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

Case No. IPR2024-00183
Patent No. 7,534,584 C1

Case No. IPR2024-00185
Patent No. 8,822,143 B2

Case No. IPR2024-00186
Patent No. 9,637,771 B2

DECLARATION OF JAMES S. DICKSON, PH.D.

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I. INTRODUCTION

I, James S. Dickson, Ph.D., declare as follows:

A. Engagement

1. I have been retained by Petitioner National Beef Packing Company, LLC ("National Beef") to provide expert opinions in connection with petitions requesting *inter partes* review (IPR) of three patents owned by Institute for Environmental Health, Inc. ("IEH" or "Patent Owner") including U.S. Patent No. 7,534,584 ("the '584 Patent"), U.S. Patent No. 8,822,143 ("the '143 Patent"), and U.S. Patent No. 9,637,771 ("the '771 Patent") (the "IEH Patents"). The'143 Patent and the '771 Patent are continuations of the '584 Patent and are thus collectively referred to as the "Continuation Patents." The IEH Patents list Mansour Samadpour as the inventor.

2. I have been asked to review relevant materials and render my opinions regarding the validity of various claims of the IEH Patents. I have used my education and decades of experience working in the fields of food science, microbiology, and food safety, and my understanding of the knowledge, creativity, and experience of a person of ordinary skill in the art of the IEH Patents in forming the opinions expressed in this declaration.

3. I am being compensated for my time in developing and rendering my opinions in this matter at my normal consulting rate for my work plus actual expenses. I have

no financial interest in the outcome of this or any related proceeding. My compensation is not dependent upon the opinions that I am providing in this declaration or the results of this or any other proceeding relating to the IEH Patents.

4. Between now and any time that I may be asked to testify further, I expect to continue my review, evaluation, and analysis of evidence presented before and/or at the hearing. I also expect to review any additional declarations and other evidence submitted by IEH. I reserve the right to amend or supplement this declaration, as appropriate, after considering the opinions set forth by other experts. If additional relevant information becomes available to me, I also reserve the right to review and consider that information in further developing, rendering, or refining my opinions.

B. Background and Qualifications

5. I have personal knowledge of the facts stated in this declaration and could competently testify to them if asked to do so.

6. A copy of my latest *curriculum vitae* (CV) is submitted with this declaration as Exhibit 1042, which includes my educational background, work history, and a listing of my publications. The following paragraphs briefly summarize my relevant expertise.

7. I am currently the Morrison Endowed Chair in Meat Science and a professor in the Department of Animal Science at Iowa State University. Prior to a reorganization, I held a joint appointment as a professor in both the Department of

Food Science and Human Nutrition and the Department of Microbiology, Immunology, and Preventive Medicine at Iowa State University. I primarily study the microbiological safety of foods of animal origins with a particular focus on Gram negative bacteria, such as *Salmonella* and *E. coli*.

8. I received a B.S. in Microbiology from Clemson University in 1977, an M.S. in Dairy Science from the University of Georgia in 1980, and a Ph.D. in Food Science and Technology from the University of Nebraska–Lincoln in 1984. While working on my Ph.D., I researched the microbiology of meat and published my doctoral dissertation on the impact of certain food safety interventions on ground beef products.

9. After obtaining my doctorate, I worked for several years in industry as a food safety manager and microbiologist. Subsequently, from 1987–1993, I worked at the USDA as a research food technologist and lead scientist studying the hazards and risks of meat and poultry processing, including pathogen reduction methods.

10. In addition to my educational background and work history, I actively participate in various professional societies and organizations, including the American Society for Microbiology, the Institute for Food Technologists, and the International Association for Food Protection.

11. I have authored more than 140 peer-reviewed journal and conference publications and numerous books and book chapters. Some of my representative publications include:

(1) Dickson, J.S. 1991. Attachment of *Salmonella typhimurium* and *Listeria monocytogenes* to beef tissue: Effects of inoculum level, growth temperature and bacterial culture age. Food Microbiology 8:143–151;

(2) Dickson, J.S., G.R. Siragusa and J.E. Wray, Jr. 1992. Predicting the growth of *Salmonella typhimurium* on beef using the temperature function integration technique. Appl. Environ. Micro. 58:3482–3487;

(3) Brodsky, M.H., C.A. Davidson, J.S. Dickson, M.J. Pettis and T.L. Tieso. 1995. Delayed incubation method for bacteriological analysis of environmental specimens and samples. Journal of Food Protection 58:879–883;

(4) Erdmann, J.J., J.S. Dickson and M.A. Grant. 2002. A new technique for *Escherichia coli* testing of beef and pork carcasses. Journal of Food Protection 65:192–195;

(5) Niebuhr, S. and J.S. Dickson. 2002. Impact of pH Enhancement on the Populations of *Salmonella*, *Listeria* and *Escherichia coli* O157:H7 in Boneless Lean Beef Trimmings. Journal of Food Protection 66:874–877;

(6) Marshall, K.M., S.E. Niebuhr, G.R. Acuff, L.M. Lucia and J.S. Dickson. 2005. The identification of *Escherichia coli* O157:H7 meat processing

indicators for fresh meat through the comparison of the effects of selected anti-microbial interventions. Journal of Food Protection 68: 2580–2586;

(7) Cabrera, E.T. Moseley, L. Lucia, J.S. Dickson, A. Castillo and G.R. Acuff. 2009. Fluorescent protein-marked *Escherichia coli* biotype I strains as surrogates for enteric pathogens in validation of beef carcass interventions. Journal of Food Protection 72:295–303;

(8) Consortium of Validation Experts (J.S. Dickson as corresponding author). 2012. Validation of Antimicrobial Interventions for Small and Very Small Processors: A How-to Guide to Develop and Conduct Validations. Food Protection Trends 33(2):95–104; and

(9) Redemann, M.A., J. Brara, S.E. Niebuhr, L.M. Lucia, G. R. Acuff, J.S. Dickson, M. Singh. 2018. Evaluation of thermal process lethality for non-pathogenic *Escherichia coli* as a surrogate for *Salmonella* in ground beef. LWT – Food Science and Technology 90:290–296.

12. In addition to my publications, I have been invited to present and discuss my work at over 150 seminars, including:

(a) Dickson, J.S. 2018. *Salmonella* and Roaster Pigs. Center for Disease Control and Prevention. Atlanta, GA 19 January 2018;

(b) Dickson, J.S. 2019. Impact of slow come up times and process deviations on bacteria on processed meats. North American Meat Institute Meat Industry Food Safety Conference. Rosemont, IL 04–05 September 2019;

(c) Dickson, J.S. 2023. Building the Scientific Support or Alternative Support for Lethality and Stabilization. USDA FSIS Food Safety Summit. Ames, IA 20 April 2023; and

(d) Dickson, J.S. 2023. Food Safety Challenges to the Meat and Poultry Industry: Where We Came From and Where We're Going. The National Provisioner. Ames, IA 11 July 2023.

13. Furthermore, I am an inventor on an issued patent related to a method of reducing contamination of animal carcasses during slaughtering.

14. I have been a member of various boards and committees, including:

(a) Editorial Board Member, Journal of Food Protection (1988–present);

(b) Editorial Board Member, Journal of Food Safety (1990–present);

(c) Committee Member, National Advisory Committee on Microbiological Criteria for Foods (1998–2000, 2018–2020, 2022–2023);

(d) Committee Member, National Advisory Committee for Meat and Poultry Inspection (2007–2010);

(e) Chair, ISO US Mirror Committee, Technical Committee 34, sub-committee 17 (Food Safety Management Systems); and

(f) Member, ISO US Mirror Committee, Technical Committee 34, sub-committee 9 (Microbiology).

15. Throughout my career I have received numerous honors and awards. Notably, during my time at the USDA, I was awarded several Certificates of Merit for my research contributions to the FSIS and the beef industry. I was elected as a Fellow in the American Academy of Microbiology in 1994. Additionally, in 2002 I served as the President of the International Association for Food Protection (IAFP), the leading industry organization for food safety professionals, and in 2022 I was elected as a Fellow in the IAFP. Most recently, in 2023 I received the Achievements in Microbial Research for Food Safety Award in honor of Gerhard J. Haas from the Institute of Food Technologists in recognition of my innovative research in microbial aspects of food safety assurance resulting in a positive impact and advancement of the public safety of the food supply.

16. Based on my experience, I am an expert in the fields of food science, microbiology, food safety, and the technology at issue in the IEH Patents.

C. Information Considered

17. To render my opinions in this matter, I have carefully reviewed the specification and claims of the IEH Patents as well as their prosecution history documents including the reexamination of ’584 Patent. These patent documents include:

a. Exhibit 1001 – U.S. Patent No. 7,534,584 B2, C1;

b. Exhibit 1002 – U.S. Patent No. 8,822,143;

c. Exhibit 1003 – U.S. Patent No. 9,637,771;

d. Exhibit 1005 – File History for Provisional Appl. No. 60/599,473;

e. Exhibit 1006 – File History for the ’584 Patent (Appl. No. 11/199,871);

f. Exhibit 1007 – File History for Reexamination of the ’584 Patent;

g. Exhibit 1008 – U.S. Patent No. 8,389,233;

h. Exhibit 1009 – File History for the ’233 Patent (Appl. No. 12/360,796);

i. Exhibit 1010 – File History for the ’143 Patent (Appl. No. 13/784,606);

j. Exhibit 1011 – File History for the ’771 Patent (Appl. No. 14/472,144); and

k. Exhibit 1034 – File History for Non-Provisional Appl. No. 15/499,719.

18. My analyses are based on my years of education, research, and work experience, as well as my investigation and study of relevant materials. In my analyses, I have reviewed the publications listed below:

a. Exhibit 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”);

b. Exhibit 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”);

c. Exhibit 1014 – David Gombas et al., "Survey of *Listeria monocytogenes* in Ready-to-Eat Foods." J. Food Prot., vol. 66, no. 4, pages 559–569 (Apr. 2003) ("Gombas");

d. Exhibit 1015 – Denise Hughes et al., "*Salmonella* in Foods—A New Enrichment Procedure for Use with the TECRA *Salmonella* Visual Immunoassay: Collaborative Study," J. AOAC Int'l, vol. 82, no. 3, pages 634–647 (May/June 1999) ("Hughes 1999") or ("Hughes");

e. Exhibit 1016 – Denise Hughes et al., "*Salmonella* in Foods: New Enrichment Procedure for TECRA Salmonella 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");

f. Exhibit 1017 – W.R. Price et al., "*Salmonella* Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples," Appl. Microbiol., vol. 23, no. 4, pages 679–682 (Apr. 1972) ("Price");

g. Exhibit 1018 – Diana Stewart et al., "Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water," J. AOAC Int'l, vol. 85, no. 2, pages 395–403 (Mar./Apr. 2002) ("Stewart");

h. Exhibit 1019 – Pina Fratamico et al., "Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method," Food Microbiol., vol. 9, no. 2, pages 105–113 (June 1992) ("Fratamico");

i. Exhibit 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");

j. Exhibit 1021 – Jean-Yves D'Aoust, "Update on Preenrichment and Selective Enrichment Conditions for Detection of *Salmonella* in Foods," J. Food Prot., vol. 44, no. 5, pages 369–374, 393 (May 1981) ("D'Aoust");

k. Exhibit 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") or ("BAM");

l. Exhibit 1023 – U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), "Microbiological Testing Program and Other Verification Activities for *Escherichia coli* 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") or ("FSIS");

m. Exhibit 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");

n. Exhibit 1025 – J.H. Silliker & D.A. Gabis, "ICMSF methods studies. I. Comparison of analytical schemes for detection of *Salmonella* in dried foods," Can. J. Microbiol., vol. 19, no. 4, pages 475–479 (1973) ("Silliker");

o. Exhibit 1026 – D.A. Gabis & J.H. Silliker, "ICMSF methods studies. II. Comparison of analytical schemes for detection of *Salmonella* in high-moisture foods," Can. J. Microbiol., vol. 20, no. 5, pages 663–669 (1974) ("Gabis");

p. Exhibit 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");

q. Exhibit 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");

r. Exhibit 1029 – U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), "Microbiology Laboratory Guidebook," Chapter 8 (3rd ed. 1998) ("MLG 1998");

s. Exhibit 1030 – Madhu Badoni et al., "Development and testing of a prototype automatic trim sampler," Food Control, vol. 77, pages 82–87 (July 2017) ("Badoni");

t. Exhibit 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");

u. Exhibit 1032 – U.S. Food & Drug Admin., "Bacteriological Analytical Manual," Chapter 10, § 10.04 (January 1969) ("BAM 1969");

v. Exhibit 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); and

w. Exhibit 1063 – Assurance® GDS *Salmonella* Tq Data Sheet from MilliporeSigma.

19. I may rely on these and additional materials to respond to arguments raised by IEH. My review and assessment of the materials provided in this proceeding is ongoing, and I will continue to consider any new material as it is provided. I reserve the right to review, supplement, and amend my analyses based on new information and on my continuing review of the materials already provided.

II. UNDERSTANDING OF THE RELEVANT LAW

20. For the purposes of this declaration, National Beef's counsel has informed me about certain aspects of the law that are relevant to my opinions. My understanding

of the relevant law as described below, is based on my discussions with National Beef's counsel because I am not an attorney.

21. National Beef's counsel informed me that patentability of each claim challenged in the Petition is assessed based on documents that predate the IEH Patents, such as other patents and printed publications, and that these documents are referred to as "prior art." I have been informed that the IEH Patents have an effective filing date of August 6, 2004, which is the filing date of the earliest provisional patent application from which the IEH Patents claims priority. I understand that publicly available documents, such as patents and printed publications, in existence and filed before August 6, 2004, are considered to be prior art with respect to the IEH Patents.

A. Person of Ordinary Skill in the Art

22. I am informed by National Beef's counsel that prior art references should be understood from the perspective of a person of ordinary skill in the art ("POSA") to which the patent is related, based on the understanding of that person at the time of the patent's priority date. I understand that a POSA is presumed to be aware of all pertinent prior art and the conventional wisdom in the art, and is also a person of ordinary creativity.

23. The subject matter of the IEH Patents relates to a two-stage compositing process with steps including sampling lots, testing for microbial contamination, and validating the lots. I agree with the level of skill in the art described in each Petition,

in that a POSA in August 2004 would have been someone with "a working knowledge of microbiology and would have been involved in developing sampling and testing methodologies for analysis of food products ('validation methodologies')." Petition at § V. I also agree that "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 in developing validation methodologies." *Id.* Additionally, I agree that "the POSA would have been familiar with relevant scientific literature and industry regulations, directives, and guidelines relating to validation methodologies." *Id.*

24. My analyses in this declaration are from the perspective of a POSA, as described above. At the time of the priority date of the IEH Patents, August 2004, and prior to August 2004, I was an individual having at least ordinary skill in the art according to the description above.

B. Written Description

25. I understand that a patent claim is valid if the patent contains an adequate written description of the claimed invention. I understand that the test for compliance with the written description requirement is whether the disclosure of the application relied upon reasonably conveys to a POSA that the inventor had

possession of the claimed subject matter as of the filing date, even though the claims may have been changed or new claims added since that time.

26. I understand that the written description requirement does not require that the patent claims use the same terminology as the patent specification. The test instead is focused on the meaning and content of the disclosure, not any particular form of expression. In other words, a claim can use terminology different from that in the patent specification, so long as the same concepts appearing in the claim are described in the specification.

27. I understand that the level of detail required to satisfy the written description requirement varies depending on factors such as existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue. In particular, I understand that patent applications are written for a POSA and, therefore, need not include background or knowledge already held by a POSA. I also understand that courts have encouraged patent applicants to omit what is well known in the art.

C. Anticipation

28. I understand that to anticipate a claim of a patent, a prior art reference must disclose all limitations of the claim as those limitations are arranged in the claim.

29. I understand that for a reference to anticipate a claim, the reference must disclose the relevant technology in a manner such that a person of ordinary skill in

the relevant art would be able to carry out or utilize the technology that the reference describes without having to undertake undue experimentation. I also understand that prior art references are presumed to be enabling.

D. Obviousness

30. National Beef's counsel informed me that a patent claim is invalid if the subject matter of the claim was considered to have been obvious to a POSA at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a POSA at the time the application was filed.

31. I understand that obviousness and related issues (such as what a POSA would or would not be motivated to do) must be evaluated at the time of the invention. Even when I state things in this declaration in the present tense, that should be understood as being from the perspective of a POSA on or before August 6, 2004.

32. I have been advised and understand that a claimed invention is unpatentable if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious, at the time the invention was made, to a person of ordinary skill in the art to which the subject matter pertains.

33. It is my understanding that obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the

differences between the claims and the prior art; (3) the level of skill in the art; and (4) objective considerations of nonobviousness.

34. I understand that for one or more references to render the claimed invention obvious, a POSA must have a sufficient reason to combine the teachings of the references to arrive at the challenged claims. I further understand that a basis to combine teachings from the references need not be stated expressly in any prior art reference. However, there must be an articulated reasoning with rational underpinnings to support a reason to combine the teachings.

35. I understand that when considering whether a patent claim is obvious, a POSA should consider whether a teaching, suggestion, or motivation to combine the references existed at the time of invention so as to avoid impermissibly applying an analysis based on hindsight.

36. I understand that if two or more prior art references are combined to challenge a claim, and if a proposed modification would render the prior art invention being modified unsuitable for its intended purpose, then there is no suggestion or motivation to make the proposed modification. I also understand that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims obvious.

E. Claim Construction

37. I have been informed that claim terms in IPR proceedings are construed from the perspective of a POSA at the time of the invention. I also understand that the claim terms are construed by a POSA in light of the specifications of the IEH Patents and the prosecution and litigation histories pertaining to the IEH Patents.

