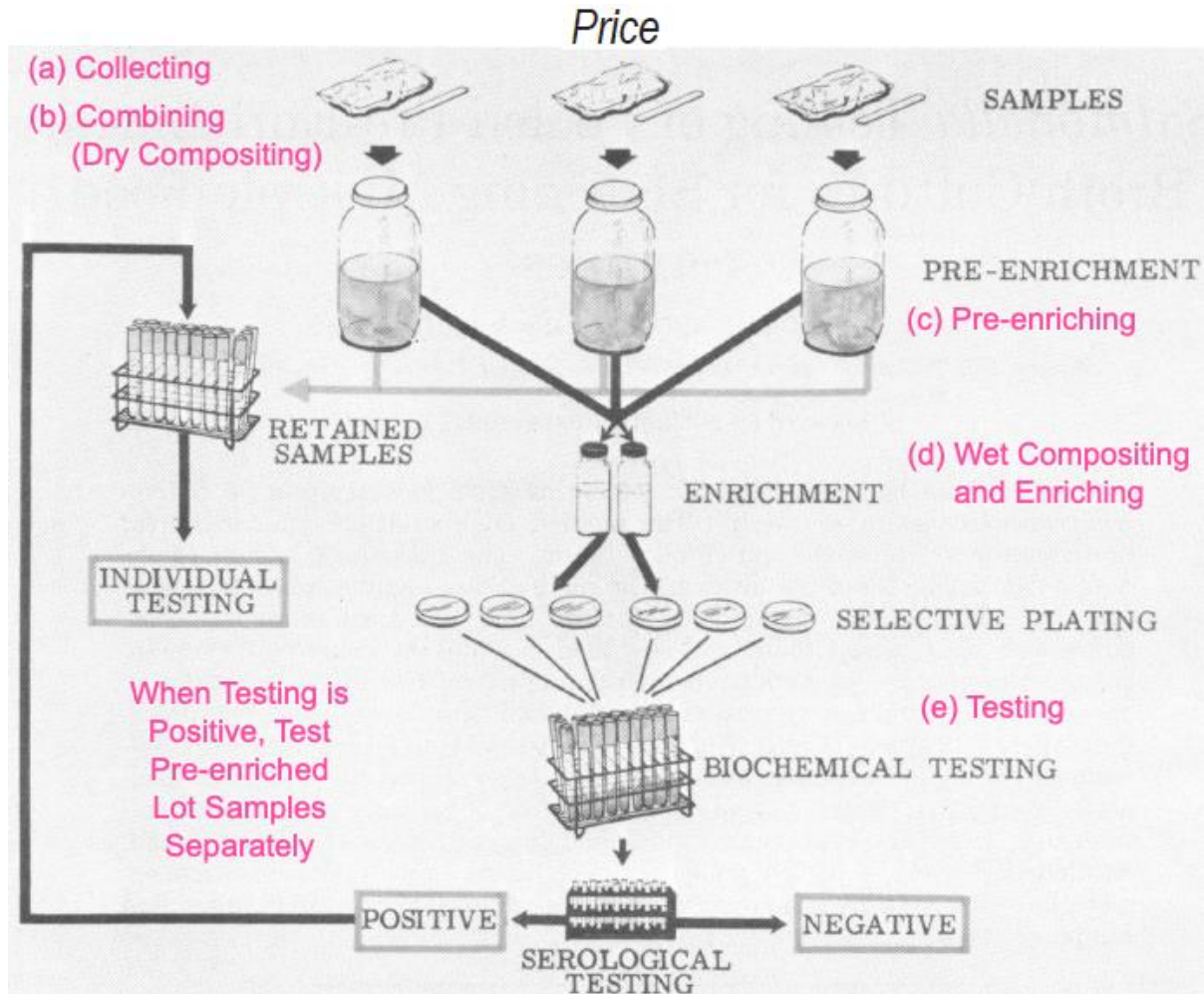


Dickson ¶¶ 250-60. Hughes 2003 confirms the pooling of enrichments shown above. Ex. 1016, 775, 776; Dickson ¶ 260.

4. Price

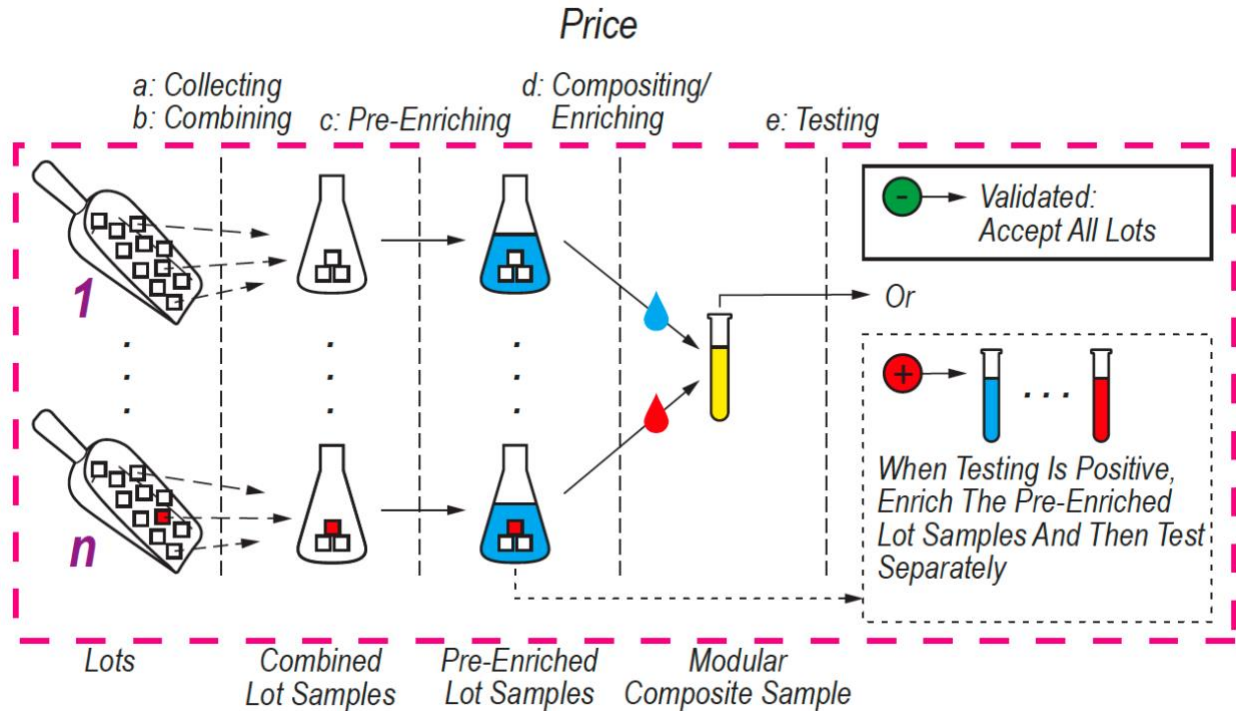
Price established that “*Salmonella* pre-enrichment broths can be pooled for analysis without loss in sensitivity to *Salmonella* in the individual samples.” Ex. 1017, 679. Price tested dry food materials that had been inoculated (purposefully contaminated) with *Salmonella*. *Id.*

Below is Price's Figure 1 with annotations for independent claim steps highlighted in pink:



Id., 680, (Figure 1 (annotated)). Price's framework discloses the independent claim steps except: (1) the food samples are not meat, and (2) after the samples have been collected from the lots and combined, the combined lot samples are pre-enriched, not selectively enriched, before compositing. Dickson ¶¶ 261-67. Other depictions of Price's framework include IEH's Figure 3 as provided at § VIII-B-2 *supra* with color annotations including scoops representing collecting dry food from the

depicted bins and the diagram below styled like the diagram of the independent claims.



Dickson ¶¶ 268-70.

B. Ground References for Dependent Claims

Stewart, Fratomico, D’Haese, and D’Aoust are relied upon for several dependent claim grounds. Dickson ¶¶ 271-86.

C. State-of-the-Art References for Steps (a)-(b)

1. BAM

The Bacteriological Analytical Manual (BAM) is the FDA’s official methods of microbiological analysis for foods. Exhibit 1022 includes Chapters 1, 5, and 10

of BAM 2003. Chapter 1 provides guidance on collecting sub-samples according to statistical sampling procedures. Chapters 5 and 10 describe testing procedures for *Salmonella* and *Listeria*, respectively. Dickson ¶¶ 287-90.

2. FSIS Directive

USDA's Food Safety and Inspection Service (FSIS) published the FSIS Directive, which discloses randomly collecting sub-samples from beef lots according to sampling plans and combining the sub-samples. Ex. 1023, 1, 27-28; Dickson ¶¶ 292-94.

3. Midura

Midura is a chapter from a compendium providing details about sample collection under statistical-based sampling plans. Ex. 1024, 13-17; Dickson ¶ 295.

D. State-of-the-Art References for Steps (c)-(e)

1. Silliker and Gabis

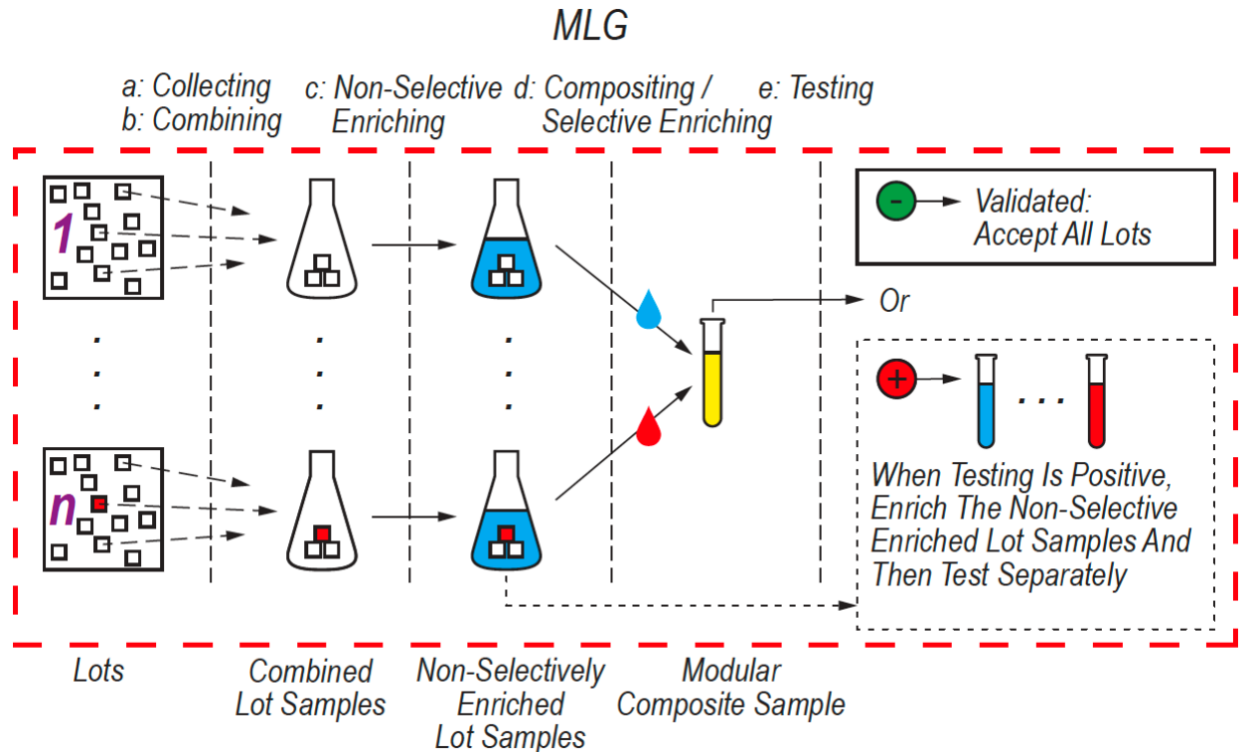
Others built on Price's procedural framework for two-stage compositing including Silliker (Ex. 1025) and Gabis (Ex. 1026), which tested meat, as discussed by ICMSF. Ex. 1012, 187; Dickson ¶¶ 296-315.

2. Jarvis

Jarvis discloses compositing methods. Ex. 1027, 141-142; Dickson ¶¶ 316, 317.

3. MLG

FSIS publishes guidelines for analytical methods for meat and poultry, known as the Microbiology Laboratory Guidebook (MLG). Exhibit 1028 includes chapters 4.02, 5.03, and 8.03, which respectively relate to *Salmonella*, *E. Coli*, and *Listeria*, of MLG 2003. Dickson ¶¶ 321-29. MLG's description of two-stage compositing for meat, which built upon Price's template, also pools non-selectively enriched lot samples as shown below.



Dickson ¶¶ 318-20. MLG's description of two-stage compositing, which built on Price's template, reflects industry acceptance. *Id.*

XI. CLAIM CONSTRUCTION

IEH's Patents specifically define terms in a "Definitions" section. Ex. 1003, 5:34-7:63. Some terms were defined were relied on during reexamination. Ex. 1007, 184. Some were defined by IEH in *Primus Grp., Inc. v. Inst. for Env'tl. Health, Inc.*, No. 3-18-cv-00005 (N.D. Cal.) ("Primus Litigation"). See Exs. 1035-38.

A. "Lots"

IEH's Patents use various terms to describe "lots" including test lots, single production lots, and single-unit production lots. Claim 1 recites "lots." Claim 37 refers to "lots" in its preamble but recites "single production lots" in its body. These terms are all types of "lots."

The specification defines "test lot":

The term "test lot" . . . [refers] to **an assemblage of one or more specimens** . . . of products of a production process . . . 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. 1003, 5:43-54 (emphases added).

The specification also defines “single-unit production lots”:

The term . . . “single-unit production lot” as used herein is a form of test lot, and refers to a single unit of production (e.g. for beef trim a “combo,” or for almonds a “bin”).

Id., 5:55-60. The specification further states:

[A] test lot (or test unit) (e.g., a single-unit production lot or single production unit lot) is defined and taken as one or more operationally-linked specimens of a medium or process. A test lot may be a single unit of production (e.g., a single combo, bin, pallet, or segment of production, etc.).

Id., 7:54-63; *see also id.*, 11:37-41, 13:17-22. These quotes show single-unit production lots and single production unit lots are test lots, all of which are forms of lots. Dickson ¶¶ 330-40; *see also id.* ¶¶ 205, 206, 228, 229.

Based on these definitions, 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. Recitation of the term “operationally-linked” in the claims is superfluous because the term is included in the above-quoted definitions.

B. “Separately Sampled”

Step 1(a) recites “collecting” from “lots” that are “separately sampled.” The specification describes “separately collecting a plurality of portions from each of a plurality of test lots” so “each test lot sample is attributed to a particular corresponding test lot.” Ex. 1003, 9:36-45; *see also* 4:26-28, 5:13-15. Similarly, the specification also states sampling occurs so “information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot.” *Id.*, 5:51-54. The claim language and the specification indicate each lot is separately sampled when collecting samples from lots. Dickson ¶¶ 341-49.

Sampling 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.” *Id.*, 6:5-6:11. In the Primus Litigation, IEH asserted “the inherent meaning of a ‘sample’ implies a collection of elements that would be *representative* of the lot being sampled.” Ex. 1037, 7 (emphasis in original). National Beef agrees and 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.

In the Primus Litigation, IEH indicated the collecting step means “collecting multiple samples from different, non-contiguous locations from each of multiple

separate” lots. Ex. 1036, 2. The district court agreed. Ex. 1038, 4-6. While the term “non-contiguous locations” is not in the specification, National Beef agrees 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. The need to randomly collect from different, disparate, physical locations within lots of beef (*e.g.*, beef trim combos weighing 2,000 lbs.) is implicit in Example I of the specification (Ex. 1003, 11:31-12:55) because “microbial contaminants are unevenly spread throughout the products.” *Id.*, 3:27-28; *see* Ex. 1037, 7-9.

However, Example II also indicates that “samples are collected at random times over a production shift (*e.g.*, from ‘cleanup to cleanup’), and from several product lines.” Ex. 1003, 13:2-4. Thus, obtaining representative samples using randomness of two variables—time and location. Representative samples are obtained via randomness of a single variable, time, in Example III, which states “final almond products of each type are collected at random times over a production shift.” *Id.*, 14:16-18. Thus, 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 operationally applicable to all specimens of the assemblage, and thus to the test lot.” *Id.*, 5:51-53.

C. “Combining”/“Compositing”

Step 1(b) recites compositing samples to provide a corresponding set of separate composited lot samples. The specification defines “compositing” as “combining a number of single product portions to form one larger sample.” Ex. 1003, 6:5-7. Because the meaning for the synonyms “compositing” and “combining” is clear, construction is unnecessary. Dickson ¶¶ 350, 351.

D. “Enrichment”/“Enriching”

“Enrichment” is defined as “incubating a test lot sample . . . under conditions suitable . . . to allow levels of a target agent/organism . . . to reach detectable levels and become uniform or substantially uniform throughout the enriched test lot sample.” Ex. 1003, 6:30-36; Dickson ¶ 352. Thus, in the Primus Litigation, IEH agreed “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.” Ex. 1036, 2. National Beef also agrees.

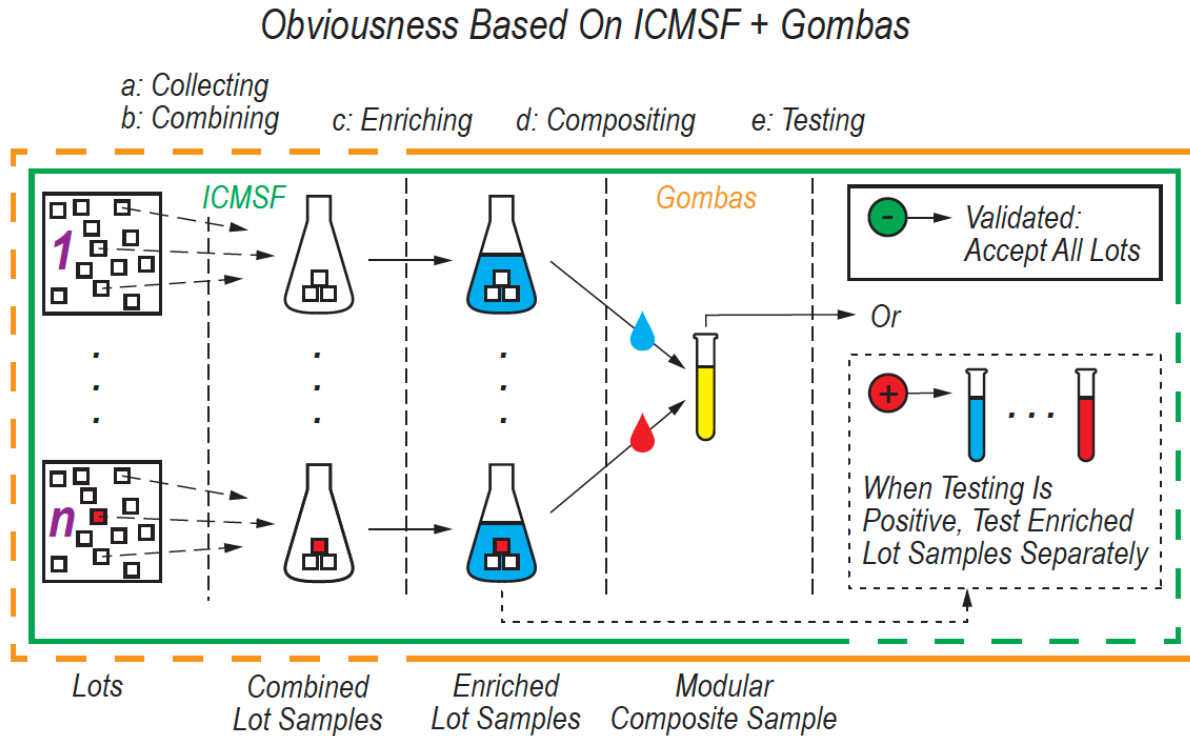
E. “Validated”

“Validation” is defined as “determining that a particular sample tests negative using the detection assay.” Ex. 1003, 7:27-29; Dickson ¶¶ 353, 354. Similarly, IEH agreed in the Primus Litigation “validate” means “to ‘determine that a particular sample tests negative using the detection assay.’” Ex. 1036, 2. National Beef agrees.