III. SUMMARY OF OPINIONS

38. Based on my review and analysis of the materials in this matter, as well as my experience and education, my opinions are summarized below.

a. In Ground 1 of each Petition, ICMSF discloses steps (a)–(d) and most of step (e) and Gombas discloses at least steps (c)–(e) for each independent claim of the IEH Patents, including claims 1 and 17 of the '584 Patent, claims 1 and 35 of the '143 Patent, and claims 1 and 37 of the '771 Patent. For reasons discussed in this declaration, a POSA would have modified ICMSF based on Gombas and thus the independent claims of the IEH Patents would have been obvious.

b. Also in Ground 1, the following dependent claims would have been obvious based on ICMSF and Gombas: claims 2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, and 29–33 of the '584 Patent; claims 2, 3, 5–7, 11, 12, 14–20, 22–24, 26, 29, 31–34, and 36 of the '143 Patent; and

claims 2–4, 6, 8–11, 15, 16, 18–24, 26–31, 33, 38, 41–44, 46, 48, and 49 of the ’771 Patent.

c. In Ground 2, Hughes discloses steps (c)–(e). For reasons discussed in this declaration, a POSA would have modified ICMSF based on Hughes. On this basis, the independent claims of the IEH Patents would have been obvious based on the combination of ICMSF and Hughes.

d. Also in Ground 2, the following dependent claims would have been obvious based on ICMSF and Hughes: claims 2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, 29, and 31–33 of the ’584 Patent; claims 2, 3, 5–7, 11, 12, 14–20, 22–24, 26, 29, 31, 33, 34, and 36 of the ’143 Patent; and claims 2–4, 6, 8–10, 15, 16, 18–24, 26–31, 33, 38, 41–44, 46, 48, and 49 of the ’771 Patent.

e. In Ground 3, Price discloses most of the subject matter recited in steps (a)–(e). For reasons discussed in this declaration, a POSA would have modified Price based on ICMSF and further based on Hughes. On this basis, the independent claims of the IEH Patents would have been obvious based on the combination of Price, ICMSF, and Hughes.

f. Also in Ground 3, the following dependent claims would have been obvious based on Price, ICMSF, and Hughes: claims 2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, 29, and 31–33 of the ’584 Patent; claims 2, 3,

5–7, 11, 12, 14–20, 22–24, 26, 29, 31, 33, 34, and 36 of the ’143 Patent; and claims 2–4, 6, 8–10, 15, 16, 18–24, 26–31, 33, 38, 41–44, 46, 48, and 49 of the ’771 Patent.

g. In Grounds 4 and 5, claim 3 of the ’584 Patent, claim 4 of the ’143 Patent; and claim 5 of the ’771 Patent would have been obvious based respectively on the references of Grounds 1 and 2 in combination with Stewart.

h. In Ground 6, claims 5, 6, 29, and 30 of the ’584 Patent; claims 6, 7, 31, and 32 of the ’143 Patent; and claims 8–11 of the ’771 Patent would have been obvious based on the references of Ground 1 in combination with Fratamico.

i. In Ground 7, claims 5 and 29 of the ’584 Patent; claims 6 and 31 of the ’143 Patent; and claims 8 and 9 of the ’771 Patent would have been obvious based on the references of Ground 2 in combination with Fratamico.

j. In Ground 8, claim 6 of the ’584 Patent; claim 7 of the ’143 Patent; and claim 10 of the ’771 Patent would have been obvious based on the references of Ground 2 in combination with D’Haese.

k. In Grounds 9 and 10, claim 28 of the ’584 Patent, claim 30 of the ’143 Patent; and claim 7 of the ’771 Patent would have been obvious based

respectively on the references of Grounds 1 and 2 in combination with D'Aoust.

l. Below are tables summarizing the grounds related to my above-listed opinions regarding the claims of the '584 Patent.

Ground	References	Indep. Claims	Dependent Claims
1	ICMSF and Gombas	1 and 17	2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, and 29–33
2	ICMSF and Hughes		Same as ground 1 excluding claim 30
3	Price, ICMSF, and Hughes		

Ground	Base Ground	Additional Reference	Dep. Claims
4	1	Stewart	3
5	2		
6	1	Fratamico	5, 6, 29, and 30
7	2		5 and 29
8	2	D'Haese	6
9	1	D'Aoust	28
10	2		

m. Below are tables summarizing the grounds related to my above-listed opinions regarding the claims of the ’143 Patent.

Ground	References	Indep. Claims	Dependent Claims
1	ICMSF and Gombas	1 and 35	2, 3, 5–7, 11, 12, 14–20, 22–24, 26, 29, 31–34, and 36
2	ICMSF and Hughes		Same as ground 1 excluding claim 32
3	Price, ICMSF, and Hughes		

Ground	Base Ground	Additional Reference	Dep. Claims
4	1	Stewart	4
5	2		
6	1	Fratamico	6, 7, 31, and 32
7	2		6 and 31
8	2	D’Haese	7
9	1	D’Aoust	30
10	2		

n. Below are tables summarizing the grounds related to my above-listed opinions regarding the claims of the ’771 Patent.

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		

IV. TECHNICAL BACKGROUND — STATE OF THE ART

39. The older methods for detecting foodborne pathogens, primarily *Salmonella*, were deficient in many ways. Initially, food samples were simply plated on agar media that was designed to select for and inhibit other types of microorganisms or in some cases, the samples would be enriched in a selective broth to reduce the background microbiome and to allow for the growth of *Salmonella* before plating onto selective media. These methods could easily lead to false negative results, as

bacteria stressed by heat or drying during the food process would often fail to grow in the inhibitory media. By 1961, it had been suggested that the addition of a non-selective pre-enrichment would assist in the recovery of stressed or injured bacteria.

40. Microorganisms in foods may be determined either quantitatively (i.e., by enumeration) or qualitatively (i.e., by presence/absence detection). Quantitative methods are commonly used for quality assessment of foods, such as the estimated population of coliforms as an indicator of the hygienic quality of certain foods. These methods usually rely on traditional bacteriology, with various media in petri dishes.

41. Qualitative methods are more commonly associated with foodborne pathogens, such as *Salmonella* or pathogenic *Escherichia coli*. The methodology to qualitatively detect foodborne pathogens has constantly evolved over the years. Using *Salmonella* as an example, the historical method of detection involved, dating from the 1950s, involved use of media that would select for and differentiate *Salmonella* from other bacteria. It was recognized that food processes could injure these bacteria to the extent that they would not grow in or on selective media, and to overcome this limitation, a non-selective pre-enrichment was added to allow the injured bacteria to resuscitate and grow further. The traditional bacteriological method, still in use today, relies on a non-selective pre-enrichment followed by a selective enrichment, with the selectively enriched samples transferred to several

different types of selective and differential agar plates. Several different types of selective or differential agars are used because not every *Salmonella* will grow on every medium. The selectively enriched cultures are streaked onto the plates in a manner to produce individual isolated colonies, which are then further characterized by biochemical tests to confirm that they are *Salmonella*.

42. The traditional bacteriological methods are time consuming and imprecise. Each step in the process requires an incubation period of up to 24 hours, resulting in a total time to a negative sample of a minimum of three days and to a confirmed positive sample of four to five days. This does not include the time required to collect the samples and transport them to the laboratory. Many presumptive positive samples on the selective and differential agar plates would be later identified as negative samples during further characterization of the isolated colonies. For many perishable food products, this delay in obtaining results was difficult because of the limited shelf life of the foods.

43. An inherent weakness in the traditional bacteriological method is in selecting "typical" colonies from the selective and differential agar plates. This requires a thorough understanding of what a typical *Salmonella* will appear as on the different selective and differential agar plates. This is compounded by the individual colonies not being a pure culture, but occasionally a mixture of two or more bacteria, resulting

in an atypical appearance. The mixed colonies would have to be further purified before biochemical analysis could proceed.

44. Beginning in the 1960s, there was considerable research devoted to shortening the analysis time and improving efficiency in the laboratory. As the traditional methods were labor intensive, alternate screening methods were developed to reduce both the amount of labor as well as improve sensitivity and specificity. The earliest screening methods, dating from the early 1970s, involved antigen/antibody tests, where antibodies were used to determine the presence of *Salmonella* in selectively enriched samples. These screening tests were rapid, in the sense that a presumptive result could be obtained in a few minutes from a selectively enriched sample, rather than waiting 24 hours for colonies to grow on selective and differential agar plates. These methods, commonly known as enzyme-linked immunosorbent assays (ELISAs), are widely in use today. While an improvement in analysis technology, ELISAs have an inherent limitation in that some of the antibodies in the tests will cross react with other bacteria which are not *Salmonella*. *Salmonella* is a very diverse group of bacteria, and some of the antibodies that are capable of detecting all of the different serotypes of the organism will cross react with other genera that are in the same microbiological family as *Salmonella* (i.e., the *Enterobacteriaceae*), resulting in a false positive result.

45. Another inherent limitation of these assays is that they require relatively high population densities of the target bacterium to produce a visual result. Most if not all of the currently used ELISAs employ a chromogenic dye to indicate a positive result, and commonly it may require a population density of up to 1 million cells per milliliter (*see, e.g.,* Lee et al., 1990) of the target bacterium in the selective enrichment to produce a visual reaction, depending on the method format. While the pre-enrichment and selective enrichment procedures should result in this population density, it is possible that it will not, resulting in a false negative result.

46. The latest evolution of screening methods involves the use of genetic markers. These tests, which were introduced in the mid-1980s, are commonly based on the polymerase chain reaction (PCR) and use the genetic material of the bacterial cells as a means of identification. These screening methods still require the use of a pre-enrichment to recover injured bacteria but are more specific and sensitive than traditional bacteriology or ELISAs. The methods use specific primers to increase the number of copies of DNA fragments from the bacteria and then typically use a chromogenic marker to determine if the sample is positive or negative. While still requiring a certain population density of the target bacterium, the necessary population density to result in a positive result is much lower, usually in the range of 1,000 to 10,000 cells per milliliter. This results in a shorter analysis time, as there is often not a need for a selective enrichment step and in some cases the pre-

enrichment time may be shortened. For some methods, the total analysis time may be 26 to 30 hours, in comparison to approximately 72 hours for the traditional bacteriological methods. Although more precise and sensitive than other methods, genetic methods still have concerns with false positive and false negative results.

47. Sampling and laboratory analytical methods have developed further since the granting of the IEH Patents. Sampling combo bins of beef trim by removing 60 individual samples is time consuming and cumbersome. Because of this, alternative sampling methods which involve swabbing the trim have been developed which have been shown to be equivalent to the traditional sampling method as described by Badoni (Ex. 1030 at 82) and Wheeler (Ex. 1031 at 1605). Briefly, these methods involve using a cloth or sponge to sample a large area of trim surfaces, where the microbial contamination is generally found. These methods may be performed manually or may be automated to sample continuously. The swabbing methods are much less labor intensive than other forms of sampling and have become an attractive alternative for the meat and poultry industry.

48. In addition, microbiological laboratory methods have also evolved with the further development of genetic based protocols, for example the polymerase chain reaction (PCR). There are commercially available test methods which no longer require the use of a selective enrichment step for the detection of *Salmonella*, such as Assurance® GDS *Salmonella* Tq from MilliporeSigma. *See* Ex. 1063.

49. Any new method, whether it is sampling or analytical, must be shown to be substantially equivalent to the existing method to be accepted by the government and industry. The above-described swab sampling has been shown to be equivalent to the standard excision method for beef trim in separate peer-reviewed research publications. The laboratory analytical methods undergo certification by independent organizations to demonstrate equivalency to existing methods, and the newer analytical methods which do not require selective enrichment have received those certifications.

50. Taken together, these developments indicate that two-stage compositing, such as the two-stage compositing disclosed in the IEH Patents, is not as relevant today as in 2004.

V. THE IEH PATENTS

A. Disclosure and AAPA

51. The disclosure and claims of the IEH Patents relate to a combination of a series of steps, all known and used for years in the food processing industry, to sample and test meat for bacteria before the items are released into the food supply. The purported improvement of the IEH Patents is to combine (i.e., dry composite) samples within an individual lot before enrichment, and then after enrichment, perform a second compositing step (i.e., wet composite) to combine the enriched

samples from individual lots into one sample for testing, and then further test a portion of the individual enriched lot samples if a test is positive.

52. In the specification, IEH included many acknowledgements to subject matter that is known in the art. I have been informed by Petitioner's counsel that such subject matter is known as applicant-admitted prior art (AAPA). The AAPA appears throughout the specification of the IEH Patents but is primarily in the Background section. Some of these AAPA statements by IEH prompted the Examiner to request clarification because "the information . . . does not transparently clarify, whether applicant performed those inspection methods . . . or is only referring to the . . . methods and protocols applied/required by the regulatory authorities." Ex. 1006 at 223–24. The Examiner cited five statements, which are discussed below, and are listed as AAPA #1–#5. Two additional sections are included and are listed as AAPA #6–#7. IEH's responses are cited below with respect to each AAPA. *Id.* at 254–257. Unsatisfied with IEH's responses, the Examiner requested more accurate clarifications (*id.* at 288) but IEH essentially repeated the same responses (*id.* at 336–340).

1. AAPA #1 — Beef Sampling Plans

53. A first statement is in the Background section and relates to the collecting step:

> Under recent United States Department of Agriculture, **Food Safety and Inspection Service (FSIS) directives** and guidelines, many food producers in the United States **have adopted sampling plans** that involve testing, for example, of raw **beef** trims and/or ground **beef** for ***E. coli* O157:H7**, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella*.

Ex. 1001 at 1:40–45 (emphasis added); Ex. 1002 at 1:52–57 (emphasis added); Ex. 1003 at 1:59–65 (emphasis added); *see also* Ex. 1006 at 255.

54. AAPA #1 refers to FDA guidelines, such as the Bacteriological Analytical Manual, which broadly discloses methods for collecting and combining food products. Ex. 1001 at 1:66; Ex. 1002 at 2:11; Ex. 1003 at 2:19–20; *see* Ex. 1022 (BAM 2003) as discussed at § X-C-1, *infra*.

55. AAPA #1 establishes that under FSIS directives it was known to adopt sampling plans to test beef for *E. coli*. *See* Ex. 1023 (FSIS Directive) as discussed at § X-C-2, *infra*. The same applies for other FSIS guidelines such as the Microbiology Laboratory Guidebook (MLG). *See* Ex. 1028 (MLG 2003) as discussed at § X-D-3, *infra*.

2. AAPA #2 — RTE Sampling Plans

56. Similarly, a second statement establishes that under USDA FSIS "guidelines, producers of **Ready-to-Eat (RTE) meat** and poultry products may adapt an 'end

product' **sampling program** as verification that their product is free of the pathogen *Listeria monocytogenes*." Ex. 1001 at 12:29–33 (emphasis added); Ex. 1002 at 12:35–39 (emphasis added); Ex. 1003 at 12:62–67 (emphasis added); *see also* Ex. 1006 at 255.

57. The third paragraph of the Background section describes collecting samples of RTE products such that "the standard size production lot . . . is one composite sample per production line per shift." Ex. 1001 at 2:29–34; Ex. 1002 at 2:41–46; Ex. 1003 at 2:50–55. This standard size production lot for testing RTE for *Listeria* and *Salmonella* is equated to the standard size production lot for testing raw beef trim for *E. coli* O157 in the U.S. beef industry. Ex. 1001 at 2:27–45; Ex. 1002 at 2:39–57; Ex. 1003 at 2:48–67.

3. AAPA #3 — Lots in Beef Industry

58. A third statement also relates to the collecting step:

> At present, the standard size 'production **lot'** for trim **testing** for ***E. coli* O157 in the beef industry** in the USA is a combination of **five combos**, where each combo represents a **single production unit** and weighs approximately 2,000 pounds.

Ex. 1001 at 11:12–16 (emphasis added); Ex. 1002 at 11:18–22 (emphasis added); Ex. 1003 at 11:37–41 (emphasis added). IEH characterized this statement as the well-recognized fact "that [a] production lot for purposes of trim testing consists of

five separate 'combos,' each combo lot being a single production unit weighing about 2,000 lbs." Ex. 1006 at 255. The third paragraph of the Background section discusses the same and variables to consider for forming a test lot. Ex. 1001 at 2:27–45; Ex. 1002 at 2:39–57; Ex. 1003 at 2:48–67.

4. AAPA #4 — Producer Defines Lots

59. A fourth statement, which also relates to the collecting step, states:

> Preferably, **the producer defines** and produces these single-unit **lots** in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to **all of the product produced by a particular production line (or produced by a particular production line in a particular period of time)**, 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.

Ex. 1001 at 12:46–55 (emphasis added); Ex. 1002 at 12:52–61 (emphasis added); Ex. 1003 at 13:12–22 (emphasis added). IEH characterized this statement as the well-recognized fact "that single unit production lots can take different forms such as all of the product produced on a particular production run, or alternatively a portion of the production run corresponding to a certain time period of production

during the run, or a corresponding to a volume amount of the production run (e.g., a 2,000 lb combo lot as referred to above)." Ex. 1006 at 256–57.

5. AAPA #5 — RTE Sampling Plans

60. A fifth statement relates to collecting samples, dry compositing, and enriching a composite sample:

> The frequency of end product sampling is selected by the producer/establishment, based on **valid sampling statistics**. Typically, **samples 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 *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis.

Ex. 1001 at 12:34–43 (emphasis added); Ex. 1002 at 12:40–49 (emphasis added); Ex. 1003 at 12:67–13:9 (emphasis added). IEH characterized this statement as the well-recognized fact "that composite samples are formed and enriched to provide more material for testing." Ex. 1006 at 256.

6. AAPA #6 — Statistical-Based Sampling Plans and Composite Samples

61. The second paragraph of the Background section was not addressed by the Examiner but describes collecting samples from lots according to a sampling plan and then combining the samples as recited in steps (a) and (b) of the IEH Patents' independent claims:

> The operative art . . . comprises various different sampling plans, typically **pursuant to** International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA . . . **guidelines** [in which] . . . . **several samples representing production lots** . . . are **combined 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 pieces from a given sample lot (combined production lot), to form a composite sample for testing**. The number of pieces taken to form the composite sample depends . . . . With respect to *E. coli* O157 testing, for example, a typical plan calls for taking **60 samples (e.g., sample pieces) from a production lot to form a single composite sample** . . . .

Ex. 1001 at 1:62–2:16 (emphasis added); Ex. 1002 at 2:7–28 (emphasis added); Ex. 1003 at 2:14–36 (emphasis added). The above-quoted section and the additional

variables discussed (Ex. 1001 at 2:16–26; Ex. 1002 at 2:28–38; Ex. 1003 at 2:36–47) correlate to teachings of a statistical-based sampling plan.

62. AAPA #6 establishes that under ICMSF and FSIS guidelines it was known to adopt sampling plans to test beef for *E. coli*. *See* Ex. 1028 (MLG 2003) as discussed at § X-D-3, *infra*. Similarly, the AAPA refers to FDA guidelines, such as the Bacteriological Analytical Manual, which also broadly discloses methods for collecting and combining food products. Ex. 1001 at 1:66; Ex. 1002 at 2:11; Ex. 1003 at 2:18–19; *see* Ex. 1022 (BAM 2003) as discussed at § X-C-1, *infra*.

7. AAPA #7 — Enrichment

63. The fourth paragraph of the Background section was also not addressed by the Examiner. However, it describes the well-known benefits of enrichment:

> Typically, once a **composite sample** is constructed (following the art with respect to particular testing) it is then **enriched** for the presence of a given pathogen/microbe by addition of appropriate amounts of enrichment media and incubation at an appropriate temperature for a given amount of time. If the pathogen/microbe is present, then it grows and multiplies under the favorable conditions of enrichment, thereby providing more material which can be detected by subsequent analysis. The composite sample is then tested by one or more available, art recognized methods

> including, for example, enrichment followed by **immunoassay-based tests** or **PCR-based methods**, or **culturing** of the organism of interest, or other **DNA- or immunochemical-based methods**.