XII. DETAILED ANALYSIS OF CHALLENGE GROUNDS

A. Ground 1: Obviousness Over *ICMSF* In View Of *Gombas*

As depicted below, *ICMSF* discloses steps (a)-(d) and most of step (e) and *Gombas* is relied on primarily for disclosing steps (c)-(e).



Dickson ¶ 356.

1. Claims 1 and 37

a. Preamble

Claim 1	Claim 37
A method of sampling and testing products	
for microbe in multiple separate lots, comprising:	for microbe(s) in multiple separate lots, comprising

See §§ XII-A-1-b and XII-A-1-f to XII-A-1-i *infra*; Dickson ¶¶ 357-59.

b. Step (a) — Collecting

Claim 1	Claim 37
separately collecting multiple independent samples from each of multiple separate	
lots,	single production lots,
wherein each separate	
lot	single production lot
is separately sampled by taking said multiple independent samples thereof;	

ICSMF states:

Many 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. . . . 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.

Ex. 1012, 225 (emphases added). The lots may be beef or poultry. *Id.*, 184-91, 226, 230. Thus, ICMSF discloses collecting a plurality of samples or sample units (other synonyms include portions, specimens, and sub-samples) from lots of beef or poultry. *See id.*, 114, 119; Dickson ¶¶ 360-64, 372.

ICMSF describes collecting from a lot or lots:

If 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. 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.

Ex. 1012, 119 (emphases added). Additionally, 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 separately collecting multiple independent samples from multiple separate lots.

ICMSF describes a lot as “a collection of units of a product.” Ex. 1012, 119. ICMSF further indicates a lot has been defined 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. 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., 327. Thus, ICMSF discloses separately collecting multiple independent samples from multiple separate single production lots. Dickson ¶¶ 366-68.

c. Step (b) — Combining

Claim 1	Claim 37
separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited	
lot samples,	single production lot samples,
wherein each of the separate composited	
lot samples	single production lot samples
is attributed to a particular corresponding separate	
lot;	single production lot;

ICMSF states:

To **reduce laboratory effort** while maintaining the stringency of the sampling plan, it would be helpful to **combine either groups of analytical units or the enrichment cultures therefrom**, using plans in which the presence of a single positive rejects the consignment. . . . This finding suggests that considerable reductions may be made in the cost of laboratory analyses **by compositing (pooling) analytical units**. Such compositing offers the prospect of large increases in the number of analytical units, n, with corresponding increase in the stringency of examination, without correspondingly increasing laboratory effort.

Id., 187 (emphases added). Similarly, ICMSF states, “There is the very great technical advantage of combining many analytical units for bacteriological examination.” Ex. 1012, 188; *see also id.*, 187. ICMSF also describes composites prepared by combining “15 (25 g analytical units)” and “composites of 100 g, 200 g, or more.” *Id.*, 195, 232; *see* AAPA #5; *see also* Dickson ¶¶ 375-79.

ICMSF states, “All steps up to the analysis must be controlled . . . to allow reliable traceability.” Ex. 1012, 227. ICMSF indicates lot samples are traceable to a particular corresponding lot:

It is therefore helpful . . . to give **identifiable code numbers** to batches (lots) of food produced over short time periods (e.g., a day or part of a day) for particular processes. The choice of **coding system** will vary from process to process depending on the type of process and degree of homogeneity within the batch. For example, a continuous process may produce a relatively homogeneous product, in which case **a lot** could include units produced continuously **over a relatively long time**, whereas a **batch process**, such as batch retorting, may require the **coding** of relatively few product units as one lot (e.g., one retort load). . . .

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.**

Id., 119 (emphases added).

Gombas states, “Samples were assigned codes” and product information was recorded for the luncheon meats including “sampling location.” Ex. 1014, 563. The system disclosed by Gombas for testing individual samples, when composited samples test positive, inherently requires tracking the individual samples that contributed to the composite. See § XII-A-1-h *infra*. Thus, Gombas also discloses that each of the separate composited lot samples is attributed to a particular corresponding separate lot. Dickson ¶¶ 374, 380.

d. Step (c) — Enriching

Claim 1	Claim 37
enriching	
each	
of the separate composited	
lot samples	single production lot samples
to provide a set of separate composited	
lot samples	single production lot samples
enriched for the target microbe(s);	

ICMSF states:

To **reduce laboratory effort** while maintaining the stringency of the sampling plan, it would be helpful to **combine either groups of analytical units or the enrichment cultures therefrom**, using plans in which the presence of a single positive rejects the consignment.

Ex. 1012, 187 (emphases added). Also, ICMSF describes preparing composites of analytical units then diluting “for qualitative (enrichment)” analysis. *Id.*, 231-32; *see also* AAPA #5, #7. By enriching the composite lot samples, they are enriched for a target microbe. Dickson ¶¶ 284-86, 381-85; *see also* Ex. 1021, 372.

Gombas also discloses enriching:

[A]pproximately 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 ± 2 h**.

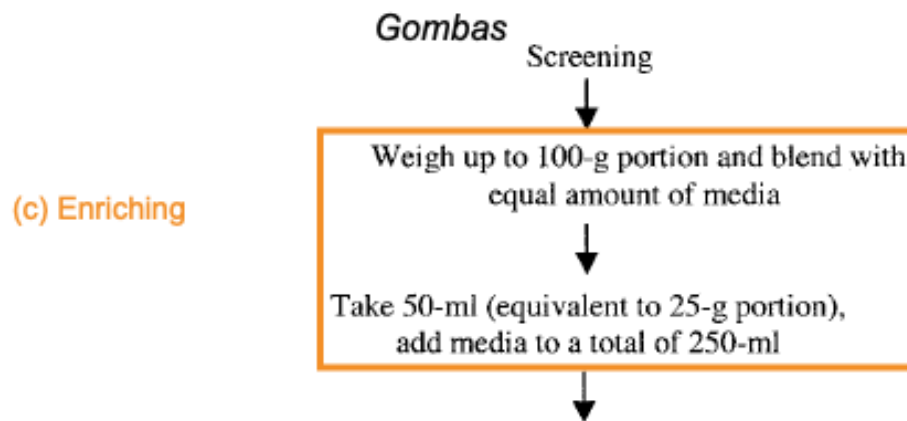
Ex. 1014, 563 (emphases added); *see also id.*, 564.

Gombas further indicates that:

For each California sample, 0.1 ml of the demi-Fraser enrichment culture was transferred to 10 ml of morpholinepropanesulfonic acid-*Listeria* **enrichment broth and incubated** at 35°C for 20 to 24 h. After the secondary enrichment, 1 ml of the broth culture was used for screening with the BAX assay as described below.

Id., 564 (emphasis added). Dickson ¶¶ 386-90.

Gombas's Figure 1 depicts an incubating/enriching step as shown in the excerpt below:



Id., 563 (Figure 1 (annotated)).

e. Step (d) — Wet Compositing

Claim 1	Claim 37
d) removing portions of each separate enriched composited	
lot sample,	single production lot sample,

and combining the removed portions to provide a pooled modular composite sample; and

ICMSF describes compositing the enriched lot samples:

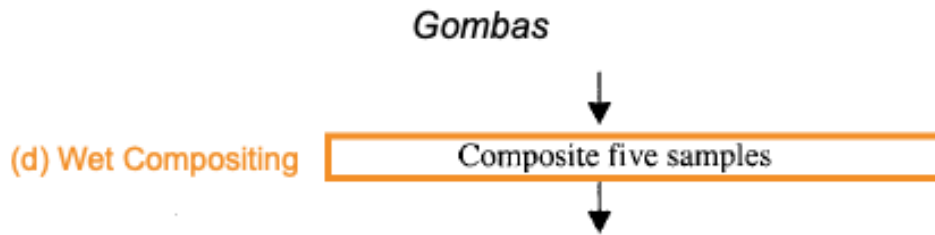
To reduce laboratory effort while maintaining the stringency of the sampling plan, it would be helpful to **combine** either groups of analytical units or the **enrichment cultures** therefrom, using plans in which the presence of a single positive rejects the consignment. . . . This finding suggests that considerable reductions may be made in the cost of laboratory analyses by **compositing (pooling) analytical units**. Such compositing offers the prospect of large increases in the number of analytical units, n , with corresponding increase in the stringency of examination, **without correspondingly increasing laboratory effort**.

Ex. 1012, 187 (emphases added); Dickson ¶¶ 391-93.

Additionally, Gombas discloses wet compositing of enriched samples:

Up to five like-product samples were composited and screened. . . . For California samples, **five 1-ml samples of secondary enrichment broths were composited**.

Ex. 1014, 564. Gombas's Figure 1 depicts wet compositing as shown in the excerpt below:

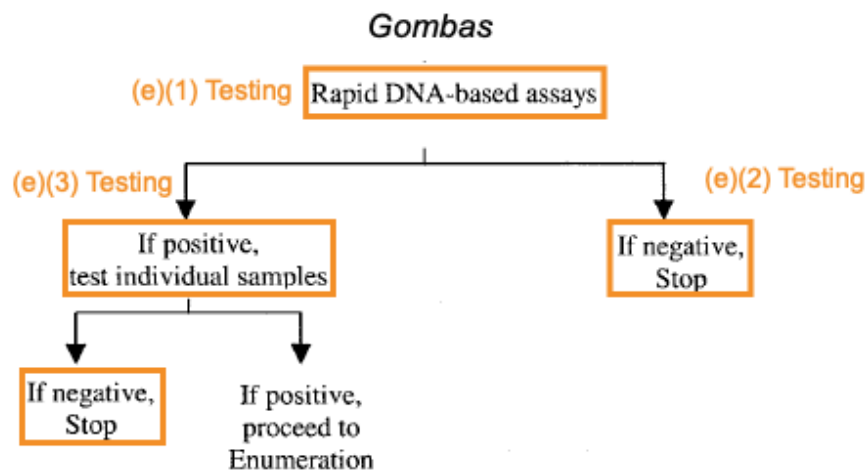


Id., 563 (Figure 1 (annotated)); Dickson ¶ 394.

f. Step (e)(1) — Testing

Claim 1	Claim 37
testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s),	

While ICMSF describes testing enrichment cultures of composite samples with suitable detection assays (Ex. 1012, 187) and “presence/absence tests” (*id.*, 233), testing methodologies are not the focus of ICMSF. Dickson ¶¶ 395-96. However, Gombas provides a complete framework for testing, and a POSA would have been motivated to modify ICMSF based on Gombas’s framework:



Ex. 1014, 563 (Figure 1 (annotated)). Gombas also discloses a suitable detection assay:

For California samples, . . . the 5-ml composite was **tested** by the **BAX assay** according to the manufacturer's procedures.

Ex. 1014, 564. These assay types were “art recognized.” Ex. 1003, 3:9-13 (AAPA #7); Dickson ¶¶ 397, 398.

g. Step (e)(2) — Tested Negative

Claim 1	Claim 37
wherein when such testing is negative all of said samples that were composited to form the separate composited	
lot samples	single production lot samples
are deemed negative for the target microbe(s) and each of the multiple separate	
lots	single production lots
is validated, and	

As discussed regarding step (a) (§ XII-A-1-b *supra*), ICMSF describes correlating lots in a consignment with lot samples so a negative or positive test result enables a lot to be validated or rejected. *Id.*, 118-19.

ICMSF describes sampling plans in which “*c* is the maximum allowable number of sample units yielding a positive result.” *Id.*, 115. For many scenarios, the requirement is $c = 0$, which indicates the testing is negative. *Id.*, 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. Dickson ¶¶ 399-402. Thus, ICMSF teaches step (e)(2).

To the extent ICMSF is considered not to disclose some aspect of step (e)(2), Gombas indicates a negative test result is the end of the process:

If a composite tested **negative**, all samples in the composite were considered negative (in 25 g) and were **not tested further**.

Ex. 1014, 564 (emphases added). In the combination, a negative test result equates to being validated. Dickson ¶¶ 403, 404. Figure 1 of Gombas also depicts stopping after a negative test, as shown above regarding step (e)(1).

h. Step (e)(3) — Further Testing After Positive Test

Claim 1	Claim 37
wherein when such testing is positive, each of the individual separate composited	
lot samples	single production lot samples
that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited	
lot samples	single production lot samples
is positive for the target microbe(s), wherein the	
lots	single production lots

corresponding to any negatively testing composited	
lot samples	single production lot samples
are validated.	

The combination of ICMSF and Gombas describes retaining a portion of the enriched lot samples (steps (b)-(d), §§ XII-A-1-c to XII-A-1-e). Additionally, ICMSF states:

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.

Id., 119 (emphases added). Additionally, ICMSF states, “There is often a desire to retest retained samples.” *Id.*, 191; *Dickson* ¶¶ 405-08.

Gombas, more specifically teaches:

If a composite tested **positive**, samples in the composite were tested **individually** . . . by the **BAX assay** with the secondary enrichment broths. **Individual samples that tested negative were not tested further.**

Id., 564 (emphases added). Thus, Gombas teaches further testing of a retained portion of the respective enriched separate lot sample using the same protocol (BAX assay) used in step (e)(1). Figure 1 of Gombas, as shown above regarding step (e)(1),

also depicts testing individual enriched samples if the composited sample tests positive and stopping after a negative result. Dickson ¶ 409.

The combination of ICMSF and Gombas teaches that after the composited samples test positive, then the individual samples used to form the composited sample are individually tested with the same protocol to determine which of the separate composited lot samples is positive for the target microbe(s). Dickson ¶¶ 410, 411. Based on the combination, any lots corresponding to any negatively testing composited lot samples are considered to be validated. *Id.*

2. Obviousness Rationales

ICMSF would have guided a POSA seeking to test a consignment of lots, such as lots containing beef or poultry, to collect portions from lots, to combine the portions into lot samples, to enrich the lot samples, to remove portions of each lot sample and to combine the portions to provide a composite sample. See §§ XII-A-1-b to e *supra*. ICMSF would have further guided a POSA to test the composite samples with the objective of obtaining a negative test to validate the corresponding lots for release into commerce. See §§ XII-A-1-f to g *supra*; Dickson ¶ 416.

As explained above, ICMSF and Gombas have interrelated teachings because ICMSF teaches steps (a)-(d) and most of step (e) while Gombas teaches at least steps

(c)-(e). For example, ICMSF extols the benefits of traceability and Gombas also teaches tracking codes. *See* § XII-A-1-c *supra*.

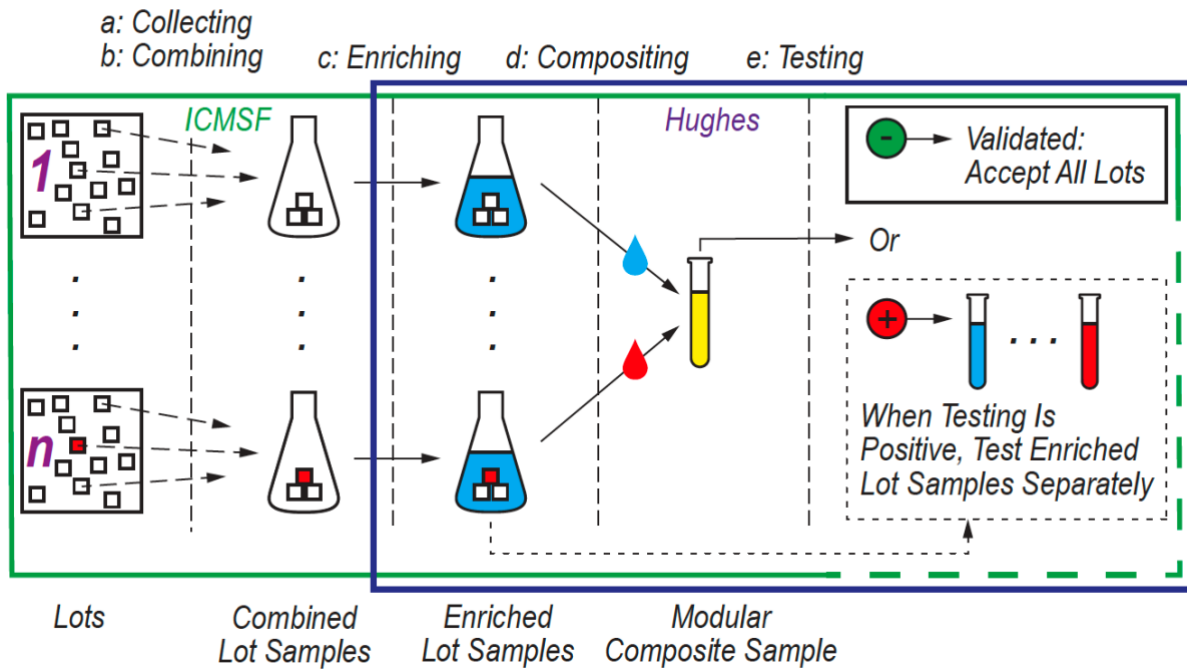
A POSA would have been motivated to modify ICMSF based on Gombas under the teaching-suggestion-motivation test so portions of the enriched, retained samples are further tested after a positive test of a composite sample by the same protocol, with a reasonable expectation of success for efficient validation.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

Moreover, 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). 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.

B. Ground 2: Obviousness Over ICMSF In View Of Hughes

As depicted below, ICMSF discloses steps (a)-(d) and most of step (e) while Hughes discloses steps (c)-(e):

Obviousness Based On ICMSF + Hughes



Dickson ¶¶ 421, 422.