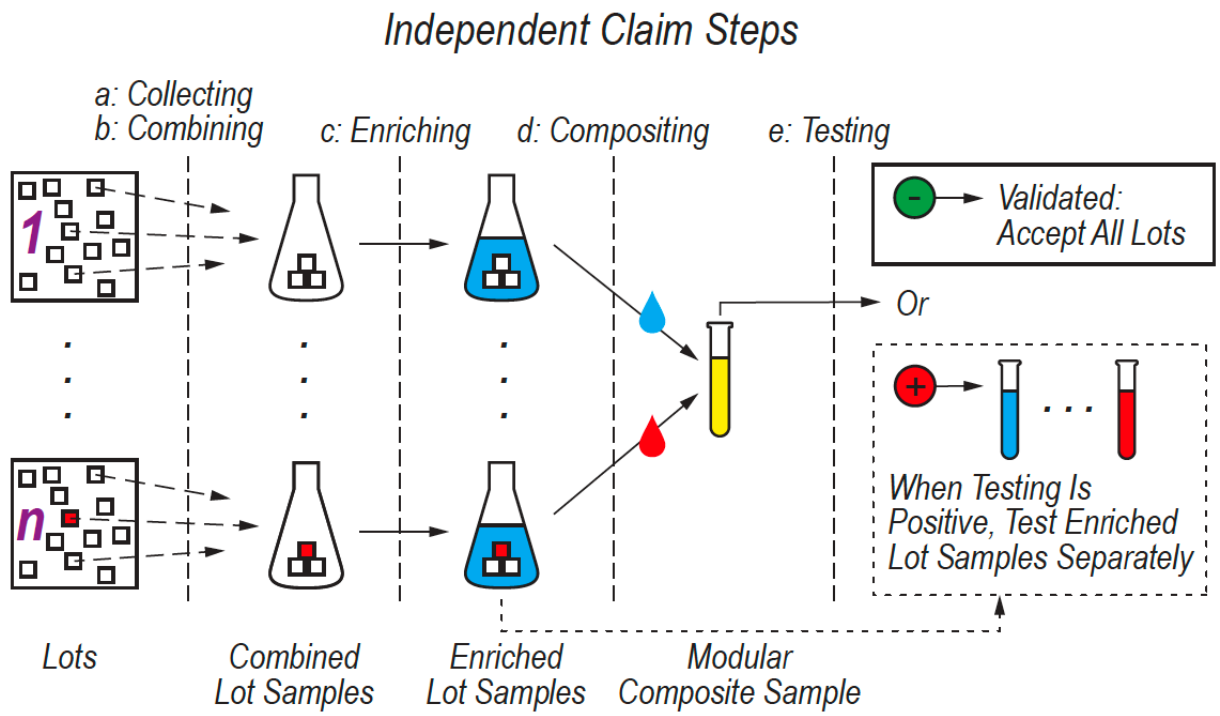
Ex. 1001 at 2:46–58 (emphasis added); Ex. 1002 at 2:58–3:3 (emphasis added); Ex. 1003 at 3:1–12 (emphasis added).

B. Claims of the IEH Patents

64. Each of the IEH patents includes a first independent claim and a second independent claim. These independent claims include: claims 1 and 17 of the ’584 Patent, claims 1 and 35 of the ’143 Patent, and claims 1 and 37 of the ’771 Patent.

65. The only independent claims that identify the food product to be tested are those of the ’584 Patent, which were amended in reexamination, such that claim 1 recites “a plurality of separate operationally-linked test lots of beef” and claim 17 recites “a plurality of operationally-linked single-unit production lots of meat or poultry.” Because the meat recited in claim 17 includes beef, both independent claims of the ’584 Patent cover beef testing.

66. Other than specifying the food product to be tested in the independent claims of the ’584 Patent, all of the independent claims of the IEH Patents recite steps (a)–(e), as depicted in the diagram below.



67. Step (a) of each independent claim may be referred to as the **collecting** step. In this step, portions or samples (or more accurately, the subsamples) are collected from lots. Such collecting is also referred to in the art as sampling.

68. Step (b) is referred to herein as the **combining** step even though some independent claims use a different gerund, compositing, instead of combining. Nevertheless, these terms mean the same thing because the independent claims require that the collected portions or samples are combined or composited to provide a set of separate test lot samples. Thus, there is a separate test lot sample comprising all the portions taken from each lot. Such combining and compositing is also referred to in the art as dry compositing.

69. In step (c), the **enriching** step, the combined/composited test lot samples are selectively enriched. While the '584 Patent's independent claims recite "incubating," they also recite that the end result is "a set of separate test lot samples enriched for the target microbial agent or organism." The enriching step also implicitly involves retaining portions of the combined and enriched lot samples such that they are available for further testing, as explained below regarding step (e).

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

71. Step (e), the **testing** step, tests the composite sample using a "suitable detection assay." Step (e) is broken into several sub-steps. If the outcome is negative, as expected, then the lots are validated/released. If the outcome is positive, then each separate, enriched, combined/composited lot sample from step (c) is individually tested to determine which is positive for the target microorganism.

72. Each of the first independent claims of the '584 Patent and the '143 Patent, recites "test lots." Each of the second independent claims of the '584 Patent and the '143 Patent recites "single-unit production lots." IEH used simpler terms in the first and second independent claims of the '771 Patent, which respectively recite "lots" and "single production lots." However, as explained at § XI-B-1 *infra*, a single production lot or a single-unit production lot is a type of a test lot or lot.

73. As explained at § XIII-A *infra*, claim 1 of both the ’143 Patent and ’771 Patent have scopes that are identical to or broader than the scope of claim 1 of the ’584 Patent before reexamination. As also explained at § XIII-B *infra*, claim 35 of the ’143 Patent and claim 37 of the ’771 Patent both have scopes that are identical to or broader than the scope of claim 17 of the ’584 Patent before reexamination.

1. Claim 1 of the ’584 Patent

74. Claim 1 is presented below as amended after reexamination.

Claim 1 of the ’584 Patent	
Pre	A method of sampling, testing and validating a plurality of operationally-linked test lots of beef for release into commerce, comprising:
(a)(1)	collecting a plurality of portions from each of a plurality of separate operationally-linked test lots of beef, each to be validated for release into commerce, the test lots each comprising an assemblage of one or more specimens from which the portions are collected,
(a)(2)	wherein each test lot is separately sampled to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the test lot into commerce;
(b)	combining the collected conforming plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;
(c)	incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;
(d)	removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and
(e)(1)	testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism,
(e)(2)	wherein when such testing is negative all of said separate test lots are validated for release into commerce, and
(e)(3)	wherein when such testing is positive, each of the individual separate test lots are validated for release into commerce, according to the statistical-based sampling plan, by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result for each test lot,
(e)(4)	wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate test lots with no requirement for further enrichment thereof, and with no requirement for further sampling in a).

75. The limitations added in reexamination are listed in the reexamination certificate and are reproduced at § VIII-D-16 *infra*.

2. Claims Depending from Claim 1 of the '584 Patent

76. Claims 2–23, 26–30, and 32 depend from claim 1. These claims are listed below. Note that the number of the claims that are challenged are highlighted in orange while no color is associated with the number of a claim that is not challenged.

Claims Depending from Claim 1 of the of the '584 Patent	
2	The method of claim 1, wherein each of the test lots is a single-unit production lot, comprised of operationally-linked product specimens.
3	The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).
4	The method of claim 1, wherein incubating each separate test lot sample in c) comprises incubating each separate test lot sample with enrichment medium suitable to enrich for the target microbial agent or organism, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate test lot sample and combining the removed portions to provide a modular composite sample.
5	The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay further comprises a concentration step to concentrate the target microbial agent or organism.
6	The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples are further tested, such further testing comprises the more sensitive protocol.
7	The method of claim 1, further comprising, forming an additional modular composite sample from the set of enriched separate test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing result.

Claims Depending from Claim 1 of the of the '584 Patent — cont'd	
8	The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched separate test lot sample along with any enriched separate test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.
9	The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the set of enriched separate test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.
10	The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
11	The method of claim 1, wherein the number of separate test lots is from 3 to 10.
12	The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual separate test lots are positive, application of remedial measures to said separate positive test lots, and validating by further testing of a portion of the respective remediated separate test lots and obtaining a negative test result.
13	The method of claim 1, wherein, in a), separately collecting said plurality of portions from each of said plurality of separate test lots comprises separately collecting from each separate test lot a number of portions from 5 to 100.
14	The method of claim 1, wherein, in a), separately collecting said plurality of portions from each of said plurality of separate test lots comprises separately collecting from each separate test lot 30 to 60 portions.
15	The method of claim 1, wherein, in a), separately collecting said plurality of portions from each of said plurality of separate test lots comprises separately collecting 30 portions from each separate test lot.
16	The method of claim 1, wherein, in a), separately collecting said plurality of portions from each of said plurality of separate test lots comprises separately collecting from each separate test lot about 60 portions.
18	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 test lot samples.

Claims Depending from Claim 1 of the of the '584 Patent — cont'd	
19	The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria, Salmonella,* and *Escherichia coli.*
20	The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.
21	The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.
22	The method of claim 1, wherein removing portions of each enriched separate test lot sample comprises removing equal volume portions of each enriched separate test lot sample.
23	The method of claim 1, wherein testing of the 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.
24	*Cancelled in reexamination*
25	*Cancelled in reexamination*
26	The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.
27	The method of claim 2, wherein product specimens are synonymous with product portions.
28	The method of claim 4, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.
29	The method of claim 5, wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.
30	The method of claim 6, wherein the more sensitive protocol further comprises a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol that is used to test the modular composite sample.
32	The method of claim 1, wherein the beef specimens are meat trim pieces.

3. Claim 17 of the ’584 Patent

77. Claim 1 recites beef lots while claim 17 recites lots of meat or poultry. Also, claim 1 recites test lots while claim 17 recites single-unit production lots. However, as explained at § XI-B-1 *infra*, a single-unit production lot is a type of test lot. Thus, claims 1 and 17 are presented below in a side-by-side comparison of the respective claim language to show the minimal differences between the claims.

	Claim 1 of the ’584 Patent	Claim 17 of the ’584 Patent
Pre	A method of sampling, testing and validating a plurality of operationally-linked test lots of	
	beef	meat or poultry
	for release into commerce, comprising:	
(a)(1)	collecting a plurality of portions from each of a plurality of	
	separate	
	operationally-linked	
	test lots of beef,	single-unit production lots of meat or poultry,
	each to be validated for release into commerce,	
	the test lots	the single-unit production lots
	each comprising an assemblage of one or more	
	specimens	production specimens
	from which the portions are collected,	
(a)(2)	wherein each	
	test lot	single-unit production lot
	is separately sampled to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the	

	Claim 1 of the ’584 Pat. — cont’d	Claim 17 of the ’584 Pat. — cont’d
	test lot	single-unit production lot
	into commerce;	
(b)	combining the collected conforming plurality of	
	portions	product portions
	corresponding to each of the separate	
	test lots	single-unit production lots
	to provide a corresponding set of separate	
	test lot samples,	single-unit production lot samples,
	wherein each separate	
	test lot sample	single-unit production lot sample
	is attributed to a particular corresponding	
	separate test lot;	separate single-unit production lot;
(c)	incubating the set of separate	
	test lot samples	single-unit production lot samples
	under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate	
	test lot samples	single-unit production lot samples
	to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate	
	test lot samples,	single-unit production lot samples,
	to provide a set of separate	
	test lot samples	single-unit production lot samples
	enriched for the target microbial agent or organism;	
(d)	removing portions of each enriched separate	
	test lot sample,	single-unit production lot sample,
	and combining the removed portions to provide a modular composite sample; and	

	Claim 1 of the ’584 Patent — cont’d	Claim 17 of the ’584 Patent — cont’d
(e)(1)	testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism,	
(e)(2)	wherein when such testing is negative all of said separate	
	test lots	single-unit production lot samples
	are validated for release into commerce, and	
(e)(3)	wherein when such testing is positive,	
	each of the individual separate test lots	individual separate single-unit production lots
	are validated for release into commerce, according to the statistical-based sampling plan, by further testing of a portion of the respective enriched separate	
	test lot sample	single-unit production lot sample
	using the same or a more sensitive protocol and obtaining a negative test result for each	
	test lot,	single-unit production lot,
(e)(4)	wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate	
	test lots	single-unit production lots
	with no requirement for further enrichment thereof, and with no requirement for further sampling in a).	

4. Claims Depending from Claim 17 of the ’584 Patent

78. Claims 31 and 33 depend from claim 17 and are listed below.

Claims Depending from Claim 17 of the ’584 Patent	
31	The method of claim 17, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate single-unit production lot samples.
33	The method of claim 17, wherein the meat is that of beef, pork, sheep or bison.

C. Claims of the ’143 Patent

1. Claim 1 of the ’143 Patent

79. Claim 1 is listed below.

Claim 1 of the ’143 Patent	
Pre	A method of sampling and testing for microbes in multiple separate test lots, comprising:
(a)	separately collecting multiple independent samples from each of multiple separate test lots, wherein each separate test lot is separately sampled by taking said multiple independent samples thereof;
(b)	separately compositing the collected multiple independent samples from each of the separate test lots to provide a corresponding set of separate composited test lot samples, wherein each of the separate composited test lot samples is attributed to a particular corresponding separate test lot;
(c)	enriching each of the separate composited test lot samples to provide a set of separate composited test lot samples enriched for the target microbe(s);
(d)	removing portions of each separate enriched composited test 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 test lot samples are deemed negative for the target microbe(s) and each of the multiple separate test lots is validated, and
(e)(3)	wherein when such testing is positive, each of the individual separate composited test lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited test lot samples is positive for the target microbe(s), wherein the test lots corresponding to any negatively testing composited test lot samples are validated.

2. Claims Depending from Claim 1 of the ’143 Patent

80. Claims 2–23, 26–30, and 32 depend from claim 1 and are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
2	The method of claim 1, wherein each of the multiple separate test 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-unit product lot comprising multiple operationally-linked product specimens, and combinations thereof.
3	The method of claim 1, wherein each of the multiple separate test lots is a single-unit production lot, comprised of operationally-linked product specimens.
4	The method of claim 1, further comprising incubating the pooled modular composite sample of d), prior to testing in e).
5	The method of claim 1, wherein enriching each separate composited test lot sample in c) comprises incubating each separate composited test 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 test lot sample and combining the removed portions to provide a pooled modular composite sample.
6	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).
7	The method of claim 1, wherein where testing in e) of the pooled modular composite sample is positive, and wherein the separate individual composited test lot samples are further tested using a more sensitive protocol.
8	The method of claim 1, further comprising, 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 the same or a different suitable assay, to confirm the testing status.

Claims Depending from Claim 1 of the ’143 Patent — cont’d	
9	The method of claim 1, further comprising, forming an additional pooled modular composite sample from an additional enriched separate composited test lot sample along with any enriched separate composited test 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.
10	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.
11	The method of claim 1, wherein each the test lots is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
12	The method of claim 1, wherein the number of separate test lots is from 3 to 10.
13	The method of claim 1, further comprising, where testing of the pooled modular composite sample is positive, determining which individual separate test lots are positive, application of remedial measures to said separate positive test lots, and validating by further testing of the respective remediated separate test lots and obtaining a negative test result.
14	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting from each separate test lot a number of samples from 5 to 100.
15	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting 30 to 60 samples from each separate test lot.
16	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting at least 30 samples from each separate test lot.
17	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting at least 60 samples from each separate test lot.

Claims Depending from Claim 1 of the '143 Patent — cont'd	
18	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 test lot samples.
19	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria, Salmonella,* and *Escherichia coli.*
20	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.
21	The method of claim 1, wherein the target microbe(s) comprises a spoilage organism.
22	The method of claim 1, wherein removing portions of each separate enriched composited test lot sample comprises removing equal volume portions of each separate enriched composited test lot sample.
23	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.
24	The method of claim 1, wherein each of the multiple separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
25	The method of claim 1, wherein each of the multiple separate test lots are separate production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.
26	The method of claim 1, wherein each of the multiple separate test lots are separate production lots of a ready-to-eat product.
27	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 test lot samples for the target microbe(s) to enhance confidence in the negative testing results prior to deeming the test lots validated or releasable into the chain of commerce.

Claims Depending from Claim 1 of the ’143 Patent — cont’d	
28	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 test lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited test lot samples is positive for the target microbe(s), retesting of the separate negatively testing composited test lot samples to enhance confidence in the negative testing results prior to deeming the test lots corresponding to the negatively testing composited test lot samples validated or releasable into the chain of commerce.
29	The method of claim 3, wherein product specimens are synonymous with product portions.
30	The method of claim 5, wherein the enrichment medium comprises a selective agent that will inhibit a competing non-target microbe.
31	The method of claim 6 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.
32	The method of claim 7, 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.
33	The method of claim 24, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.
34	The method of claim 24, wherein the meat is that of beef, pork, sheep or bison.

3. Claim 35 of the ’143 Patent

81. The difference between the independent claims of the ’143 Patent is that claim 1 recites test lots while claim 35 recites single-unit production lots. As explained at § XI-B-1 *infra*, a single-unit production lot is a type of test lot. Thus, claims 1 and 35 are presented below in a side-by-side comparison of the respective claim language to show the minimal differences between the claims.

	Claim 1 of the ’143 Patent	Claim 35 of the ’143 Patent
Pre	A method of	
	sampling	sampling,
	and testing for	
	microbes	microbe(s)
	in multiple separate test lots, comprising:	
(a)	separately collecting multiple independent samples from each of multiple separate	
	test lots,	single-unit production lots,
	wherein each separate	
	test lot	single-unit 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 test lots to provide a corresponding set of separate composited	
	test lot samples,	single-unit production lot samples,
	wherein each of the separate composited	
	test lot samples	single-unit production lot samples
	is attributed to a particular corresponding separate	
	test lot;	single-unit production lot;
(c)	enriching	
	each	
	of the separate composited	
	test lot samples	single-unit production lot samples
	to provide a set of separate composited	
	test lot samples	single-unit production lot samples
	enriched for the target microbe(s);	
(d)	removing portions of each separate enriched composited	
	test lot sample,	single-unit production lot sample,

	Claim 1 of the ’143 Patent — cont’d	Claim 35 of the ’143 Patent — cont’d
	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	
	test lot samples	single-unit production lot samples
	are deemed negative for the target microbe(s) and each of the multiple separate	
	test lots	single-unit production lots
	is validated, and	
(e)(3)	wherein when such testing is positive, each of the individual separate composited	
	test lot samples	single-unit production lot samples
	that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited	
	test lot samples	single-unit production lot samples
	is positive for the target microbe(s), wherein the	
	test lots	single-unit production lots
	corresponding to any negatively testing composited	
	test lot samples	single-unit production lot samples
	are validated.	

4. Claims Depending from Claim 35 of the ’143 Patent

82. Claims 36–38 depend from claim 35 and are listed below.

Claims Depending from Claim 35 of the ’143 Patent	
36	The method of claim 35, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate composited single-unit production lot samples.

Claims Depending from Claim 35 of the ’143 Patent — cont’d	
37	The method of claim 35, further comprising in (e) wherein when such testing of the pooled modular composite sample is negative, nonetheless testing each of the separate composited single-unit production lot samples for the target microbe(s) to enhance confidence in the negative testing results prior to deeming the single-unit production lots validated or releasable for processing or into the chain of commerce.
38	The method of claim 35, further comprising, in (e) wherein when such testing of the modular composite sample is positive, each of the individual separate composited single-unit production lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited single-unit production lot samples is positive for the target microbe(s), retesting of the separate negatively testing composited single-unit production lot samples to enhance confidence in the negative testing results prior to deeming the single-unit production lots corresponding to the negatively testing composited single-unit production lot samples validated or releasable into the chain of commerce.