1. Claims 1 and 37

a. Preamble

See §§ XII-B-1-b, XII-B-1-f to XII-B-1-I *infra*; Dickson ¶ 423.

b. Step (a) — Collecting

Step (a) is taught by ICMSF. See § XII-A-1-b *supra*; Dickson ¶ 424.

c. Step (b) — Combining

Step (b) is taught by ICMSF. See § XII-A-1-c *supra*; Dickson ¶ 425.

d. Step (c) — Enriching

Step (c) is taught by ICMSF (*see* § XII-A-1-d *supra*) and also by Hughes. Hughes instructs that, after pre-enrichment, portions of the “incubated pre-enrichment mixtures” should be transferred to two separate selective enrichment broths, Rappaport-Vassiliadis R10 broth and TT broth, and incubated for 16-20 hours at 41°-43°C. Ex. 1015, 636. Additionally, Hughes instructs that these selective broths should be removed from incubation and mixed by hand or by Vortex mixer. *Id.* Hughes further instructs to then remove 1 mL from the TT tube and 1 mL from the Rappaport-Vassiliadis R10 tube and transfer to separate, sterile M broths. *Id.*, 636, 638. The separate M broths are then incubated (“16-20 h at 35°-37°C” for “all foods other than raw foods or foods having a high microbial load” or “6 h at 35°-37°C” for “raw foods or foods having a high microbial load”). *Id.*, 638; Dickson ¶¶ 426-28.

e. Step (d) — Wet Compositing

Step (d) is taught by ICMSF (*see* § XII-A-1-e *supra*) and also by Hughes. Hughes instructs to “[c]ombine equal volumes (0.5-1 mL) from each M broth tube in a clean screw-cap tube.” *Id.*, 638. Thus, Hughes instructs combining removed portions of enrichments to provide a modular composite sample. Dickson ¶¶ 429, 430.

f. Step (e)(1) — Testing

Step (e)(1) is taught by ICMSF (*see* § XII-A-1-f *supra*) and also by Hughes because Hughes states testing of the composite sample is “by an enzyme immunoassay (EIA) method.” Ex. 1015, 635, 638; Dickson ¶¶ 431, 432; *see* AAPA #7.

g. Step (e)(2) — Tested Negative

Step (e)(2) is taught by ICMSF (*see* § XII-A-1-g *supra*). Dickson ¶ 433.

Because Hughes explains the steps to be taken when testing is positive (*see* § XII-B-1-h *infra*), a POSA would also expect negative testing results. Ex. 1015, 638; Dickson ¶ 434.

h. Step (e)(3) — Further Testing After Positive Test

The teachings of ICMSF as related to step (e)(3) are explained at § XII-A-1-h *supra*. Dickson ¶ 435.

Step (e)(3) is also taught by Hughes, which 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. (emphasis added). Hughes indicates “[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must

be streaked on selective media.” *Id.*, 635. Culture confirmation using streaking is more sensitive than the EIA method, as was commonly understood and confirmed by the teachings of D’Haese. Ex. 1018, 979; Dickson ¶ 436.

2. Obviousness Rationales

ICMSF’s teachings related to the independent claim steps are summarized at § XII-A-2 *supra* with citations to §§ XII-A-1-b to XII-A-1-i *supra*. As explained above, ICMSF and Hughes have interrelated teachings because ICMSF teaches steps (a)-(d) and most of step (e) while Hughes teaches steps (c)-(e).

A POSA 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 ¶¶ 438-40.

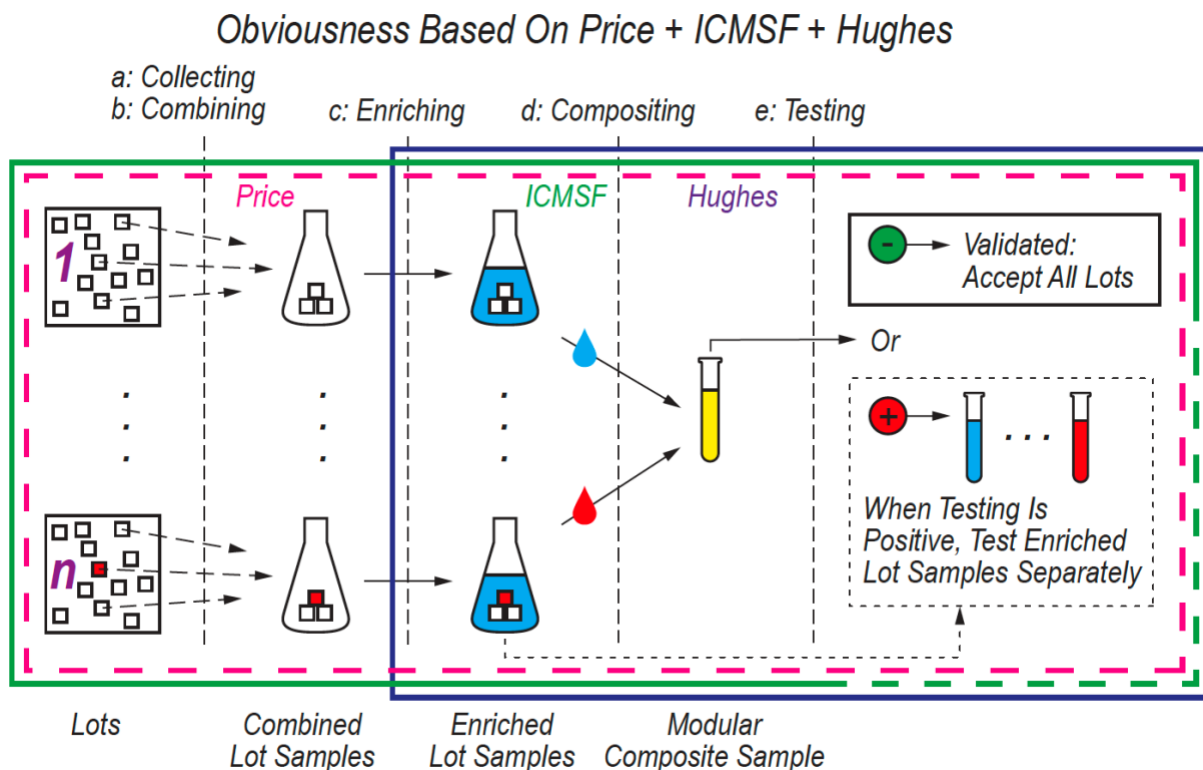
Further, a POSA would have improved ICMSF with the similar methods of Hughes to yield efficient validation, which is a predictable result. *KSR*, 550 U.S. at 417. MPEP § 2143(I)(B). In this combination, a POSA would have simply substituted steps of ICMSF, as described above, with those of Hughes so portions 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.

Dickson ¶ 441.

C. Ground 3: Obviousness Over *Price* In View Of *ICMSF* And *Hughes*

As depicted below, *Price* discloses most of steps (a)-(e) except it is not related to meat and involves the pooling of pre-enrichments, not enrichments. As also depicted below, *ICMSF* discloses steps (a)-(d) and most of step (e), and *Hughes* discloses steps (c)-(e):



Dickson ¶¶ 442, 443.

Price provided a template enabling others such as Silliker, Gabis, Jarvis, and MLG (Exs. 1025-28; Dickson ¶¶ 296-329, 447) to expand on Price’s framework for two-stage compositing, as succinctly summarized in Price’s Figure 1, which is reproduced at X-A-4. Ex. 1017, 680, Figure 1; Dickson ¶¶ 261-70. ICMSF’s discussion of studies that built on Price shows a POSA would have looked to ICMSF when modifying Price for testing lots such as meat lots. Ex. 1012, 187; Dickson ¶¶ 377-79, 447.