D. Claims of the ’771 Patent

1. Claim 1 of the ’771 Patent

83. Claim 1 is listed below.

Claim 1 of the ’771 Patent	
Pre	A method of sampling and testing 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;

Claim 1 of the ’771 Patent — cont’d	
(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.

2. Claims Depending from Claim 1 of the ’771 Patent

84. Claims 2–36 depend from claim 1 and are listed below.

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).

Claims Depending from Claim 1 of the '771 Patent — cont'd	
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.
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.

Claims Depending from Claim 1 of the '771 Patent — cont'd	
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 test lot a number of samples from 5 to 100.
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 test 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 test 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 test 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 *Listeria, Salmonella,* and *Escherichia coli.*
24	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.
25	The method of claim 1, wherein the target microbe(s) comprises a spoilage organism.

Claims Depending from Claim 1 of the ’771 Patent — cont’d	
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.
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 test lot samples to enhance confidence in the negative testing results prior to deeming the lots corresponding to the negatively testing composited test lot samples validated or releasable into the chain of commerce.

Claims Depending from Claim 1 of the ’771 Patent — cont’d	
36	The method of claim 1, wherein each of the multiple separate lots are production lots of produce, fruits, vegetable, herbs, or spices.

3. Claim 37 of the ’771 Patent

85. The difference between the independent claims of the ’771 Patent is that claim 1 recites lots while claim 37 recites single production lots. As explained at § XI-B-1, *infra*, a single production lot is a type of lot. Thus, claims 1 and 37 are presented below in a side-by-side comparison of the respective claim language to show the minimal differences between the claims.

	Claim 1 of the ’771 Patent	Claim 37 of the ’771 Patent
Pre	A method of sampling and testing for	
	microbes	microbe(s)
	in multiple separate lots, comprising:	
(a)	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;	
(b)	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	

	Claim 1 of the ’771 Patent — cont’d	Claim 37 of the ’771 Patent — cont’d
	lot;	single production lot;
(c)	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);	
(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	
(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	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	
(e)(3)	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	

	Claim 1 of the ’771 Patent — cont’d	Claim 37 of the ’771 Patent — cont’d
	lot samples	single production lot samples
	are validated.	

4. Claims Depending from Claim 37 of the ’771 Patent

86. Claims 38–49 depend from claim 37 and are listed below.

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.

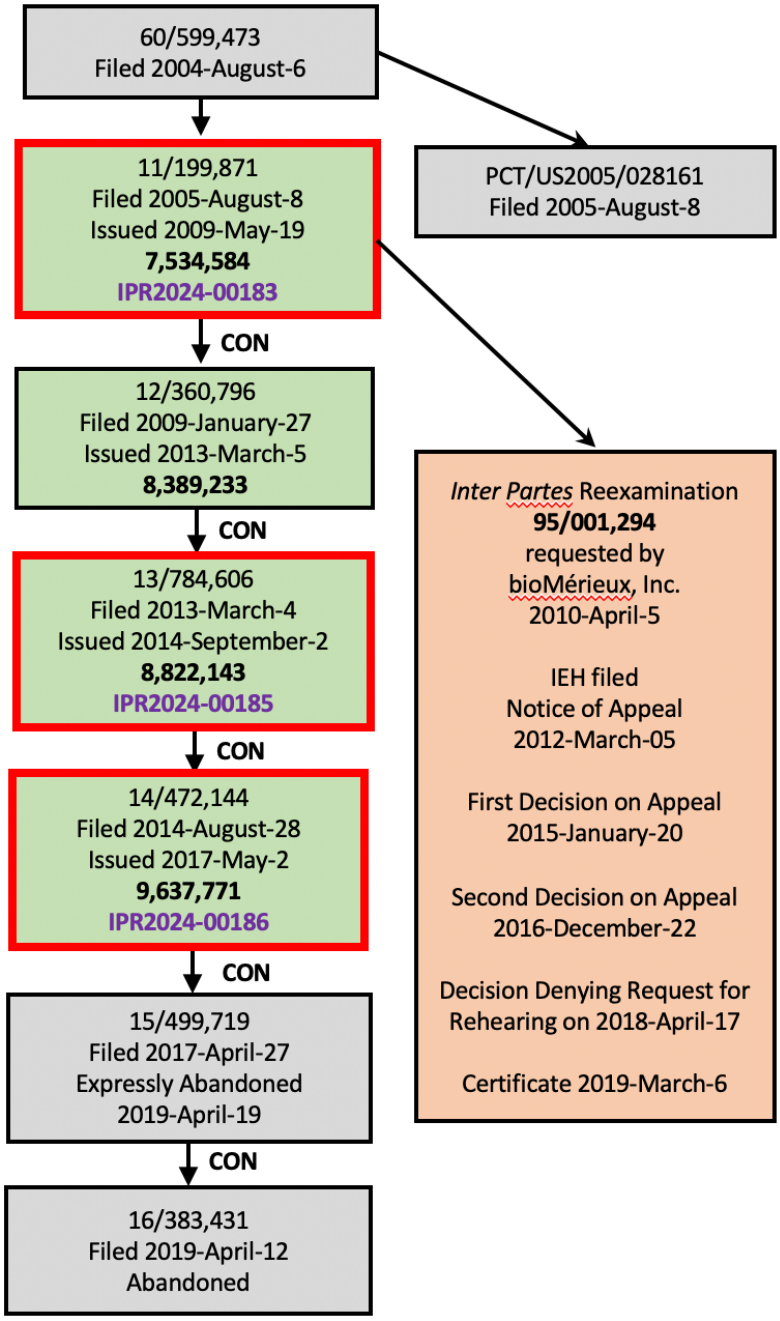
Claims Depending from Claim 37 of the '771 Patent — cont'd	
42	The method of claim 41, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.
43	The method of claim 42, wherein the meat is that of beef, pork, sheep, or bison.
44	The method of claim 43, wherein the meat is that of beef.
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 *Listeria, Salmonella*, and *Escherichia coli.*
49	The method of claim 48, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms, and fecal coliforms.

VI. FAMILY TREE OF IEH'S PATENTS

87. As depicted below, IEH has four patents in this family. The '584 Patent, its continuations, and the related international application were examined by the same examiner. Non-Provisional Application No. 15/499,719 was examined by a different examiner and expressly abandoned after the reexamination. Ex. 1034. Non-Provisional Application No. 16/383,431 is not publicly accessible.

88. The prosecution history of the '584 Patent is summarized at § VII *infra*. The '584 Patent was reexamined as discussed at § VIII *infra*.

89. Three continuations of the ’584 Patent resulted in patents including the ’233 Patent, the ’143 Patent, and the ’771 Patent, as discussed at § IX *infra*.



VII. PROSECUTION HISTORY OF '584 PATENT

90. The '584 Patent issued from Non-Provisional Application No. 11/199,871 ("the '871 Application"), which was filed on August 8, 2005.

A. Provisional Application No. 60/599,473

91. The '584 Patent claims priority to Provisional Application No. 60/599,473, which was filed on August 6, 2004. Ex. 1005 at 1. Provisional Application No. 60/599,473 has a background section, a detailed description section, and an abstract. The background section describes plans calling for 60 samples to form a single composite sample. *Id.* at 2 (Application at 1). Also, the background section describes a test lot with reference to the beef industry in the United States in which the standard size for trim testing is five combos (of approximately 2000 pounds/combo). *Id.* at 3 (Application at 2). Additionally, "lotting" protocols are described in the background section. *Id.* The detailed description section provides examples of a single production unit including "the single combo, bin, pallet, or segment of production, etc." *Id.* at 6 (Application at 5).

B. Initial-Stage of Prosecution

92. The specification of the '584 Patent states that

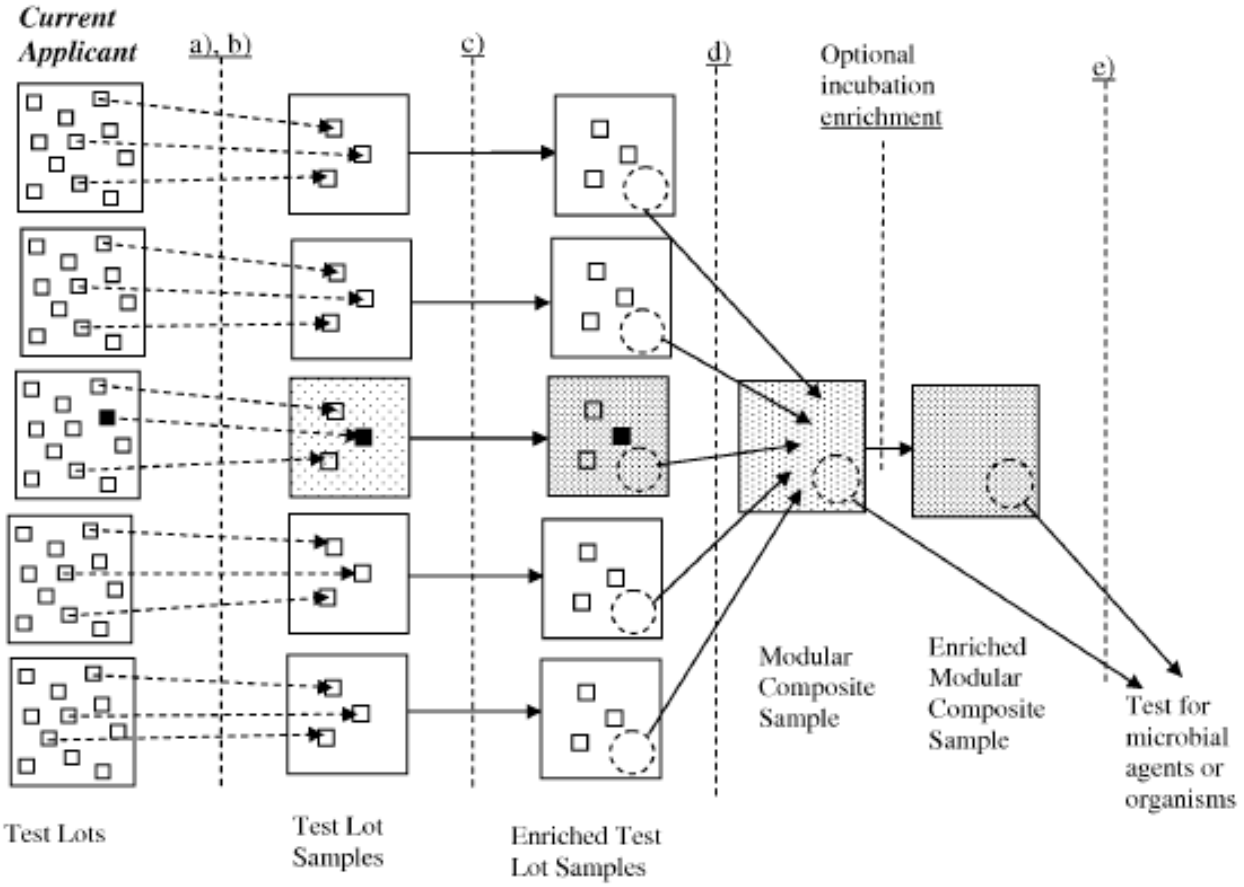
> [t]he methods are broadly applicable to many product areas including, but not limited to . . . all manners of raw and processed foods, environmental samples (water,

> wastewater, soil, surface samples, air samples taken by impingers and filtration, etc), pharmaceuticals, and other types of samples to be analyzed using microorganism enrichment-detection protocols.

Ex. 1001 at 1:24–33. Based on this breadth, Examiner Srivastava asked IEH on October 9, 2007 to restrict the claims to a single species by choosing from one of an environmental lot, a pharmaceutical lot, or a single-unit product lot. Ex. 1006 at 59. On October 16, 2007, IEH filed a response and a preliminary amendment and elected a single-unit product lot. *Id.* at 69. IEH stated that "the portions collected from each test lot are combined together (not mixed with portions taken from any other test lot) to provide a set of corresponding test lot samples." *Id.*

93. An Office Action issued on January 10, 2008 with objections to numerous terms in the claims and rejecting claims considered to be indefinite. *Id.* at 140–54. The pending claims were rejected based on two references, Renter and Samadpour 2002, both of which were co-authored by Mansour Samadpour, the sole inventor of the IEH Patents. *Id.* at 146–49. Claim 1 was rejected as anticipated by Renter, which teaches a method to evaluate cattle feces for *E. coli* O157. *Id.* at 146. Claim 1 was also rejected as anticipated by Samadpour 2002, which analyzes *E. coli* O157 in recreational water as a source of outbreaks from various fecal sources. *Id.* at 147–48. The pending claims were also rejected as obvious based on Samadpour 2002 and Renter. *Id.* at 148–49.

94. IEH filed a response and amendment on April 25, 2008. *Id.* at 155–87. The response included the diagram below, which depicts the steps (a)–(e) of the independent claims along the vertical dashed lines. *Id.* at 173.



Id. at 187.

95. As shown by the above diagram, steps (a)–(e) recited in the independent claims during prosecution were essentially the same as those of steps (a)–(e) of the independent claims in the reexamination certificate for the '584 Patent. In the response, IEH amended the claims in a manner characterized as "minor." *Id.* at 216.

For example, step (c) was amended to clarify that incubating results in enrichment, which is the inherent result of incubation after adding enrichment broth. *Id.* at 157.

96. IEH emphasized that the references merely disclose enriching and testing individual samples. *Id.* at 172. IEH correctly asserted that neither reference discloses (1) combining samples to provide a test lot sample prior to enrichment, (2) combining enriched test lot samples to yield a modular composite sample, or (3) testing individual enriched test lot samples after a test of a modular composite sample reveals the presence of microorganism(s). *Id.* at 171–73.

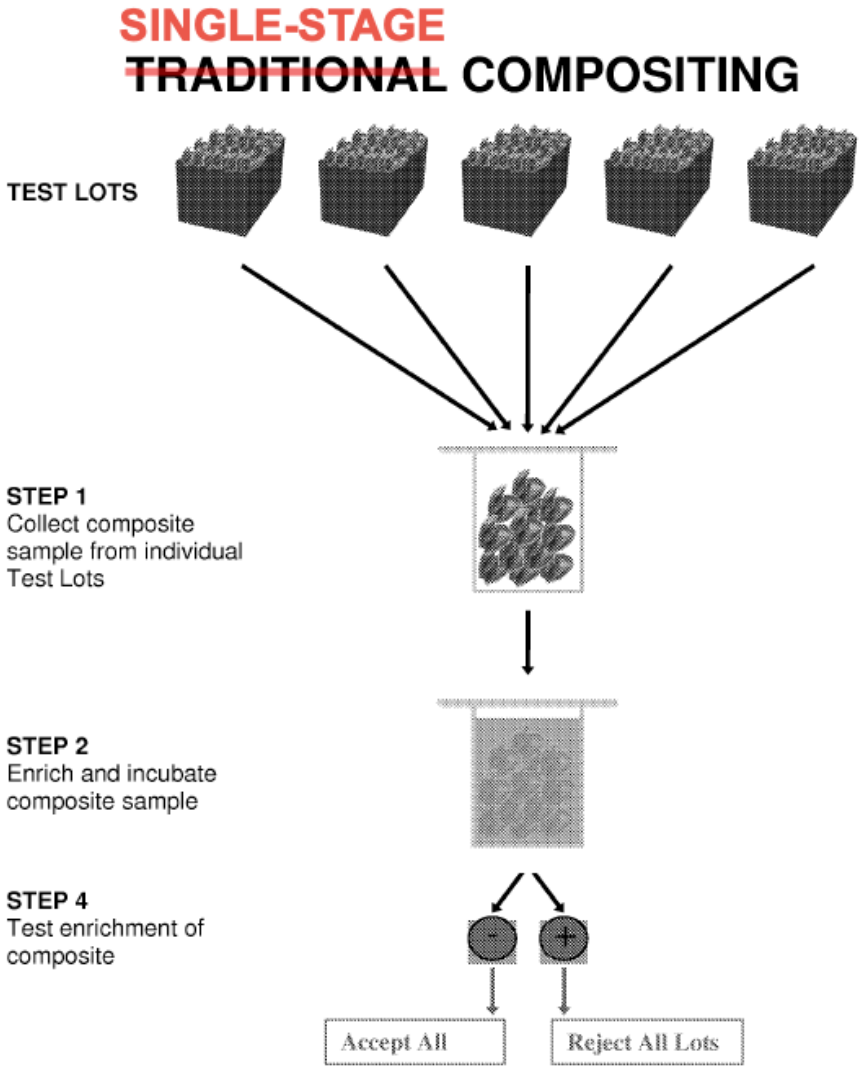
97. An interview was held on July 16, 2008 between the Examiner and Dr. Barry Davison, IEH's representative. *Id.* at 210–19. An agreement was not reached and both parties noted that Dr. Davison asserted that the Examiner "did not understand the invention" when conducting the initial search. *Id.* at 213, 215–16.

C. Second and Third Office Actions

98. A second Office Action issued on August 20, 2008. *Id.* at 220–232. The Examiner concluded that the independent claims were anticipated by Davies and by Skov and were obvious based on Kuo and Budiman. *Id.* The Examiner requested clarification about AAPA. *Id.* at 223–24; *see also supra* V-A-1.

99. IEH filed a response and amendment on October 24, 2008. *Id.* at 244–270. IEH asserted that Davies, Skov, and Kuo only teach simple sample pooling "to make a classical composite sample" and then "assaying the classical composite sample

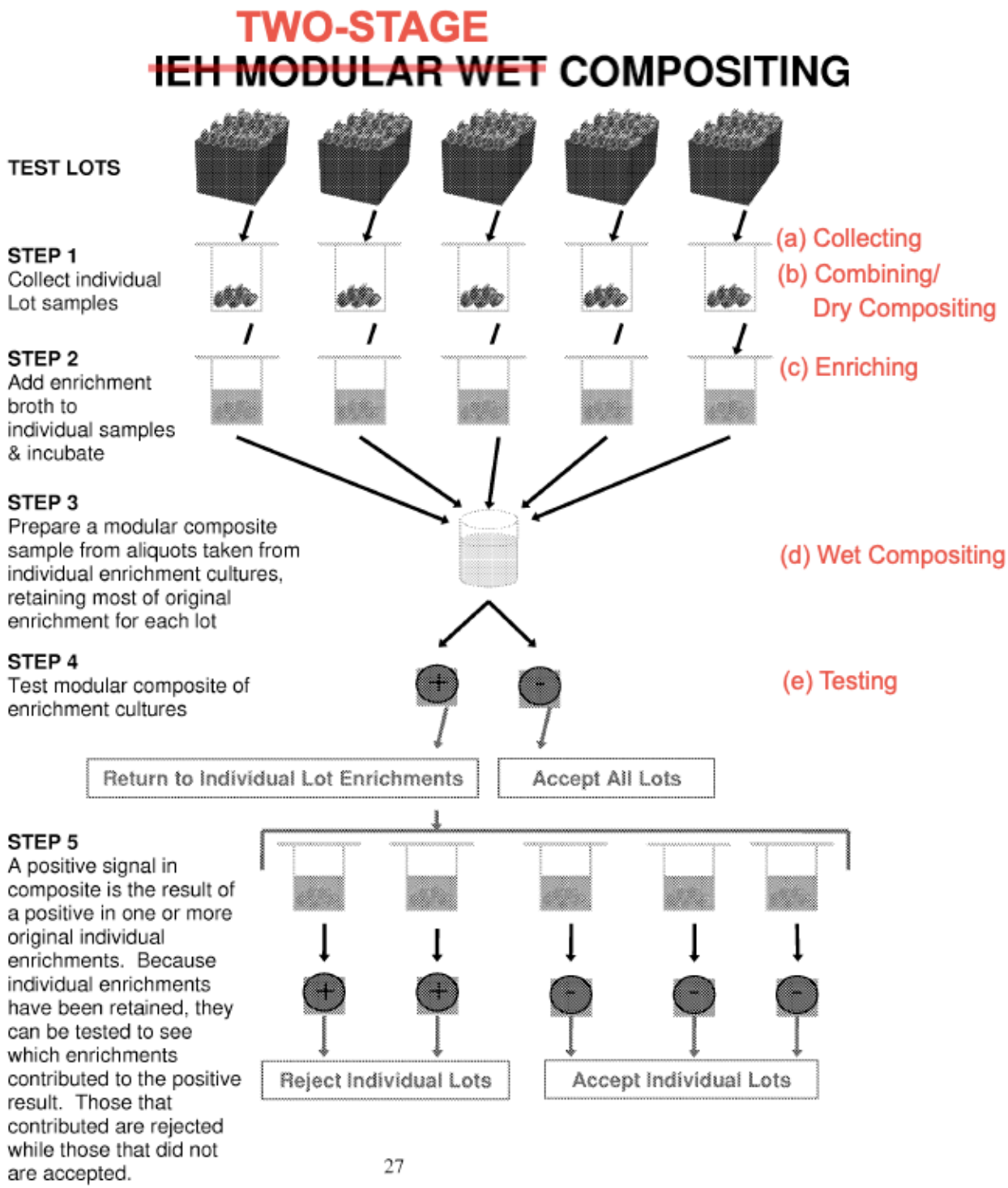
directly," which "only amounts to preparation and enrichment of 'a test lot sample.'" *Id.* at 259, 263, 265. IEH characterized these references as disclosing traditional compositing as depicted in the image below and Petitioner has annotated the title of the image to more accurately describe the single stage compositing that is shown.



Id. at 269 (annotated). IEH asserted that Davies, Skov, and Kuo do not disclose "preparing and assaying a modular composite sample." *Id.* at 259, 263, 265. IEH concluded that in the absence of a modular composite sample, in the case of a

positive testing modular composite sample, it is not possible to "to assay the retained individual enriched test lot samples [to] determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted." *Id.* at 259, 263, 266.

100. The response included a diagram (provided below), which was titled "IEH Modular Wet Compositing." Petitioner has corrected the diagram by retitling it as "Two-Stage Compositing," because that is what is depicted. Additionally, the diagram has been annotated by adding terms that correspond to each independent claim step.



Id. at 270 (annotated).

101. On January 5, 2009, a final Office Action issued in which the claims were rejected. The rejection of the claims as being anticipated by Davies was maintained. *Id.* at 288–90. Davies discloses evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*. The rejection of the claims as obvious based on Kuo, Budiman, Davies, and Skov was also maintained. *Id.* at 290–94. The Examiner did not rely on prior art submitted by IEH in an information disclosure statement on December 4, 2008 including Price (Ex. 1017; *see* § X-A-4, *infra*) or Silliker (Ex. 1025; *see* § X-D-1, *infra*). The information disclosure statement listing these two references was initialed by the Examiner on December 24, 2008. *Id.* at 279, 306.

D. More Interviews and Allowance

102. Interviews were held in early 2009. *Id.* at 307–27. An interview was held on January 29, 2009 between the Examiner, his supervisor, Jon Weber, Dr. Samadpour, and Dr. Davison as summarized in an interview summary dated February 17, 2009. *Id.* at 317–22. The summary indicates that the prior art of record was discussed but does not identify which references. *Id.* at 318. The summary states:

> the inventive step over the prior art of record is the enrichment of individual pooled sampling lots comprised of plurality of samples, subsequently pooling enriched samples together and then testing the pooled, enriched sample for the presence/absence of a pathogenic

> microorganism. In the event of a positive test for the presence of a pathogen, the invention allows to test each of the individual enrichments to identify the pooled lot that gave the positive test for the pathogenic microorganism.

Id. at 320.

103. The summary concludes that the Examiner and IEH's representative would work together to amend the claims. *Id.* IEH's summary does not mention discussion of any specific reference. *Id.* at 335–36.

104. The Examiner and Dr. Davison spoke on February 4 and 5, 2009 as summarized in an interview summary dated February 11, 2009. *Id.* at 312–16. The summary indicates no prior art was discussed. *Id.* at 313. The Examiner proposed amendments to the claims. *Id.* at 315–16.

105. Another interview summary dated February 17, 2009 indicated that no prior art was discussed, but the Examiner did propose amendments to the claims as shown below. *Id.* at 323–327.

Examiner's Suggested Amendment to Claim

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

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

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

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

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

Id. at 327.

106. On February 19, 2009, IEH filed a response and amendment. *Id.* at 328–51. The independent claims were amended as proposed by the Examiner. *Id.* at 329, 332–33. Another interview was held on March 4, 2009 and summarized. *Id.* at 358–363.

107. A notice of allowance was mailed on April 3, 2009. *Id.* at 354–357. The issue fee was paid on April 8, 2009. *Id.* at 385. The '584 Patent then issued on May 19, 2009. *Id.* at 391. On March 1 and 2, 2010, Dr. Davison contacted the Examiner regarding the filing of the reexamination request. *Id.* at 393.

VIII. REEXAMINATION OF THE '584 PATENT

A. Summary

108. The '584 Patent was the subject of an *inter partes* reexamination, Control No. 95/001,294, which was brought by bioMérieux, Inc. The Request was initially filed on January 13, 2010 and then refiled on April 5, 2010. In the reexamination, IEH pivoted from its position in prosecution that the prior art did not teach the steps of forming a modular composite sample and retesting during a validation process (Ex. 1006 at 259, 263, 266) because references relied on in the Request, such as Price (Ex. 1017), Jarvis (Ex. 1027), and Silliker (Ex. 1025), disclose methods with these steps.

109. The reexamination had a prosecution-phase at the Central Reexamination Unit ("CRU") in which all of the claims were concluded to be not patentable. This was followed by an appeal in which the Patent Trial and Appeal Board ("PTAB") concluded in a Decision dated January 20, 2015 ("First Board Decision") that the claims were not patentable. After filings by the parties, including an amendment from IEH narrowing claims 1 and 17 respectively to sampling, testing, and validating

lots of beef and lots of meat or poultry, the Examiner maintained the rejections. Then, in a Decision dated December 23, 2016 ("Second Board Decision"), the PTAB reversed the Examiner. The prior art in the reexamination emphasized wet pooling after enrichment with a non-selective enrichment (pre-enrichment) while the claims recite wet pooling after enrichment, meaning selective enrichment. Despite the PTAB's prior position that this was a minor distinction, it was amplified in the Second Board Decision. The PTAB also relied on IEH's declarations about commercial success and skepticism.

110. Based on my review of the reexamination documents (Ex. 1007), IEH failed to inform the Office about its related continuation applications (Exs. 1009–1011) during the reexamination.

B. References Considered in Reexamination

111. The Request included many references. The references disclosing steps (a)–(b) include Chapter 1 of BAM 2003 (Ex. 1022), FSIS Directive (Ex. 1023), and Midura (Ex. 1024). Those disclosing at least steps (c)–(d) of two-stage compositing, but with retention of pre-enriched samples instead of enriched samples, include Price (Ex. 1017), Silliker (Ex. 1025), Gabis (Ex. 1026), and Jarvis (Ex. 1027). These references are summarized below at § X-C and § X-D.

C. Prosecution-Phase of Reexamination

1. Request dated April 5, 2010

112. The Request challenged all the claims with nine substantial new questions of patentability ("SNQs") directed to the two independent claims. Ex. 1007 at 1–144.

2. Order and Office Action dated May 26, 2010

113. Reexamination was ordered in an Order signed by Examiners Brumback, Ponnaluri, and Jones at the CRU. Ex. 1007 at 145–178. In the Order, the SNQs for the independent claims were listed as shown below:

> **SNQ 1.** A substantial new question of patentability for claims 1 and 17 is raised by Jarvis in combination with FSIS and Midura (see the 04/05/10 Request at pages 28-34).
>
> **SNQ 2.** A substantial new question of patentability for claims 1 and 17 is raised by FSIS in combination with Price (see the 04/05/10 Request at pages 34-36).
>
> **SNQ 3.** A substantial new question of patentability for claims 1 and 17 is raised by Jarvis in combination with Patent owner's admissions regarding the prior art (see the 04/05/10 Request at pages 36-38).
>
> **SNQ 4.** A substantial new question of patentability for claims 1 and 17 is raised by Patent owner's admissions regarding the prior art in combination with Price (see the 04/05/10 Request at pages 38-39).
>
> **SNQ 5.** A substantial new question of patentability for claims 1 and 17 is raised by Andrews in combination with Price in view of Midura (see the 04/05/10 Request at pages 39-43).
>
> **SNQ 6.** A substantial new question of patentability for claims 1 and 17 is raised by Silliker in combination with Price in view of Midura (see the 04/05/10 Request at pages 43-46).
>
> **SNQ 7.** A substantial new question of patentability for claims 1 and 17 is raised by Gabis in combination with Price in view of Midura (see the 04/05/10 Request at pages 46-51).
>
> **SNQ 8.** A substantial new question of patentability for claims 1 and 17 is raised by Jarvis in combination with BAM (see the 04/05/10 Request at pages 51-52).
>
> **SNQ 9.** A substantial new question of patentability for claims 1 and 17 is raised by Price in combination with BAM and Davies (see the 04/05/10 Request at pages 52-53).

Ex. 1007 at 152–53 (Order at 5–6). SNQs were also listed for the dependent claims. *Id.* at 153–158 (Order at 6–11).

114. Because ICMSF 2002 (also known as ICMSF 7) is relied on in the Petition, I note that portions of ICMSF 1, which was published in 1978, were included with the reexamination request to challenge dependent claim 32. Ex. 1007 at 1341–97. ICMSF 1 was relied on for its teaching that "trimmings may be used when sampling raw meat" with a citation to "p. 135" (*id.* at 1378) but the citation is incorrect. *Id.* at 102–03, 127. The Office listed ICMSF 1 in SNQ 77 as the fifth reference in combination with Jarvis, FSIS Directive, Midura, and BAM. *Id.* at 154. The Office characterized ICMSF 1 as teaching "a method of sampling and testing food samples for *Salmonella* contamination wherein multiple analytical units are combined or lumped to provide larger units for testing purposes." *Id.* at 167. However, the Office declined to adopt the ground based on the combination because FSIS Directive teaches meat trim pieces and bioMérieux failed to identify a deficiency that would require modification by ICMSF 1. *Id.* at 226–27. The portions of ICMSF 1 that were included with the Request include the following sections: (1) "Indicator microorganisms" on pages 3–11; (2) "Important considerations for the analyst" on pages 90–102; (3) "PART II Recommended methods for microbiological examination" and "Introduction" on pages 103–105; (4) "Preparation and dilution of the food homogenate" on pages 106–111; (5) "Enumeration of mesophilic

aerobes: the agar plate methods" on pages 112–124; (6) "Coliform bacteria" at 125–139; (7) "Enterobacteriaceae" on pages 140–143; (8) "The enterococci" on pages 144–148; (9) "Hemolytic streptococci" on pages 149–156; (10) "The enumeration of yeasts and molds" on pages 157–159; (11) "Salmonellae" on pages 160–172; and (12) "Shigellae" on page 173. *Id.* at 1341–97.

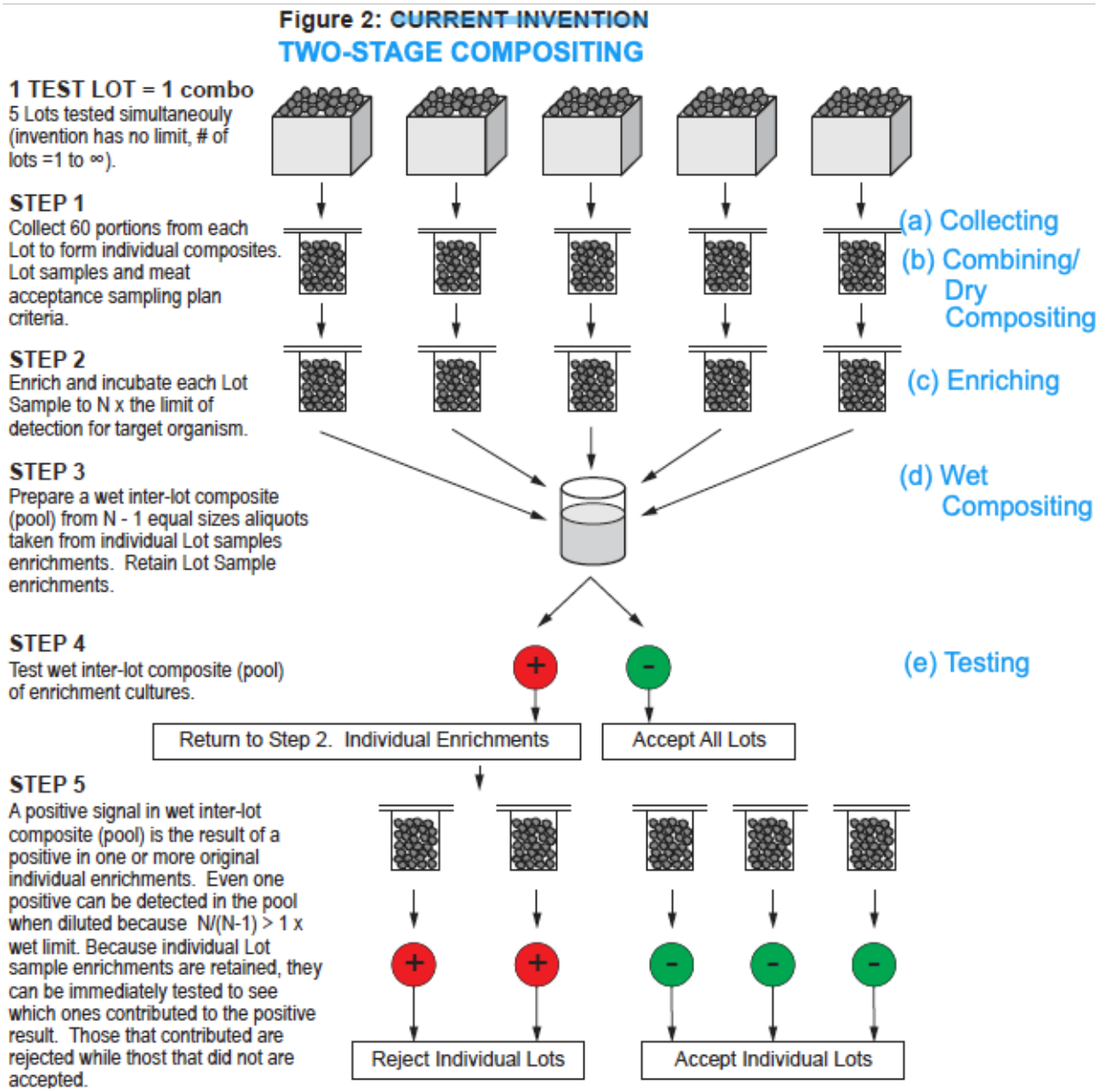
115. An Office Action also issued on May 26, 2010. *Id.* at 179–231 (Office Action at 1–49). All of the grounds raised in the Request were adopted except for SNQ #4 as shown in the table below. The CRU indicated that SNQ #4 could not be adopted because AAPA cannot be the basis of a ground in reexamination. *Id.* at 195 (Office Action at 16).

SNQ	Primary Reference	Secondary Reference(s)	Rejection Adopted	Rej. Not Adopted
1	Jarvis	FSIS Directive and Midura	✓	
2	FSIS Directive	Price and Midura	✓	
3	Jarvis	AAPA	✓	
4	AAPA	Price		✓
5	Andrews	Price and Midura	✓	
6	Silliker	Price and Midura	✓	
7	Gabis	Price and Midura	✓	
8	Jarvis	Chapter 1 of BAM 2003	✓	
9	Price	Chapter 1 of BAM and Davies	✓	

Id. at 185–209 (Office Action at 6–30).

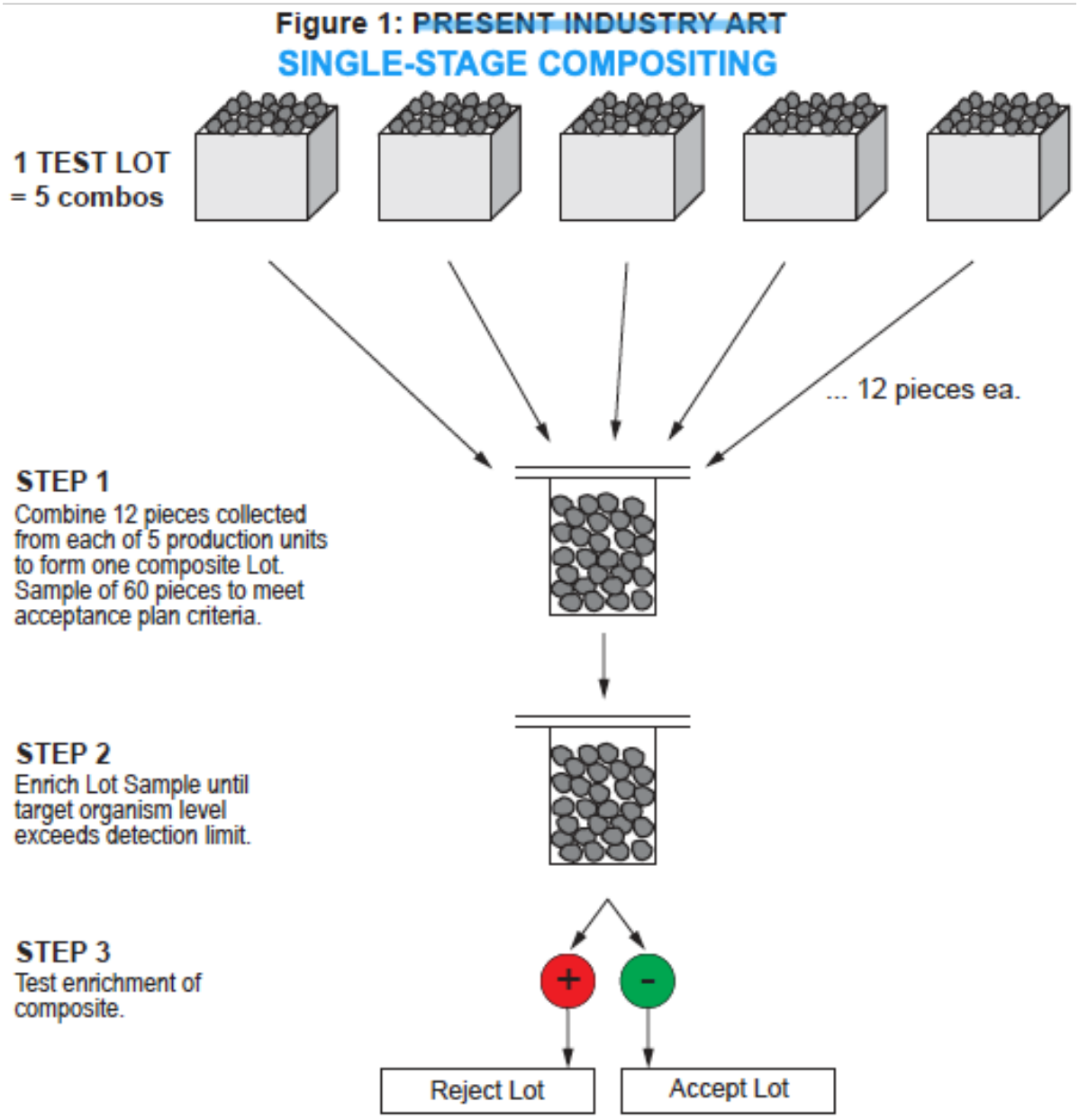
3. Response of July 26, 2010

116. IEH filed a Response on July 26, 2010. Ex. 1007 at 232–299 (Response at 1–68). IEH provided the diagram below to depict the independent claims:



Id. at 297 (annotated). The image has been reproduced for clarity and annotated by adding color, revising the title to "Two-Stage Compositing" and adding terms for the independent claim steps.