1. Claims 1 and 37

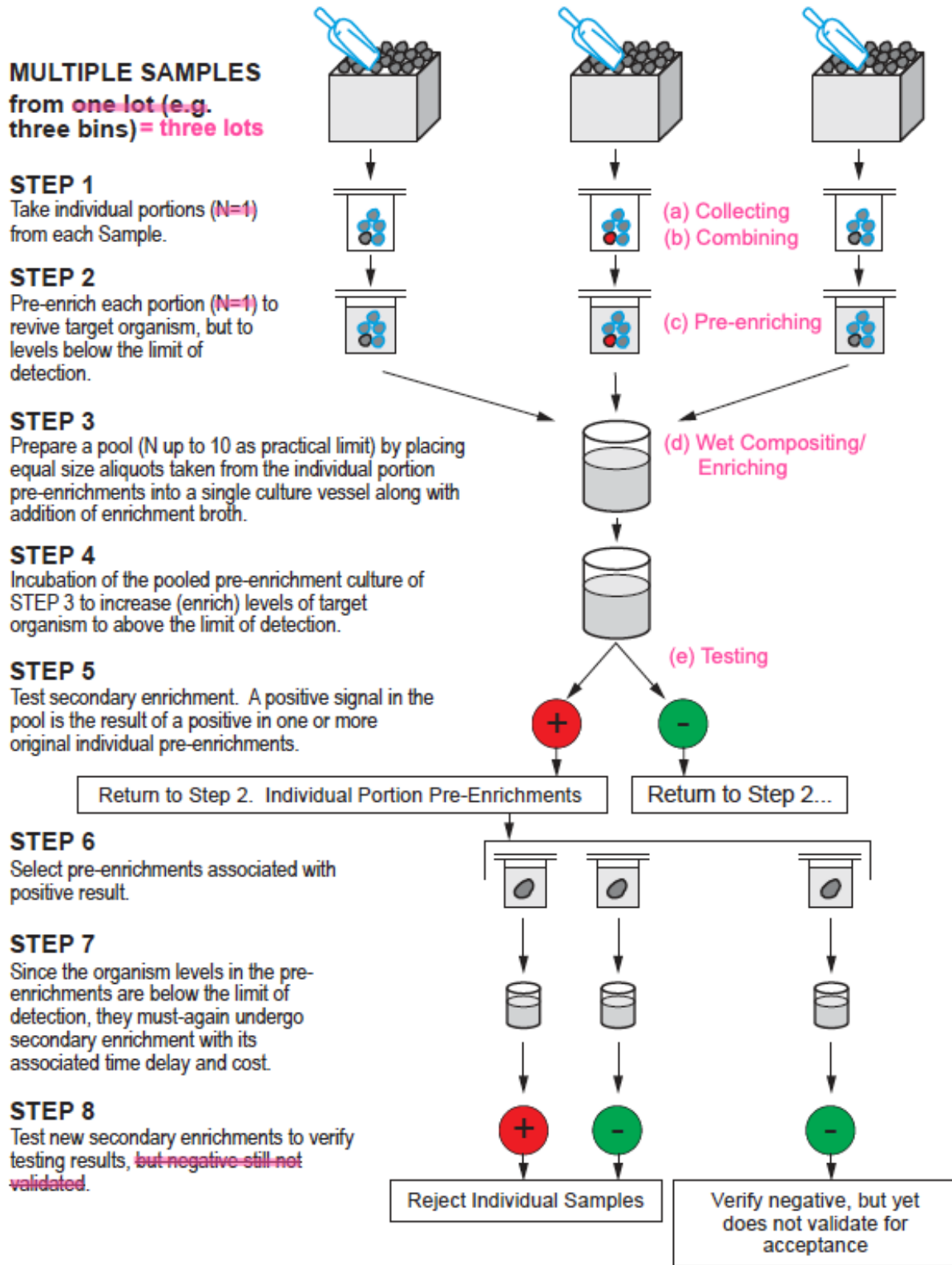
a. Preamble

See §§ XII-C-1-b, XII-C-1-f to XII-C-1-i *infra*; Dickson ¶ 444.

b. Step (a) — Collecting

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.

Figure 3: CITED PRIOR ART (PRICE et al, 1972)



Ex. 1007, 298 (annotated).

IEH's diagram also indicates multiple samples are taken from three bins, analogous to three lots rather than a single lot because each bin is an assemblage of specimens. Dickson ¶ 446. Additionally, the specification describes a bin of dry food materials (almonds), like those in Price, as one example of a test lot/single unit of production, akin to a combo of beef. Ex. 1003, 5:55-60.

ICMSF teaches step (a). *See* § XII-A-1-b *supra*.

c. Step (b) — Combining

While 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. Dickson ¶¶ 454-56.

ICMSF teaches step (b). *See* § XII-A-1-c *supra*.

d. Step (c) — Enriching

Price states “[i]n the multiple pooling of pre-enrichment broth cultures . . . , 1-ml quantities of cultures were transferred, generally, to a volume of enrichment broth.” Ex. 1017, 682; Dickson ¶¶ 457-60. Price also states “[a]lternatively, problems with interfering organisms may warrant the use of direct selective enrichments.” *Id.* Based on this statement, the Board noted “there is a suggestion in Price (at 682) . . . of direct enrichment.” Ex. 1007, 1576.

ICMSF and Hughes each teach step (c). *See* § XII-A-1-d and § XII-B-1-d *supra*; Dickson ¶ 461.

e. Step (d) — Wet Compositing

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.” Ex. 1017, 679; Dickson ¶¶ 462, 463.

ICMSF and Hughes also each teach step (d). *See supra* §§ XII-A-1-e and XII-B-1-e; Dickson ¶ 464.

f. Step (e)(1) — Testing

Testing the composite sample using a detection assay for *Salmonella* is taught by Price. Ex. 1017, 680 (Figure 1), 681; Dickson ¶ 465.

ICMSF and Hughes also each teach step (e)(1). *See supra* §§ XII-A-1-f and XII-B-1-f; Dickson ¶ 466.

g. Step (e)(2) — Tested Negative

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.” Ex. 1017, 679; Dickson ¶ 467.

ICMSF and Hughes each teach step (e)(2). *See* §§ XII-A-1-g and XII-B-1-g *supra*; Dickson ¶ 468.

h. Step (e)(3) — Further Testing After Positive Test

Price states, “If the Salmonella test of the pooled preenrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed Salmonella to the pool.” Ex. 1017, 679. However the claims require retention of enriched, composited lot samples not just those that are pre-enriched. Dickson ¶ 469.

ICMSF and Hughes each teach step (e)(3) as described *supra* at §§ XII-A-1-h and § XII-B-1-h. See Dickson ¶¶ 470-73.

2. Obviousness Rationales

As explained above, Price, ICMSF and Hughes overlap and respectively disclose most of steps (a)-(e), steps (a)-(d) and most of step (e), and steps (c)-(e). See §§ XII-C-1-a to XII-C-1-i *supra*. A POSA seeking to test meat lots would have followed Price’s framework for two-stage compositing and made modifications based on ICMSF and Hughes. Dickson ¶ 475.

For steps (a)-(b), a POSA would have replaced Price’s collection and combination of dry food (§§ XII-C-1-b and XII-C-1-c *supra*) with ICMSF’s collection and combination of portions from a consignment of lots of meat, such as beef or poultry. See §§ XII-A-1-b and XII-A-1-c *supra*; Dickson ¶ 476.

For steps (c) and (d), a POSA would have replaced Price's pre-enriching and compositing pre-enrichments (§§ XII-C-1-d and XII-C-1-e *supra*) with teachings of ICMSF and Hughes for steps (c) and (d) of enriching lot samples, removing portions of each enriched lot sample, and combining the portions to provide a composite sample. See §§ XII-A-1-d, XII-A-1-e, XII-B-1-d, and XII-B-1-e *supra*. Also, instead of retaining portions of pre-enrichments as taught by Price, a POSA would have retained portions of enriched lot samples as taught by ICMSF and Hughes. *Id.*; Dickson ¶ 477.

For steps (e)(1)-(e)(3), a POSA would have replaced Price's steps of testing a composite sample from the pre-enriched lot samples to obtain a negative result and further testing retained portions of the pre-enriched lot samples with the combined teachings of ICMSF and Hughes. See §§ XII-C-1-f to XII-C-1-h *supra*. These combined teachings provide for testing a composite made from the selectively enriched lot samples to obtain a negative result and further testing retained portions of the enriched lot samples after a positive test of the composite by a more sensitive protocol. See §§ XII-A-1-f to XII-A-1-h and XII-B-1-f to XII-B-1-h *supra*; Dickson ¶¶ 478, 479.

The modifications described above establish the obviousness of the independent claims under the teaching-suggestion-motivation test. Reasons for combining the references as described above, with a reasonable expectation of

success for efficient validation, are plentiful. For example, 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. See §§ XII-C-1-d and XII-C-1-e *supra*; Dickson ¶¶ 475-79.

Further, a POSA would have used Price's framework and improved it with the similar methods of ICMSF and Hughes to yield efficient validation, which is a predictable result. *KSR*, 550 U.S. at 417. In this combination, a POSA could have simply substituted the steps of Price, as described above, with those of ICMSF and Hughes. MPEP § 2143(I)(B). Dickson ¶ 480.

D. Dependent Claims

1. Grounds 1-3: Claims 2-4, 6, 8-11, 15, 16, 18-24, 26-31, 33, 38, 41-44, 46, 48, and 49

The below-listed claims would have been obvious based on ICMSF and any other reference in grounds 1-3.

a. Claims 2-4, 15, 16, 33, and 46 — Lots

2	The method of claim 1, wherein	each of the multiple separate lots is selected from the group consisting of an environmental lot comprising multiple operationally-linked environmental specimens, pharmaceutical lot comprising multiple operationally-linked pharmaceutical specimens, single product lot comprising multiple operationally-linked product specimens, and combinations thereof.
3		each of the multiple separate lots is a single production lot, comprised of operationally-linked product specimens.
4	The method of claim 3,	wherein product specimens are synonymous with product portions.
15	The method of claim 1, wherein	each of the lots is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
16		wherein the number of separate lots is from 3 to 10.
33	The method of claim 1,	wherein each of the multiple separate lots are separate production lots of a ready-to-eat product.
46	The method of claim 37,	

The specification indicates that a lot is a single-unit production lot (Ex. 1003, 5:43-54) such as a single combo, bin, pallet, or segment of production (*id.*, 7:54-63; *see also* AAPA #3 and #4) comprising an assemblage of operationally-linked specimens. *See* §§ XI-A, XII-A-1-b *supra*. Because ICMSF teaches collecting from “individual production batches as lots” (Ex. 1012, 119) and “[a] lot is considered as

a collection of units” (*id.*, 327), claims 2, 3, and 15 would have been obvious based on grounds 1-3. Dickson ¶ 486.

ICMSF indicates “a consignment” may be “composed of several lots.” Ex. 1012, 119-20. “Several” lots includes at least three lots, thus claim 16 is obvious based on grounds 1-3. Additionally, Gombas tests five lots (*see XII-A-1-b supra*) and Price tests at least three lots (*see § XII-C-1-b supra*). Dickson ¶ 487.

Claims 33 and 46 would have been obvious based on grounds 1-3 because ICMSF teaches collecting from “individual production batches as lots” and testing production lots of a ready-to-eat product. Ex. 1012, 119, 285-89; Dickson ¶ 488.

Claim 4 would have been obvious based on grounds 1-3 because ICMSF teaches collecting portions or samples, which were known synonyms for product portions or specimens. *See § XII-A-1-b supra*; Ex. 1012, 225; Ex. 1022, 10; Dickson ¶¶ 362, 489.

b. Claim 6 — Enrichment

6	The method of claim 1, wherein each separate composited lot sample in c) comprises incubating each separate composited lot sample with enrichment medium suitable to enrich for the target microbe(s), and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate composited lot sample and combining the removed portions to provide a pooled modular composite sample.
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Claim 6 differs from claim 1 by reciting “enrichment medium.” *See* § XII-A-1-d *supra*. ICMSF describes the well-known benefits of combining enrichment cultures from analytical units from lots in a consignment. Ex. 1012, 187. Gombas and Hughes describe incubating an enriched lot sample. Ex. 1014, 563; Ex. 1015, 636, 638; Dickson ¶ 493. Thus, claim 6 would have been obvious based on grounds 1-3.

c. Claims 8 and 9 — Concentration

8	The method of claim 1,	wherein testing of the pooled modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the target microbe(s).
9	The method of claim 8	wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

ICMSF discloses the use of “immunomagnetic beads to concentrate cells,” a well-known technique before the priority date. Ex. 1012, 318; Dickson ¶ 497. Thus, claims 8 and 9 would have been obvious based on at least ICMSF. *See also* XII-D-4 *infra*.

d. Claims 10 and 11 — More Sensitive Protocol

10	The method of claim 1, wherein where testing in e) of the pooled modular composite sample is positive, and wherein the separate individual composited lot samples are further tested using a more sensitive protocol.	
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11	The method of claim 10, wherein the more sensitive protocol comprises use of a concentration step to concentrate the target microbe(s), in combination with the same test protocol used to test the pooled modular composite sample.
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Claim 10 and 11 are obvious based on ground 1 because ICMSF discloses use of a concentration step (*see XII-D-1-c supra*), Gombas discloses retesting using the same protocol (*see XII-A-1-h supra*), and a POSA would have recognized that the concentration step could be employed to provide a more sensitive protocol for further testing. Dickson ¶¶ 500-503.

Hughes uses an EIA method followed by a more sensitive protocol—streaking on selective media. Ex. 1015, 635; *see* § XII-B-1-h *supra*. Claim 10 would have been obvious based on ICMSF and Hughes in grounds 2 and 3. Dickson ¶¶ 504, 505.

e. Claims 18-21 — Number of Portions

18	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of multiple separate lots comprises separately collecting	from each separate lot a number of samples from 5 to 100.
19		30 to 60 samples from each separate lot.
20		at least 30 samples from each separate lot.
21		at least 60 samples from each separate lot.

ICMSF teaches collecting 5, 30, 60, 95, or 100 portions, thus claims 18-21 would have been obvious based on grounds 1-3. Ex. 1012, 184-90, 276, 282, 309, 320, 326-30; MPEP § 2144.05; Dickson ¶¶ 506-509.

f. Claims 22, 26, and 38 — Equal Portions

22	The method of claim 1,	wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate composited	lot samples.
38	The method of claim 37,		single production lot samples.
26	The method of claim 1,	wherein removing portions of each separate enriched composited lot sample comprises removing equal volume portions of each separate enriched composited lot sample.	

Claims 22 and 38 recite removing “equal portions.” Similarly, claim 26 recites “equal volume portions.” Claims 22 and 38 also require “aseptically” removing the equal portions. These limitations, which are not recited in the independent claims, are considered to be standard practice. Dickson ¶¶ 513-515.

ICMSF describes aseptically withdrawing and weighing sample units into the appropriate diluent. Ex. 1012, 231, 232; Dickson ¶ 516.

Gombas indicates “a sample was aseptically transferred to a sterile stomacher bag and blended with an equal amount of enrichment broth.” Ex. 1014, 563. Gombas further indicates “five 1-ml samples of secondary enrichment broths were composited.” *Id.*, 564; see § XII-A-1-e *supra*; Dickson ¶¶ 517, 518.

Hughes instructs that after enrichment “[c]ombine equal volumes (0.5-1 mL) from each M broth tube in a clean screw-cap tube.” Ex. 1015, 638; see § XII-B-1-e *supra*; Dickson ¶ 519.

Based on the combined teachings of ICMSF and Gombas or ICMSF and Hughes, a POSA would have aseptically removed equal volume portions of each enriched separate composited lot sample. Thus, claims 22, 26, and 38 would have been obvious based on grounds 1-3. Dickson ¶¶ 515-519.

g. Claims 23, 24, 48, and 49 — Microorganisms

23	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of	<i>Listeria</i> , <i>Salmonella</i> , and <i>Escherichia coli</i> .	
24		<i>Listeria</i> spp., <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp., <i>Escherichia coli</i> O157:H7, coliforms and fecal coliforms.	
48	The method of claim 37,	wherein the target microbe(s) comprises at least one selected from the group consisting of	<i>Listeria</i> , <i>Salmonella</i> , and <i>Escherichia coli</i> .
49	The method of claim 48,		<i>Listeria</i> spp., <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp., <i>Escherichia coli</i> O157:H7, coliforms and fecal coliforms.

ICMSF describes testing for *Listeria* (Ex. 1012, 285-312), *Salmonella* (*id.*, 273-84), and *Escherichia coli* (*id.*, 313-32). Gombas focuses on *Listeria*. Ex. 1014, 559. Hughes and Price focus on *Salmonella*. Ex. 1015, 634 and Ex. 1017, 679.

Thus, claims 23, 24, 48 and 49 would have been obvious based on any of grounds 1-3. Dickson ¶¶ 520-24.

h. Claim 27 — Assay Types

27	The method of claim 1, wherein testing of the pooled modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.
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Gombas discloses use of DNA-based assays. Ex. 1014, 559 (abstract). Hughes discloses use of “an enzyme immunoassay (EIA) method,” which is an immunochemistry-based method. Ex. 1015, 635. Thus, claim 27 would have been obvious based on grounds 1-3. Dickson ¶¶ 525-28; *see also* AAPA #7.

i. Claims 28-31 and 41-44 — Meat Types

28	The method of claim 1,	wherein each of the multiple separate lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
29	The method of claim 28,	wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively
30		wherein the meat is that of beef, pork, sheep or bison.
31	The method of claim 30,	wherein the meat is that of beef.

41	The method of claim 37,	wherein each of the multiple separate single production lots are separate single production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
42	The method of claim 41,	wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively
43	The method of claim 42,	wherein the meat is that of beef, pork, sheep or bison.
44	The method of claim 43,	wherein the meat is that of beef.

Claims 28, 30, 31, and 41 would have been obvious based on grounds 1-3 because ICMSF teaches collecting of beef or poultry specimens from production lots containing an assemblage of beef or poultry specimens. Ex. 1012, 114, 119, 184-91, 225-26, 230, 285, 313-30; Dickson ¶¶ 360-64, 372.

ICMSF indicates “[t]rimmings to be used for ground beef could be pretested for *E. coli* O157:H7 by various sampling plans.” Ex. 1012, 323. Additionally, ICMSF indicates “[r]esearch has validated that up to fifteen 25 g analytical units of ground beef or trimmings can be composited without significant loss in *E. coli* O157:H7 detection sensitivity.” *Id.*, 327; *see also id.*, 226, 314, 320, and 324. Thus, claims 29 and 42-44 would have been obvious based on grounds 1-3. Dickson ¶¶ 529-36.

2. Grounds 4 and 5: Claim 5 — Incubating

5	The method of claim 1, further comprising incubating the pooled modular composite sample of d), prior to testing in e).
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Stewart discloses selective enrichment in RV and TT broths, which are combined into a single sample for further incubation then analysis. Ex. 1019, 398. A POSA would have been motivated to incubate the pooled modular composite sample of Gombas or Hughes, as taught by Stewart, for reliable testing results. Claim 5 thus would have been obvious based on the references of grounds 1 and 2 as further modified by Stewart in grounds 4 and 5. Dickson ¶¶ 537-41.

3. Grounds 6 and 7: Claims 8 and 9 — Concentration

Claims 8 and 9, which are listed at § XII-D-1-c *supra*, recite concentrating microorganisms. Fratamico discloses rapid microorganism concentration via immunomagnetic bead separation. Ex. 1020, 105-07. To the extent ICMSF's teachings are considered inadequate, a POSA would have been motivated by the well-known use of immunomagnetic beads to rapidly concentrate microorganisms as taught in more detail by Fratamico in a modular composite sample as taught by the references of grounds 1 and 2, to obtain accurate results. Thus, claims 8 and 9 would have been obvious based on grounds 6 and 7. Dickson ¶¶ 544-48.

4. Grounds 6 and 8: Claims 10 and 11 — More Sensitive Protocol

Claims 10 and 11, which are listed at § XII-D-1-d *supra*, recite a more sensitive protocol, equated in claim 11 to a concentration step. To the extent ICMSF’s teachings regarding a concentration step (*see* XII-D-1-c *supra*), are considered inadequate, a POSA would have been motivated to concentrate microorganisms as taught by Fratamico for a more sensitive protocol for further testing. Thus, claims 10 and 11 would also have been obvious based on ground 6. Dickson ¶¶ 551-53.

Claim 10 also would have been obvious based on ground 8 in which D’Haese modifies the references of ground 2. D’Haese instructs that “conventional culturing still remains the gold standard . . . on solid agar media.” Ex. 1018, 979. To the extent that the teachings in Hughes are considered unclear, modifying Hughes based on D’Haese ensures a more sensitive test is used for further testing. On this additional basis, claim 10 would have also been obvious based on ground 8. Dickson ¶ 554.