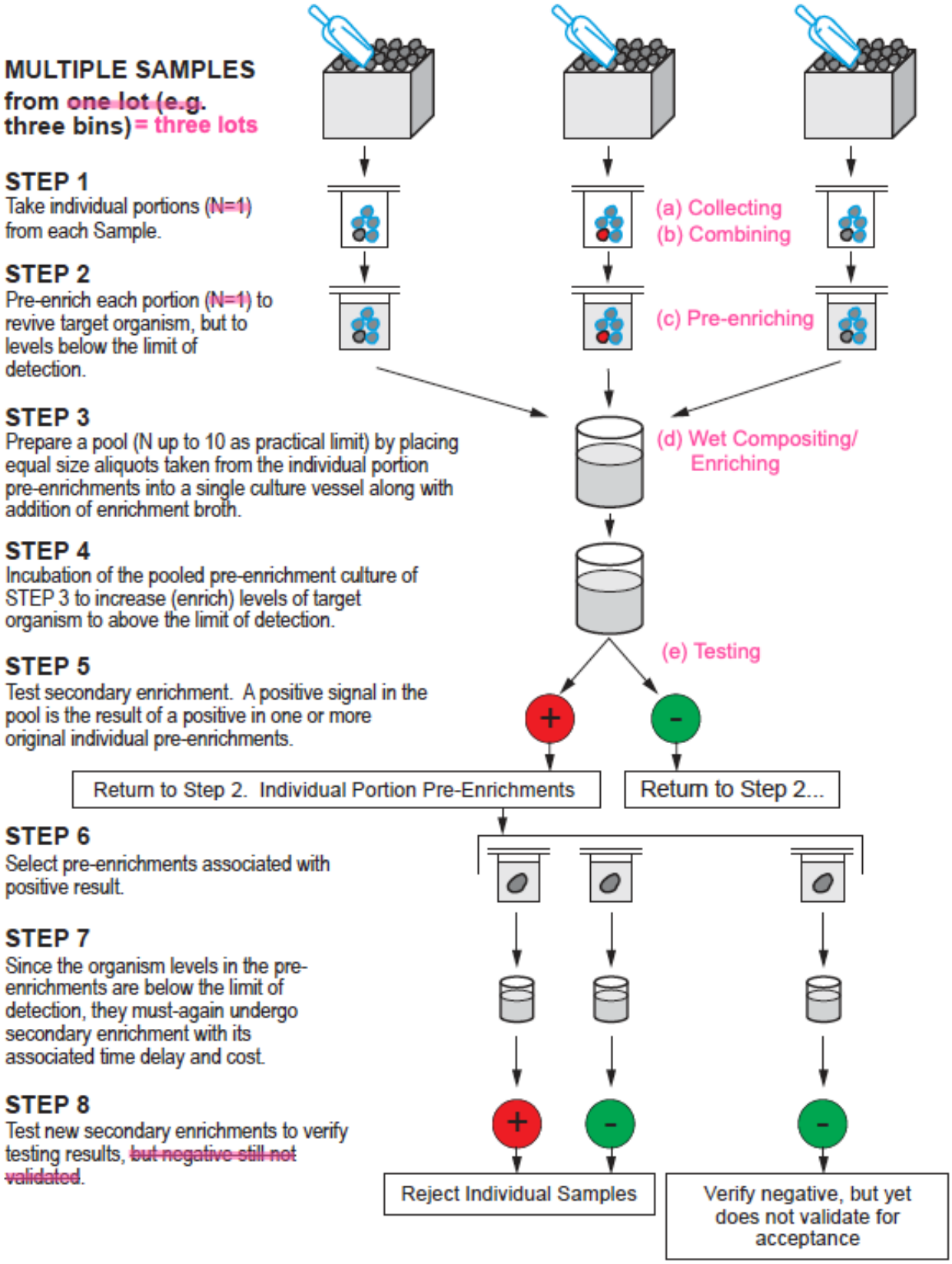
117. IEH also asserted that the diagram below depicts practices described in the Background section but incorrectly titled it as "PRESENT INDUSTRY ART":



Id. at 296 (annotated). The above diagram has been reproduced for clarity and annotated by adding color and revising the title to "Single Stage Compositing."

118. Additionally, IEH provided a diagram of Price, which is reproduced below for clarity and with corrections, annotations, and claim steps appearing in color.

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



Id. at 298 (annotated).

119. IEH correctly characterized Price, Silliker, Gabis, and Jarvis as teaching compositing after pre-enriching. *Id.* at 243–245, 256–263, 265–277 (Response at 12–14, 25–32, 34–46). IEH asserted that its use of "post-enrichment pooling" was an "important, fundamental distinction" over the prior art. *Id.* at 245 (Response at 14).

120. IEH amended the independent claims to recite adherence to a statistical sampling plan. *Id.* at 233, 236 (Response at 2, 5). However, such plans were already known, as admitted by IEH in its specification. *See* AAPA #1 and #6.

121. The Response was accompanied by a Declaration of Mansour Samadpour, Ph.D. (*id.* at 300–309 (First Samadpour Declaration at 1–10)) and a Declaration of Mohammad Koohmaraie, Ph.D. (*id.* at 310–353 (Koohmaraie Declaration at 1–44)). However, IEH's Response did not mention the First Samadpour Declaration (*id.* at 300–309) or the Koohmaraie Declaration (*id.* at 310–353). The First Samadpour Declaration is presented as a rebuttal (*id.* at 303 (First Samadpour Declaration at ¶¶ 8, 9)) to the Bailey Declaration (*id.* at 128–140), which accompanied the Request, and to make assertions about supposed widespread adoption of Samadpour's alleged invention and its related sales. Without specifying a time period, Dr. Koohmaraie, who was an employee of IEH and to my knowledge still is, asserted that IEH

provided laboratory testing for about 30% of the cattle processed in the United States. *Id.* at 313 (Koohmaraie Declaration at ¶ 14).

4. Comments of August 25, 2010 by bioMérieux

122. A document titled Third-Party Requester Comments was filed on August 25, 2010 by bioMérieux. Ex. 1007 at 357–408 (Comments at 1–49). Compelling rebuttals were made by bioMérieux regarding Price and IEH's assertions about step (c). First, bioMérieux correctly highlights that pre-enrichment satisfies the requirements of step (c), which merely requires the microbial agent or organism to reach detectable levels and become uniform. *Id.* at 358, 374 (Comments at 2, 18). Second, bioMérieux pointed to IEH's acknowledgement in the '584 Patent's Background section at 2:46–58 (discussed at V-C *supra*), which is referred to herein as AAPA #7, that it was known to enrich a composite sample for the presence of a given pathogen/microbe via enrichment media. *Id.* at 359 (Comments at 3). Third, bioMérieux emphasized IEH's acknowledgement in the Response (*id.* at 244 (Response at 13)) "that the respective use of pre-enrichment and enrichment media to resuscitate and grow cultures was known in the art." *Id.* at 362 (Comments at 6). It was correctly concluded by bioMérieux that a POSA was "well aware of direct enrichment techniques and would have been motivated to substitute them for pre-enrichment if the latter presented problems or diminished the efficiency of the testing." *Id.* at 358 (Comments at 2); *see also id.* at 375–77 (Comments at 19–21).

5. Action Closing Prosecution of December 17, 2010

123. In the Action Closing Prosecution ("ACP"), which was signed by Examiners Brumback, Ponnaluri, and Jones, it was concluded that the claims were not patentable based on the adopted grounds. Ex. 1007 at 409–76 (ACP at 1–65).

124. For step (a), the ACP states the specification "fails to set forth any demarcation of a 'lot' that renders the claim methods distinct." *Id.* at 421–22 (ACP at 12–13). Also, with respect to step (a), the ACP states that "FSIS discloses methods of sampling ground beef for *E. coli* O157:H7 contamination, comprising collecting a plurality of pieces or samples per lot and combining the pieces for a representative sample of a product lot." *Id.* at 427 (ACP at 18).

125. With respect to each step, Price was summarized as teaching:

> a method for testing multiple food samples for *Salmonella* comprising collecting a plurality of samples (or portions) from the food, inoculating the samples individually into pre-enrichment broth cultures, incubating the cultures to allow for growth of the *Salmonella*, pooling the pre-enrichment broth cultures into wet composite test lots, incubating the pooled test lots into a single enrichment broth (the "modular composite sample" of the patented claims), incubating the composite enrichment broth, and subsequently identifying any *Salmonella* organisms present in the culture.

Id. at 428 (ACP at 19). For steps (c) and (e), it was noted that "Price teaches that the procedure offers a simple, effective way to increase sample capacity in the *Salmonella* testing of foods and also permits the pre-enrichment broth cultures to be retained for subsequent individual analysis if a positive result is obtained from the pooled enrichment culture." *Id.*

126. It was concluded that Price teaches that the pre-enrichment medium facilitates recovery of the target agent from a debilitated condition, which "enable the organism to actively grow, *i.e.*, to increase in numbers." *Id.* at 420 (ACP at 11). It was further noted that a POSA "would have readily recognized that sensitive diagnostic methods, such as PCR, are capable of detecting the target agent in a sample medium at levels as low as a single organism." *Id.*

6. IEH's Comments after ACP of February 3, 2011

127. IEH filed Comments on February 3, 2011 (omitted from Exhibit 1007) and then a corrected version on May 5, 2011. Ex. 1007 at 477–624 (IEH's Comments after ACP at 1–147). The independent claims were amended to recite functions known in the prior art (*see* AAPA #1, #5 and #6) including sampling "to conform to a statistical-based sampling plan" and validating lots for "release into commerce." *Id.* at 478, 481 (IEH's Comments after ACP at 2, 5).

128. IEH incorrectly asserted that Price teaches collecting a plurality of samples from a single lot of food despite the fact that the bins shown in IEH's drawing of

Price may be considered to be three separate lots. *Id.* at 540 (IEH's Comments after ACP at 64). IEH also emphasized that Price teaches pooling of pre-enrichment test lot samples not enriched test lot samples. *Id.* at 526, 582–90 (IEH's Comments after ACP at 50, 106–14).

129. IEH's Comments were accompanied by four declarations including: a second declaration from Dr. Samadpour (*id.* at 625–46 (Second Samadpour Declaration at 1–22)) with numerous appendices (*id.* at 647–758), a third declaration from Dr. Samadpour (*id.* at 759–84 (Third Samadpour Declaration at 1–26)), a declaration of James Byron (*id.* at 793–800 (Byron Declaration at 1–8)), and a declaration of Warren Mirtsching (*id.* at 801–09 (Mirtsching Declaration at 1–9)).

130. The Second Samadpour Declaration is primarily focused on attacking the teachings of the references of record in the reexamination. *Id.* at 627–46 (Second Samadpour Declaration at ¶¶ 8–33). The appendices to the Second Samadpour Declaration include:

(A) Dr. Samadpour's curriculum vitae (*id.* at 647–51);

(B) a 2007 article by Jarvis titled "On the compositing of samples for qualitative microbiological testing" (*id.* at 652–59);

(C) Chapter 5.03 of the Microbiology Laboratory Guidebook titled "Detection, Isolation, and Identification of Escherichia coli O157:H7 and O157:NM (Nonmotile) from Meat Products" (*id.* at 660–74);

(D) a presentation by Dr. Stan Bailey (*id.* at 675–736);

(E) an IEH document titled "Independence of Combos, Single Combo vs. 5 Combo Lots" (*id.* at 737–47);

(F) Appendix D to the 1969 report "An Evaluation of the Salmonella Problem" from the National Research Council titled "'Wet Compositing' as an Approach to Control Procedures for the Detection of Salmonellae" (*id.* at 748–52);

(G) a brochure from Idaho Technology (*id.* at 753–56); and

(H) unsupported information about IEH's sales figures (*id.* at 757–58).

131. The Third Samadpour Declaration (*id.* at 759–84) indicates in its title that it is a rebuttal to the Declaration of Dr. Bailey.

132. IEH made assertions about skepticism and sales. *Id.* at 611–12 (IEH's Comments after ACP at 135–36). These assertions included citations to the Second Samadpour Declaration (*id.* at 627–46), Koohmaraie Declaration (*id.* at 310–53), the Byron Declaration (*id.* at 793–800), and the Mirtsching Declaration (*id.* at 801–09). For example, the Second Samadpour Declaration includes claims of copying by competitors (¶ 32), expert, regulatory, and customer skepticism (¶¶ 34–36), as well as increased sales (¶¶ 37–45).

133. In addition to the declarations from Dr. Samadpour, the founder and CEO of IEH and the sole inventor of the IEH Patents, all of the other declarations submitted by IEH during the reexamination came from employees of IEH.

7. Requester's Comments after ACP of March 2, 2011

134. A document titled Third-Party Requester Comments on the ACP was filed by bioMérieux on March 2, 2011. Ex. 1007 at 810–861 (Comments at 1–49). The Requester presented arguments regarding the teachings of Price. *Id.* at 834–39 (Comments at 25–30). The Requester also emphasized that with appropriate detection procedures, such as PCR detection, samples may be validated without further enrichment. *Id.* at 814, 828, 829 (Comments at 5, 19, 20). Additionally, the limitation of validation "for release into commerce" was described as not limiting (*id.* at 813 (Comments at 4)) and taught by Jarvis, FSIS, and Midura. *Id.* at 824, 841 (Comments at 15, 32). bioMérieux only challenged that the declarations were too late to be considered. *Id.* at 815–16 (Comments at 6–7).

8. Right of Appeal Notice of February 8, 2012

135. In the Right of Appeal Notice ("RAN"), which was signed by a second team of three examiners, Examiners Turner, Railey, and Stein, IEH's arguments regarding Price were rejected. *Id.* at 885–93 (RAN at 21–29). The RAN states that Price teaches:

> the positive inoculated samples were detected in pooled cultures as effectively as when analyzed individually (p. 680 columns 1-2 and Table 1) and at extremely low levels of inoculation. Moreover, Price teaches that, "problems with interfering organisms may warrant the use of direct

> selective enrichments, two selective enrichments, or possibly even a reduction in the incubation time of the pre-enrichment cultures.

Id. at 891 (RAN at 27).

136. It was concluded that the limitation, "validated for release into commerce" is taught by Jarvis and Midura. *Id.* at 872, 877, 889, 895 (RAN at 8, 13, 25, 31).

137. The RAN provided an extensive analysis of IEH's declarations, including the Second Samadpour Declaration, the Third Samadpour Declaration, the Byron Declaration, and the Mirtsching Declaration. *Id.* at 929–36 (RAN at 65–72). The RAN did not discuss the credibility of these declarations. *Id.*

138. The RAN noted that IEH's evidence of skepticism was "solely directed to testing for E. coli O157:H7, a special case scenario to which the claims are not limited." *Id.* at 933 (RAN at 69). Similarly, Dr. Samadpour's evidence of commercial success also related to "special case scenarios" that "are not the subject of the claims." *Id.* The RAN concluded Dr. Samadpour's evidence was "insufficient to overcome" the finding of obviousness. *Id.* Additionally, the RAN found that the Byron Declaration and the Mirtsching Declaration were not persuasive because the "prior art of record predict[ed] the utility of such testing" thereby "render[ing] the claimed invention obvious." *Id.* at 935–36 (RAN at 71–72).

D. Appeal-Phase of Reexamination

1. IEH's Appeal Brief of May 7, 2012

139. IEH, as appellant, filed its Notice of Appeal on March 5, 2012. Ex. 1007 at 939–40. IEH filed its Appeal Brief on May 7, 2012. *Id.* at 941–80. With its Appeal Brief, IEH filed an appendix of claims (*id.* at 981–87), an evidence appendix (*id.* at 988–91), and exhibits (*id.* at 993–1503). The Brief addresses each ground addressed in the RAN. Also, IEH addressed the analysis of skepticism and commercial success in the RAN. *Id.* at 979–80 (IEH's Brief at 39–40).

2. Requester's Respondent Brief of June 7, 2012

140. The Third-Party Requester, bioMérieux, filed a Respondent Brief on June 7, 2012. *Id.* at 1504–24. It was argued that IEH failed to address the combined teachings of the references and mischaracterized them. *Id.* at 1512 (bioMérieux's Brief at 6). Thus, even though the FSIS Directive and Midura were relied on for their teachings of testing multiple lots (*id.*), and Price was relied on for disclosing a template for two-stage compositing, IEH focused on their individual shortcomings. *Id.* bioMérieux countered IEH's assertion that Price does not teach testing of multiple lots. *Id.* at 1512–14 (bioMérieux's Brief at 6–8). For example, bioMérieux stated "Price exemplifies his method by analysis of powdered food products" and a "representative sample of such powdered materials includes numerous separate portions in the form of particles or aggregates of particles." *Id.* at 1513

(bioMérieux's Brief at 7). bioMérieux also argued that IEH's assertion regarding Price "renders meaningless Price's teaching that if composited culture tests positive, then the retained samples should be tested individually." *Id.* at 1512 (bioMérieux's Brief at 6 (citing Price at 681, Figure 1)).

141. With regard to IEH's declarations, bioMérieux countered that "[i]t is well within the Examiner's right to weigh declaration evidence and determine whether it is sufficient to overcome a rejection." *Id.* at 1521 (bioMérieux's Brief at 15).

3. Examiner's Answer of July 17, 2013

142. The Examiner's Answer issued on July 17, 2013 and is signed by the same second team of examiners at the CRU including Examiners Turner, Railey, and Jones. *Id.* at 1525–36. The Examiner's Answer did not offer any further analysis or discussion and instead relied upon the rejections and determinations of the RAN. *Id.* at 1533.