5. Grounds 9 and 10: Claim 7 — Inhibit

7	The method of claim 6, wherein the enrichment medium comprises a selective agent that will inhibit a competing non-target microbe.
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Claim 7 recites the well-known property of selective enrichment, inhibition of a competing non-target microorganism. D'Aoust describes "selective enrichment [that] inhibits growth of non-salmonellae and facilitates isolation of Salmonella on differential plating media." Ex. 1021, 369. A POSA would have been motivated to use an enrichment medium comprising a selective agent that inhibits a non-target agent or organisms as described by D'Aoust, for the lot samples described by ICMSF, Gombas, and Hughes, to ensure an accurate test. Thus, claim 7 would have been obvious based on the references of grounds 1 and 2 as further modified by D'Aoust in grounds 9 and 10. Dickson ¶¶ 557, 558.

XIII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. Section 314(a): *Fintiv* Factors Favor Institution

The district court litigation is listed at XIV-B *infra*. See Ex. 1004. The *Fintiv* factors weigh against discretionary denial in view of the parallel district court litigation in this case. See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) (precedential).

1. Institution Will Increase the Likelihood of a Stay

If this IPR is instituted and the litigation is still pending, National Beef will seek a stay. Institution would enable the Board to resolve patentability issues, advancing judicial efficiency by freeing the district court from having to assess

validity. The early stage of the litigation and the potential for issue simplification increases the likelihood that a stay will be granted based on institution. Thus, this factor favors institution.

2. Timing

A final written decision (FWD) in this IPR would likely issue in January 2026. Based on the filing of IEH's complaint in the District of Delaware on August 1, 2023 and the 38-month period reported in the most recent statistics on median time-to-trial for civil actions in the District of Delaware, any potentially foreseeable court trial date is on October 1, 2026. Exs. 1039, 1040. Thus, factor two favors institution.

3. Litigation Stage

On May 16, 2024, IEH and National Beef jointly submitted to the district court a Proposed Scheduling Order. Ex. 1111. The Proposed Scheduling Order indicates claim construction briefing will be completed by February 19, 2025. *Id.*, 8. Based on this proposed schedule, it would be very unlikely for trial in the litigation to be reached before issuance of the FWD in January 2026. Thus, the early stage of the litigation favors institution.

4. No Overlap

Based on the likely timing for a FWD and the lack of a trial date, a FWD will issue before the district court's trial date. Thus, the estoppel that would attach from the FWD pursuant to 35 U.S.C. § 315(e) would prevent grounds that were raised or reasonably could have been raised in this IPR from being raised at trial in the litigation. Because there is no possibility for overlap between the IPR and the related litigation, this factor favors institution.

5. Same Party

National Beef is the Petitioner and the defendant. However, that is typically the scenario for a patent asserted in district court and challenged at the Board. *Fintiv* “says nothing about situations in which the Petitioner is the same as, or is related to, the district court defendant.” *Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, IPR2020-00122, Paper 15 at 10 (May 15, 2020) (“the factor is neutral.”).

6. Other Circumstances

As evidenced by the analysis at §§ XII-A to XII-D *supra*, National Beef's patentability challenge presents a compelling merits case that all Challenged Claims are not patentable. This factor therefore favors institution regardless of other factors.

Thus, in view of the facts presented in this Petition, the *Fintiv* factors do not support discretionary denial.

B. Section 325(d): *Advanced Bionics* Favors Institution

1. Substantially Same Art/Arguments Not Considered

Discretionary denial under § 325(d) is not appropriate given this Petition does not present the same or substantially the same grounds/arguments previously presented to and considered by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (Feb. 13, 2020) (precedential). Moreover, there are material differences between the art/arguments in this Petition and those during prosecution and reexamination.

The base reference for every ground except Ground 3 is ICMSF. ICMSF is modified in each ground by Gombas or Hughes. Neither ICMSF, Gombas, nor Hughes were considered previously by the Office. ICMSF teaches steps (a)-(d) and most of step (e). Gombas and Hughes each squarely meet the limitations of at least steps (c)-(e) because each teaches enriching lot samples and compositing them while retaining portions of the enriched lot samples for potential additional testing. No reference was previously considered disclosing such selective enrichment steps.

Price, the base reference in Ground 3, was considered during reexamination and was substantively considered during prosecution of the grandparent of the '771 Patent. However, Price was not previously considered in combination with a reference such as ICMSF or Hughes. Because no reference was considered in combination with Price that discloses pooling enrichments, each ground presents

new art and new arguments so the *prima facie* obviousness grounds here are different and stronger.

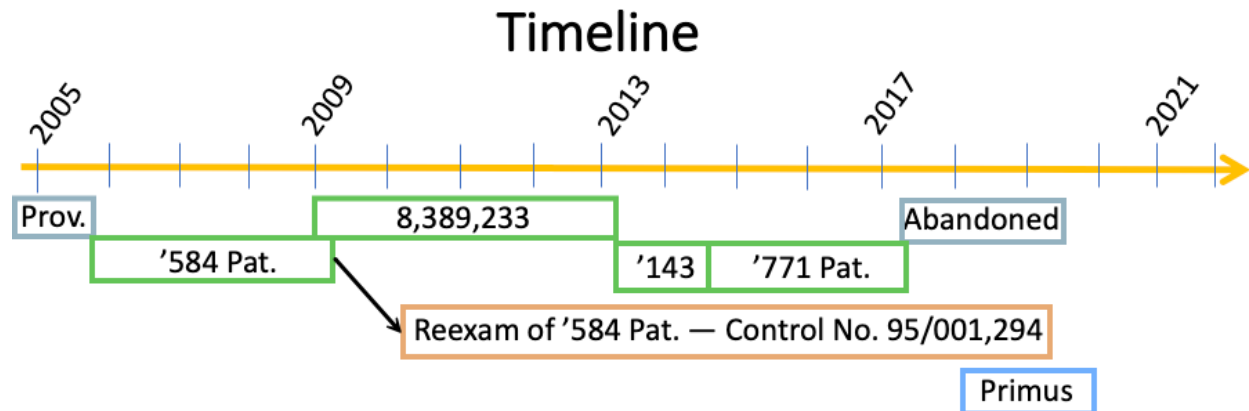
2. Office Erred

If the Board concludes that the same or substantially the same art or arguments were previously presented to the Office, then institution should not be denied because the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics* at 8-9.

First, the '771 Patent was improvidently granted because it was based on the Examiner's misunderstanding of Price. Price was simultaneously acknowledged as the closest reference of record by the Examiner during prosecution of the grandparent of the '771 Patent and mischaracterized as not teaching further testing of portions of the enriched lot samples. *See* § IX-A *supra*. The prosecution histories of the Continuation Patents provide no basis for finding that the Examiner's misunderstanding had been corrected. *See* §§ IX-A to IX-C *supra*. In fact, Price is not mentioned during the prosecution of the Continuation Patents and when the '771 Patent was allowed the Examiner incorrectly considered references that focus on sampling to be the closest art. *See* § IX-C *supra*.

Second, as shown by the timeline below, the reexamination of the '584 Patent was pending for seven years by the time the '771 Patent was granted and yet its prosecution was not conducted under the illuminating light of information from the

reexamination because IEH only submitted references from the reexamination but failed to submit any documents from the CRU, the Board, IEH, or bioMérieux, such as Office Actions, Responses, or Third-Party Comments. Dickson ¶¶ 204-234.



Thus, the Office erred in its examination because IEH failed to inform the Examiner about characterizations of Price and other references in the reexamination, and claims in the '584 Patent as not being patentable—the same claims that the Examiner concluded were not patentably distinct from those in the application resulting in the '771 Patent. See § IX-C *supra*. It is also noteworthy that IEH failed to inform the CRU about the Continuation Patents or the Primus Litigation, which involved the Continuation Patents and included claim constructions. Ex. 1007; Dickson ¶ 110.

Third, the Office erred by allowing IEH to circumvent the outcome of the reexamination by granting the '143 and '771 Patents. Each of IEH's Patents has two independent claims reciting the same steps (a)-(e). Professor Dickson provides a detailed analysis of each step recited in the corresponding independent claims of the Continuation Patents relative to the corresponding independent claims of the '584

Patent prior to reexamination. Dickson ¶¶ 545-66. This analysis shows the first independent claims of the Continuation Patents have scopes that are either the same as or broader than that of the first independent claim of the '584 Patent prior to its reexamination and that the same scenario is true for the second independent claims.

IEH successfully duplicated the scope surrendered in the reexamination by cloaking the scope in the independent claims of the Continuation Patents through use of synonyms. Misled by IEH's semantical gamesmanship and IEH's failure to share information from the reexamination in which Price was repeatedly characterized, the Examiner erred by enabling IEH to duplicate the scope afforded by the original claims of the '584 Patent. IEH should not be permitted to avoid estoppel implications from the reexamination, otherwise IEH will continue to reap undeserved rewards.

XIV. MANDATORY NOTICES

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

National Beef Packing Company, LLC certifies it is the real party-in-interest and no other party exercised control over preparation or filing of this Petition.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '584 and '143 Patents are respectively subjects of IPR2024-00183 and IPR2024-00185. IEH's Patents are the subject of a 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). See Ex. 1004.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4))

Please address all correspondence to counsel at the addresses below. Petitioner consents to electronic service via email at the email addresses listed below:

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XV. CONCLUSION

Petitioner respectfully requests that a trial be instituted.

Respectfully Submitted,

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WORD-COUNT CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that this Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). The Petition contains 13,805 words, excluding parts of this Petition exempted under 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this Petition, and by adding words appearing as annotations to Patent Owner's diagrams and those included on Petitioner's diagrams.

Respectfully submitted,

Dated: July 16, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 of the following materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 9,637,771 under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibit List
- Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 9,637,771 (Exs. 1001-1063)
- Power of Attorney
- Word Count Certification Under 37 CFR § 42.24(d)

on IEH for next day delivery at the correspondence address of record for the subject patent as listed in the records of the United States Patent and Trademark Office:

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