4. IEH's Rebuttal Brief of October 4, 2013

143. IEH filed its Rebuttal Brief on October 4, 2013 and addressed each ground. *Id.* at 1537–58. The Rebuttal Brief discusses IEH's incorrect claim that Jarvis and Price do not combine samples from separate lots of food within a single method. *Id.* at 1540–44 (IEH's Rebuttal Brief at 4–8). IEH's Rebuttal Brief also argues that forming a pool from aliquots of pre-enrichment cultures is not equivalent to pooling aliquots of enriched cultures. *Id.* at 1583. Arguments regarding IEH's declarations

were incorporated by reference from IEH's Appeal Brief. *Id.* at 1554 (IEH's Rebuttal Brief at 18).

5. First Board Decision of January 20, 2015

144. A hearing was held on December 17, 2014. *Id.* at 1590–634. A Decision on Appeal ("First Board Decision" or "DOA") issued on January 20, 2015. *Id.* at 1559–88.

145. The Board agreed with the Examiner and concluded the claims were obvious. *Id.* at 1561 (First Board Decision at 2). However, the Board established their decision on a new ground of rejection. *Id.* The new ground of rejection was based on Jarvis, Price, FSIS, and Midura. *Id.* at 1562 (First Board Decision at 3).

146. The First Board Decision lists Administrative Patent Judges Lebovitz, Delmendo, and Robertson. *Id.* at 1560 (First Board Decision at 1). This was the third team of three representatives at the Patent Office who analyzed the patentability of the claims and this was the fifth time that the Office had concluded that the claims of the '584 Patent were not patentable.

147. The Board relied on FSIS and Midura for step (a). *Id.* at 1572–74 (First Board Decision at 13–15). Additionally, the Board stated that "Price also describes collecting a plurality of samples. Price 680 (Fig. 1)." *Id.* at 1572 (First Board Decision at 13).

148. For steps (b) and (c), the Board stated that:

> it was an art-recognized goal to make food testing more efficient by reducing the number of samples test to be tested. *See* Jarvis; **Price**; Silliker 475 ("Compositing of multiple subsamples (lumping) and wet compositing of pre-enrichment cultures have been tested as economical approaches to *Salmonella* control."); Gabis 663 ("The economic advantage of lumping samples is obvious; indeed, this approach makes statistical quality control over the *Salmonella* defect economically feasible . . ."). This goal was accomplished by pooling (combining, compositing) samples. *Id.* The **purpose** of Jarvis and **Price** was to determine whether pooling samples reduced the ability to detect contaminated food lots. It would have been **commonsense** to combine samples from the **same bin** and subject them to enrichment, since **each bin represents a discrete unit of the production run** and results obtained from the enriched sample could be attributed to the bin from which the sample was obtained.

Id. at 1575 (First Board Decision at 16) (emphasis added).

149. With regard to step (c), the Board's analysis differed from the Examiner's analysis because the Board concluded that step (c) is an enrichment step and not a pre-enrichment step. *Id.* at 1569, 1571 (First Board Decision at 10, 12). The Board also concluded that "there is a suggestion in Price (at 682) . . . of direct enrichment." *Id.* at 1576 (First Board Decision at 17).

150. The Board quoted Dr. Samadpour from his declaration wherein he testified that prior to his invention, "no person of ordinary skill would have reasonably relied upon the results from a test that utilized enrichment-only, due to effects related to dilution of the target organism and competition from non-target organisms." *Id.* at 1575–76 (First Board Decision at 16–17 (quoting Samadpour 2010 Decl. ¶ 8)). The Board also referred to the Samadpour Declarations and concluded that after considering them regarding the prior art references and step (c), the Board did "not find them persuasive." *Id.*

151. For step (d), the Board stated that Price is "concerned with pooling samples to reduce workload and increase sample testing capacity." *Id.* at 1576 (First Board Decision at 17 (citing to Price at 679)). The Board concluded a POSA "would have had reason to composite samples for testing in order to reduce the number of tests necessary to perform." *Id.* at 1576–77 (First Board Decision at 17–18).

152. The Board also concluded that Price teaches step (e). *Id.* at 1578–79 (First Board Decision at 19–20). Additionally, the Board stated that validating the test lots "for release into commerce" is a "**mental step**" that does not limit the scope of the claim. *Id.* at 1578 (First Board Decision at 19) (emphasis added).

153. The Board summarized the secondary considerations and the declarations submitted by IEH. *Id.* at 1579–82 (First Board Decision at 20–23).

154. Finally, the Board concluded that the challenged claims were not patentable and that there was no correlation or connection, known as a nexus, between the scope of the claimed invention and the evidence of secondary considerations including commercial success and skepticism. *Id.* at 1582–85 (First Board Decision at 23–26).

6. IEH's Response of February 20, 2015

155. IEH filed a Response Requesting Reopening of Prosecution. *Id.* at 1635–59.

156. IEH's response narrowed the independent claims to their present form with claim 1 reciting "beef" and claim 17 reciting "meat or poultry." *Id.* at 1637, 1640 (Response at 3, 6). However, that should not have changed the analysis because references such as the FSIS Directive teach sampling beef lots. *See id.* at 1572–73 (First Board Decision at 13–14).

157. IEH presented information regarding secondary considerations. *Id.* at 1653–57 (Response at 19–23). IEH asserted that the narrowing of the claims addresses the concern in the First Board Decision "with respect to the scope of the foods covered and the sufficiency of the secondary factor data." *Id.* at 1656 (Response at 22).

158. IEH also submitted an additional declaration from Dr. Mansour Samadpour (Fourth Samadpour Declaration) regarding his interpretation of the related art and alleged initial skepticism. *Id.* at 1660–73.

7. Third-Party Requester Comments of March 20, 2015

159. bioMérieux pointed out that during the hearing, IEH acknowledged that "the definition of what constitutes the size of a lot is arbitrary." Ex. 1007 at 1676 (Comments at 3).

> (Hearing Transcript at 14) (in discussing what defines a lot, "You can define your lot as being one combo bin, if you want to stick with that example . . . You can define your lot as 500 combo bins.") (intervening comment by Judge Lebovitz omitted).

Id. (quoting *id.* at 1603 (Hearing Transcript at 14)).

160. The Board's analysis that it would have been obvious to collect samples from a plurality of separate test lots in light of the teachings of FSIS and Midura, was reviewed by bioMérieux and it was noted that IEH "fails to discuss the FSIS and Midura references." *Id.* at 1681 (Comments at 8). Requester agreed with the analysis in the First Board Decision regarding step (b). *Id.* at 1683–84 (Comments at 10–11). Requester argued that steps (c) and (d) were satisfied by pre-enriching as taught by Price. *Id.* at 1684–90 (Comments at 11–17). Requester also agreed with the analysis in the First Board Decision regarding step (e). *Id.* at 1691–92 (Comments at 18–19).

161. Furthermore, Requester agreed with the First Board Decision in that IEH failed to identify a nexus between the claimed method and commercial success and

skepticism. *Id.* at 1693–96 (Comments at 20–23). Requester also pointed out that IEH "overlook[ed]" the teachings of the prior art. *Id.* at 1693 (Comments at 20).

162. Requester explained that limiting the independent claims to types of meat "does not serve to link the alleged success of the method to a particular step that is not found in the prior art." *Id.* at 1676 (Comments at 3). Requester highlighted the lack of evidence to support IEH's claims of commercial success by stating that the only support "is a conclusory paragraph in the Samadpour declaration that cites to no evidence to support its claims" and that "[s]uch evidence should be accorded little or no weight." *Id.* at 1677 (Comments at 4).

163. Requester asserted that IEH's "claimed method is simply an aggregate of steps that were known in the prior art" and that IEH "cannot show that any commercial success was due to a particular feature of the claimed method that was not independently known in the art." *Id.* at 1694 (Comments at 21). Thus, bioMérieux, concluded "a nexus between the claimed method and any alleged secondary considerations has still not been established." *Id.* at 1696 (Comments at 23).

8. Examiner Answer of July 20, 2015

164. On June 5, 2015, the Board remanded the case to the examiner in light of IEH's request to reopen prosecution. *Id.* at 1698–702.

165. On July 20, 2015, an Examiner Answer issued. *Id.* at 1703–22. It was concluded that the claims were obvious. *Id.* at 1705.

166. The Examiner Answer was signed by a team of examiners including Examiner Turner, Ponnaluri, and Witz. *Id.* at 1722. Only Examiner Turner was in the second team of examiners that signed the last document from the CRU (the Examiner's Answer issued on July 17, 2013 (*id.* at 1525–36)), so the Examiner Answer of July 20, 2015 represents a third team of examiners at the CRU (a total of eight examiners) to have analyzed the record and conclude that the claims are not patentable.

167. For step (a), the Examiner Answer relied on FSIS and Midura and cited for support an admission by Dr. Samadpour (Ex. 1007 at 1709 (*id.* at 1662 citing Fourth Samadpour Declaration at ¶ 8). In the Fourth Samadpour Declaration, he states that the cited art "pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots . . ." *Id.*

168. Regarding step (b), the Examiner Answer agreed with the Board that Jarvis and Price teach pooling thereby motivating the artisan to combine samples from different bins representative of the lot. *Id.* at 1711 (Examiner Answer at 8). The Examiner Answer concluded that when combined with FSIS and Midura it would be obvious to combine collected portions for testing multiple different lots. *Id.*

169. With regard to step (c), the Examiner Answer concluded that Price motivates a POSA to enrich a set of separate test lot samples. *Id.* at 1712–14 (Examiner Answer at 9–11).

170. The Examiner Answer concluded that the teachings of Price render obvious the limitations of step (d) because the POSA "would have a reasonable expectation that pooling at two different steps would have the requisite sensitivity" for effective detection. *Id.* at 1714–15 (Examiner Answer at 11–12).

171. The Examiner Answer concluded that step (e) is obvious based on the combination. *Id.* at 1717–18 (Examiner Answer at 14–15). The Examiner also noted that Price teaches "dual-tier compositing steps for the benefit of reducing testing as well as enabling retesting positive samples to determine the origin of contamination" and that "such teachings are applicable to the testing of multiple lots as is particularly reflected in FSIS and Midura." *Id.* at 1718 (Examiner Answer at 15).

172. The Examiner Answer concluded that "there is insufficient nexus between any claim element, as all elements were already known in the art." *Id.* at 1719 (Examiner Answer at 16). The Examiner Answer also concluded that IEHS's arguments and the Fourth Samadpour Declaration "are not sufficient to overcome the rejection set forth in the [First Board] Decision [of 1/20/15]" because "[t]he art suitably motivates to testing multiple lots in a two-tier composite procedure." *Id.*

9. IEH's Response of August 20, 2015

173. IEH filed a Response on August 20, 2015. Ex. 1007 at 1723–54. IEH did not further amend the claims.

174. IEH attacked the Examiner Answer regarding the combined teachings of Jarvis, Price, FSIS, and Midura for the independent claims. *Id.* at 1732–45 (Response at 10–23). IEH addressed supposed secondary considerations. *Id.* at 1745–52 (Response at 23–30). In support of its position, IEH reviewed the declarations of Dr. Samadpour and the other IEH employees. *Id.*

10. Requester's Comments of September 21, 2015

175. A document titled Third-Party Requester Comments was filed by bioMérieux on September 21, 2015 to address IEH's Response. *Id.* at 1755–72. Requester explained the amendments fail to capture patentable subject matter. First, bioMérieux argued the language added by IEH to narrow the term "lots" was already within the definition provided by IEH in the specification. *Id.* at 1756–58. Second, bioMérieux argued the limitations of "beef" and "meat or poultry" in claims 1 and 17 did not recite something that was not already in the prior art. *Id.* at 1758–61.

176. Regarding step (b), bioMérieux pointed out that IEH "agrees that mere compositing (combining multiple samples taken from a single test lot to form a test lot sample) was known in the art." *Id.* at 1762–63 (Comments at 8–9 (quoting *id.* at 1735 (Response at 13))).

177. With respect to step (c), bioMérieux addressed IEH's assertion that "the prior art only teaches combining portions of pre-enrichment samples, and not enriched samples" with two important points. First, bioMérieux asserted that:

> Price also teaches that in cases in which background organisms are interfering in a pre-enrichment broth, then an **enrichment medium may be used**. (Price at 682). In other words, the **pre-enrichment** medium may be **replaced** at the **first stage** with **enrichment** medium. In this case, the enrichment cultures would have been combined. Accordingly, the Patent Owner's contention that the prior art does not suggest combining enriched samples is erroneous.

Id. at 1764 (emphasis added). Second, bioMérieux noted that:

> The Patent Owner also overlooks that the claims do not require the samples to be composited in enrichment broth. Rather, as found by both the Examiner and the PTAB, the cultures can be composited first in pre-enrichment culture, and subsequently transferred to enrichment culture. The samples from the enrichment culture can then be combined. Indeed, as the PTAB found, "[i]t would have been commonsense to combine samples from the same bin and subject them to enrichment . . ." (DOA at 16). Importantly, the Patent Owner has not set forth any evidence or argument to show why the claims preclude such a pre-enrichment step followed by transfer to enrichment culture.

Id. at 1765.

178. With respect to step (d), bioMérieux maintained the position that Price teaches a method of two-tiered compositing. *Id.* at 1766. Requester also maintained that even if Price is "directed to testing a single test lot as Patent Owner contends, it would have been obvious to have used the technique described by Jarvis and Price to test samples from multiple test lots created as described by references such as FSIS and Midura." *Id.*

179. For step (e), bioMérieux pointed out that IEH overlooked Price's teaching that direct enrichment may be used (Ex. 1017 at 682) and that the claims do not preclude pre-enrichment followed by enrichment prior to formation of the modular composite sample. Ex. 1007 at 1769–70.

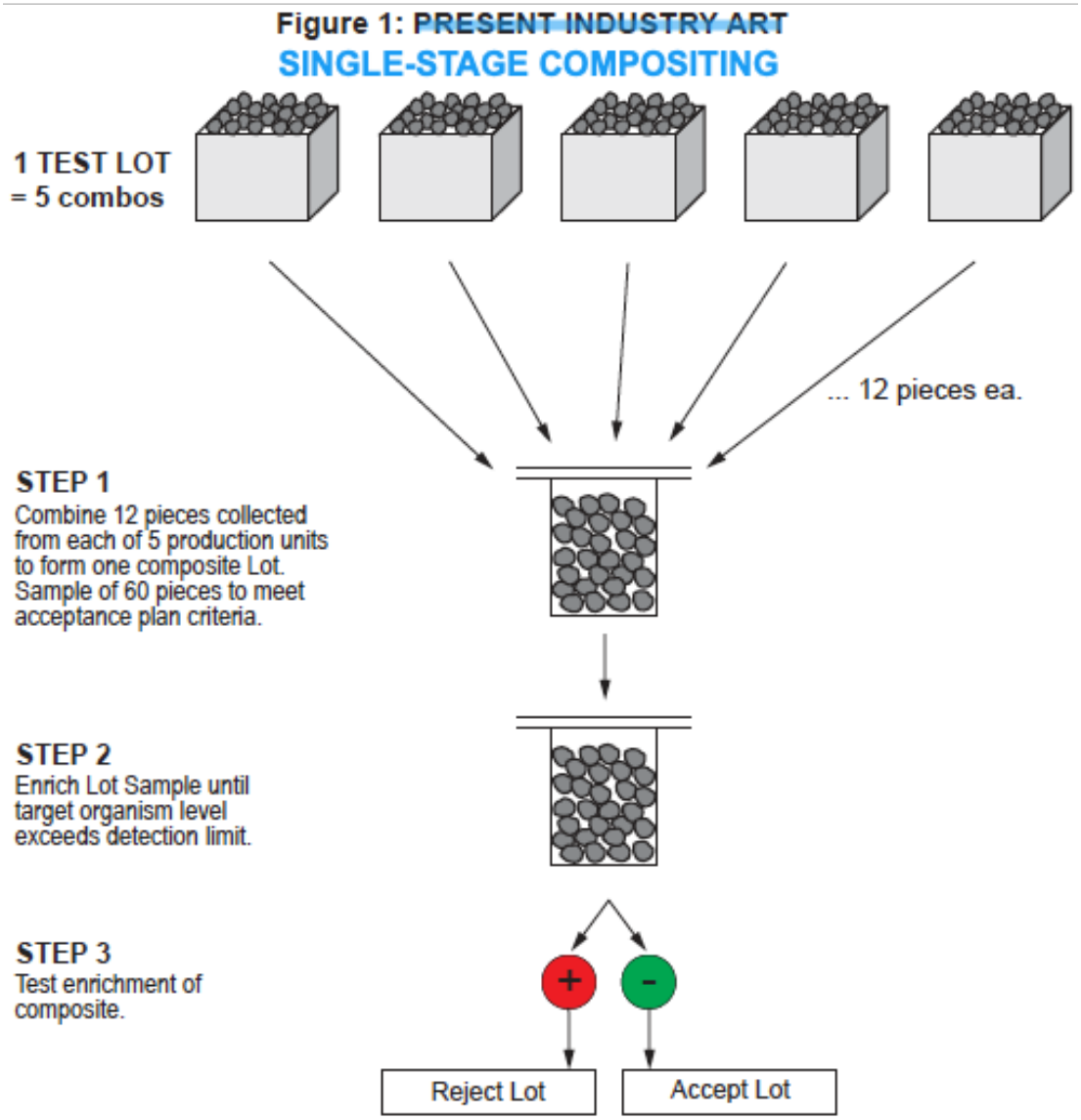
180. With respect to secondary considerations, bioMérieux concluded that a nexus with the claimed method had still not been established by the Fourth Samadpour Declaration. *Id.* at 1770–71.

11. Second Board Decision of December 22, 2016

181. The Board issued a Decision on Appeal on December 22, 2016 ("the Second Board Decision"). *Id.* at 1773–90. The Second Board Decision reversed the Examiner's Answer of July 20, 2015 and modified the First Board Decision from the same administrative patent judges. *Id.* at 1774–75 (Second Board Decision at 1–2).

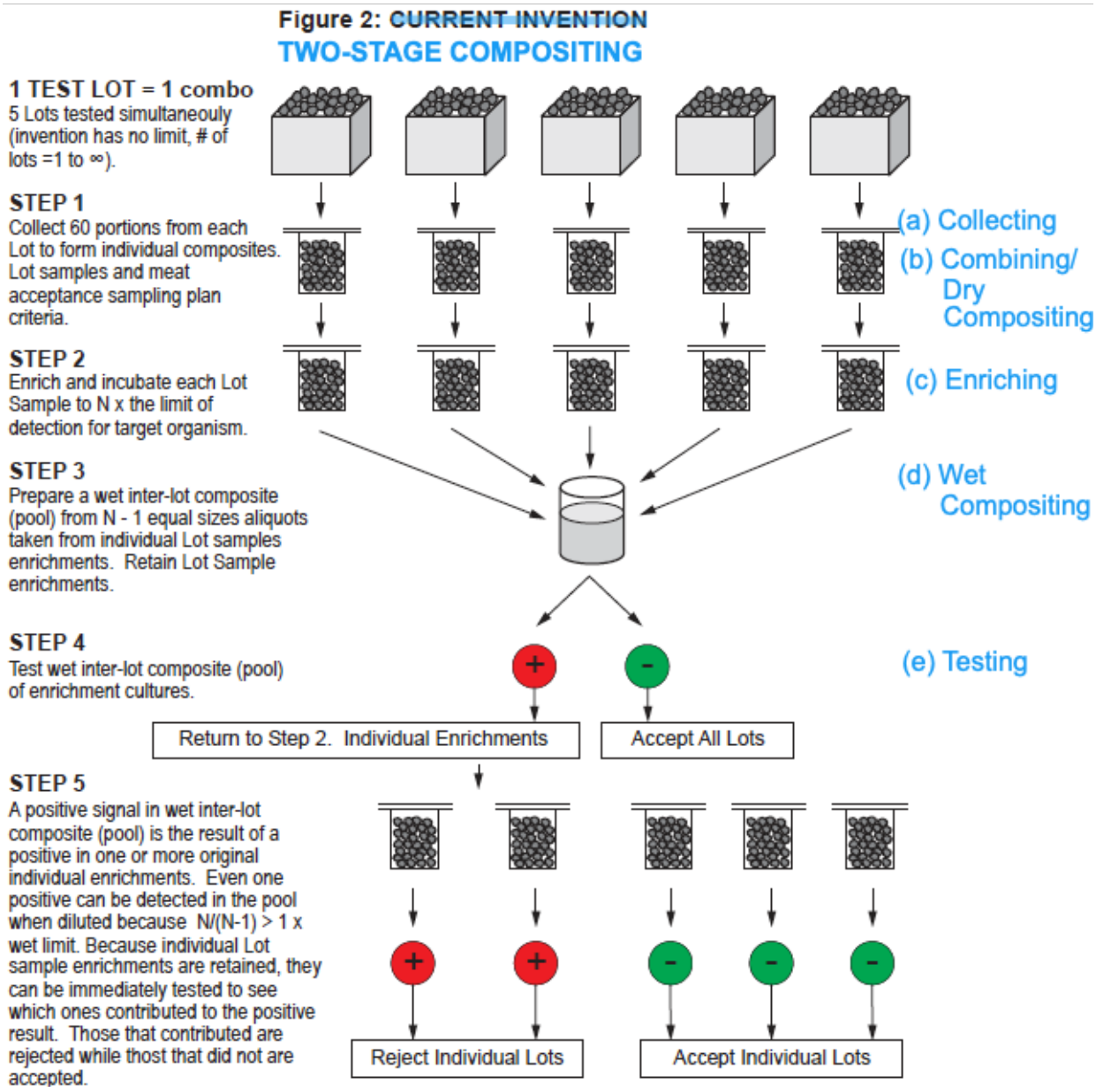
182. The Second Board Decision never addresses the technical merits of the independent claims and the related ground in the First Board Decision, which was based on Jarvis, Price, FSIS, and Midura. The Second Board Decision does not even mention FSIS and Midura. The Second Board Decision instead contradicts findings in the First Board Decision and all of the prior conclusions of the CRU.

183. The Board accepted IEH's incorrect assertion that Figure 1, recreated by Petitioner and reproduced below, depicts the "present industry art" or "classical method" for the meat industry:



Id. at 290 (annotated).

184. Because IEH narrowed claims 1 and 17 to "beef" and "meat or poultry," the Board accepted IEH's premise "that the comparison for the purposes of the stated commercial success and skepticism is between this classical method [in Figure 1] and the claimed method as illustrated in Figure 2," which has been recreated by Petitioner and reproduced below. *Id.* at 1779; *see supra* § VIII-C-3.

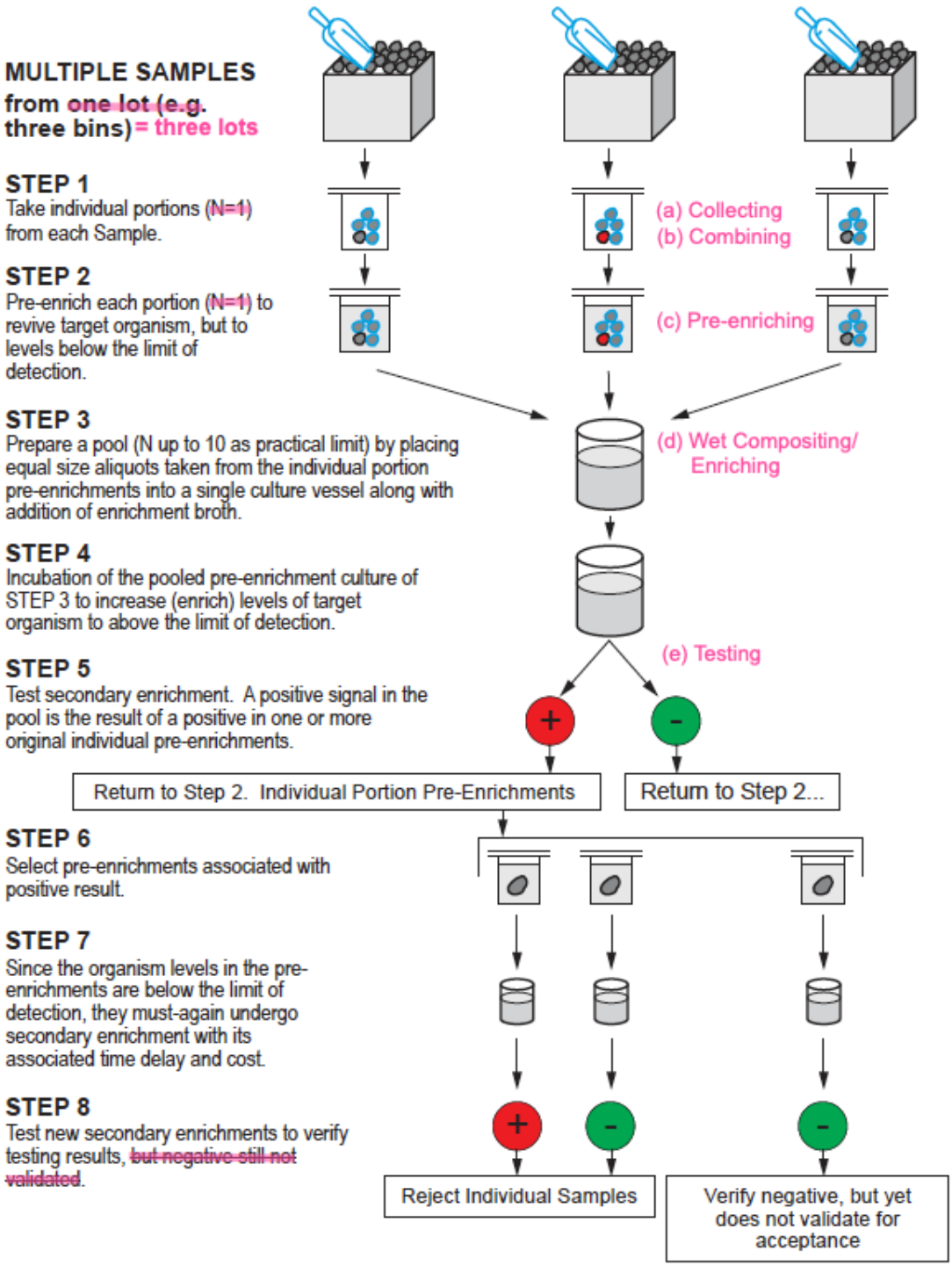


Id. at 291 (annotated).

185. Figure 1 depicts single-stage compositing, which was not the sole industry standard in 2004. Rather, methods based on Price and its progeny, were widely used. Price discloses two-stage compositing not just single stage compositing, as is readily

appreciated by Patent Owner's diagram, Figure 3, recreated by Petitioner and reproduced below.

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



Id. at 298 (annotated).

186. The Board stated that Figure 1 "is representative of the cited prior art." *Id.* at 1787 (Second Board Decision at 14). However, the image of Figure 1 is not representative of Price as shown in Figure 3.

187. The Board compared Figure 1 with Figure 2 and stated that a "key difference between the two methods is that the portions (samples) from *all* combo bins are combined into one container for culture in the Present Industry Art (Fig. 1), whereas in the claimed invention (Fig. 2), the portions from each combo bin are separately cultured." *Id.* at 1780 (Second Board Decision at 7). However, as shown in Price, the prior art teaches the portions from each lot are separately pre-enriched (i.e., separately cultured). Ex. 1017 at 680 (Figure 1).

188. The Board further concluded that:

> the sample combining step is done *before* culture in the Present Industry Art, and *after* culture in the claimed method. These are the same differences between the claimed invention and the cited prior art.

Ex. 1007 at 1780 (emphasis in original). This oversimplification inaccurately describes both the prior art, namely Price, as well as the claimed invention.

189. The Board stated that Price teaches "statistically reliable results . . . are obtained when samples are pooled together prior to the pre-enrichment and enrichment culture steps." *Id.* at 1780 (Second Board Decision at 7). However,

Price teaches the opposite because pooling occurs after pre-enrichment. Ex. 1017 at 680 (Figure 1).

190. The Board stated that another "key difference is that, in the Present Industry Art, a cultured sample from the single same container, containing portions from all the combo bins, is directly tested for the presence of microorganisms, while in the claimed invention, cultured samples from the different culture containers are combined into a 'modular composite sample' . . . and then tested for the presence of microorganisms." Ex. 1007 at 1780 (Second Board Decision at 7). This is not an accurate description of the state of the art before the priority date of the IEH Patents.

191. The Board reviewed the declarations submitted in support of IEH's assertions regarding secondary considerations without any assessment of the weight to be given to the unsupported assertions. *Id.* at 1781–89 (Second Board Decision at 8–16). The Board merely concluded, regarding Dr. Samadpour's assertions that "[w]e have been given no reason to doubt the Declarant's credibility." *Id.* at 1788 (Second Board Decision at 15). On that basis, the Board concluded that "the claimed modular composite testing is responsible for the commercial success." *Id.* at 1789 (Second Board Decision at 16). IEH's assertions about skepticism were also accepted. *Id.*

12. Request for Rehearing of January 23, 2017

192. A Request for Rehearing was filed by bioMérieux on January 23, 2017 (*id.* at 1791–806), accompanied by declarations from Nuno Reis (*id.* at 1807–10) and Dr.

Stan Bailey (*id.* at 1811–17). These late-filed declarations attempted to counter IEH's declarations.

193. Dr. Bailey's explanation, which was quoted by bioMérieux in its Request, states that "the industry at large experienced increased sales during the timeframe in question because *E. coli* outbreaks increased safety concerns and drew a greater regulatory focus on testing." *Id.* at 1805 (quoting *id.* at 1815 (¶¶ 9a–10d)) (Rehearing Request at 14). This position was reflected by Mr. Reis's data showing bioMérieux's "revenue from a product capable of testing for *E. coli* contamination of beef has increased sales year-over-year from 2009–2016 an average of 23% each year." *Id.* at 1808–10 (¶ 7b). Mr. Reis also showed that IEH engaged in business practices such that the patented methods were cheaper overall than those from others. *Id.* at 1809 (¶ 6b).

194. In the Request for Rehearing, bioMérieux primarily addressed the Board's "factual about-face" conclusion that a nexus existed. *Id.* at 1798 (Rehearing Request at 7). However, with respect to the technical merits, bioMérieux noted that the Board puzzlingly stated that steps (b), (c), and (e)(1) "were not described in the cited publications and cannot be said to have been readily available to one of ordinary skill in the art at the time of the invention." *Id.* (quoting *id.* at 1769 (Second Board Decision at 15)). Yet, in the First Decision, the Board analyzed the references in the ground that the Board used to replace the grounds of bioMérieux, and specifically

identified the teachings of the references with respect to each step. *Id.* at 1799–800 (Rehearing Request at 8, 9). For example, Requester pointed to the First Decision, in which the Board found, "one of ordinary [skill] in the art would have had reason to composite samples for testing in order to reduce the number of tests necessary to perform" and that the Board previously reasoned that "compositing within an individual lot was 'commonsense.'" *Id.* at 1793 (Rehearing Request at 2 (citing First Board Decision at 16)).

195. The Board's reversal is inexplicable because the Board failed to provide any analysis of the references to contradict its prior detailed analysis of "the ways in which improvements allegedly invented by the Patent Owner had already been disclosed in the prior art." *Id.* at 1798 (Rehearing Request at 7). Nor did the Second Board Decision discuss any evidence from bioMérieux, such as Dr. Bailey's declaration, which "thoroughly undermines the Patent Owner's evidence" as simply "self-serving declarations of the patent inventor and his employees." *Id.*

13. Opposition to Rehearing Request of Feb. 23, 2017

196. IEH filed Comments in Opposition to the Request for Rehearing on February 23, 2017. *Id.* at 1818–33.

197. IEH acknowledged in the Opposition that the Second Board Decision "gave more weight to the secondary factor evidence in view of the amended claim scope." *Id.* at 1822. For that reason, the Opposition does not mention any reference or

address the technical merits of the grounds in the First Board Decision, it just focuses on secondary considerations.

198. IEH's Opposition focused on legal arguments to block consideration of the late-filed bioMérieux declarations. *Id.* at 1825–29 (Opposition at 7–11). Additionally, the bioMérieux declarations are attacked. *Id.* at 1829–33 (Opposition at 11–15).

14. Decision Denying Rehearing of April 18, 2018

199. On April 18, 2018, the Board issued a Decision Denying Rehearing. *Id.* at 1854–72. The Board declined to modify the Second Board Decision. *Id.* at 1856. The Board concluded it could not consider bioMérieux's late-filed declarations. *Id.* at 1855–56 n.1.

200. The Board explained that, in its First Board Decision, it overlooked IEH's exhibits labeled as Figures 1 and 2 that supposedly "illustrated the differences between the claimed method and the industry method." *Id.* at 1857 (Decision at 3). The Board further explained that these diagrams "provided additional clarity as to the differences between the prior art and the claimed subject matter" and relied on the diagrams "to conclude that a 'nexus' had been established between the claims and the secondary considerations." *Id.*

201. The Board elaborated that, in addition to limiting claims 1 and 17 respectively to beef and to meat or poultry, the outcome differed because "the difference between

the claimed invention and the prior art, as practiced in the industry method, is that the claimed method composites enriched samples and then tests them." *Id.* at 1861 (Decision at 7). The Board added that such steps, particularly steps (d) and (e), "were not readily available in the prior art and appropriately constituted a 'nexus' between the sales data and the claims." *Id.* at 1862 (Decision at 8). Of course, Price teaches steps (d) and (e) but with composited pre-enrichment samples, not selectively enriched samples. *Id.* at 1864 (Decision at 10).

15. NIRC of January 24, 2019

202. The Patent Office issued a Notice of Intent to Issue *Inter Partes* Reexamination Certificate ("NIRC") on January 24, 2019. *Id.* at 1873–1875.

16. Reexamination Certificate

203. Below are claims 1 and 17 as listed in the Reexamination Certificate.

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

a) collecting a plurality of portions from each of a plurality of *separate operationally-linked* test lots *of beef, each to be validated for release into commerce*, the test lots each comprising an assemblage of one or more specimens *from which the portions are collected*, wherein each test lot is separately sampled [by taking said plurality of portions thereof] *to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to he taken sufficient to provide for validation and release of the test lot into commerce*;

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

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

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

e) testing of the *modular* composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test [lot samples] *lots* are validated *for release into commerce*, and wherein when such testing is positive, *each of the* individual separate test lots are validated *for release into commerce, according to the statistical-based sampling plan,* by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining *a negative* test result for each test lot, *wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate test lots with no requirement for further enrichment thereof, and with no requirement for further sampling in a).*

17. A method of sampling, testing and validating *a plurality of operationally-linked* test lots *of meat or poultry* for [microbial contamination] *release into commerce*, comprising:

a) collecting a plurality of portions from each of a plurality of *operationally-linked* single-unit production lots *of meat or poultry*, the single-unit production lots each comprising an assemblage of one or more production specimens *from which the portions are collected*, wherein each single-unit production lot is separately sampled [by taking said plurality of portions thereof] *to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the single-unit production lot into commerce*;

b) combining the collected *conforming* plurality of product portions corresponding to each of the separate single-unit production lots to provide a corresponding set of separate single-unit production lot samples, wherein each separate single-unit production lot sample is attributed to a particular corresponding separate single-unit production lot;

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

d) removing portions of each enriched separate single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the *modular* composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate single-unit production lot samples are validated *for release into commerce*, and wherein when such testing is positive, individual separate single-unit production lots are validated *for release into commerce, according to the statistical-based sampling plan,* by further testing of a portion of the respective enriched separate single-unit production lot sample using the same or a more sensitive protocol and obtaining *a negative* test result for each single-unit production lot, *wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate single-unit production lots with no requirement for further enrichment thereof, and with no requirement for further sampling in a).*

Id. at 1877; *see also* Ex. 1001 at 12.

IX. PROSECUTION HISTORY OF CONTINUATION PATENTS

A. Prosecution History of ’233 Patent

204. U.S. Patent No. 8,389,233 (“the ’233 Patent”) issued from Application No. 12/360,796, which was filed on January 27, 2009. As summarized below, Price was the most relevant reference discussed during the examination, but it was nevertheless mischaracterized.

205. The claims of the ’233 Patent differ from those of the ’584 Patent and the Continuation Patents by requiring in step (e) initially testing both the composite sample and the enriched lot samples, and after a positive test for any of those, retesting any initially negative enriched lot samples. Ex. 1008, 15:28–40, 17:9–23. The ’233 Patent includes two independent claims that respectively recite test lots and single-unit production lots. During prosecution of the application, these claims resulted in Examiner Srivastava asking IEH on August 29, 2011 to restrict the claims to a single species by choosing between test lots and single-unit production lots. Ex. 1009 at 164–65. On February 28, 2012, IEH filed a response, and the relevant section is shown below. *Id.* at 147–56.

Group Election

The Examiner, by way of restrictions, is requesting an initial election of one Group of claims from among Groups I-II:

Group I (claims 1-19, 21, and 23-34), drawn to a method to sample, test and validate test lots of microbial contamination comprising sampling a plurality of test lots, classified under Class 435, Subclass 30.

Group II (claims 20 and 22), drawn to a method to sample, test and validate test lots for microbial contamination comprising sampling a plurality of single-unit production lots, classified in class 435, subclass 34.

Applicant herein elects **Group I**, with traverse.

The basis of the *traversal* is that a single-unit production lot is a species of test lots and both claim 1 and claim 20 recite (in step "a") "collecting a plurality of portions from each of a plurality of test lots" and, thus, are clearly properly placed in one restriction group. Applicant respectfully contends that claims 20 and 22 should be included in Group I.

Id. at 155 (highlighting added). IEH argued the restriction was unnecessary and should be withdrawn, as provided by the text shown above, because "a single-unit production lot is a species of test lots." *Id.* IEH concluded that the claims should thus be considered in a single group and examined together. *Id.*

206. Additionally, Examiner Srivastava asked IEH to elect a species to be the focus of the examination "from the group consisting of a single combo, single bin, single pallet, or a production assemblage." *Id.* at 167. IEH elected (i.e., requested examination for) "single-unit product[ion] lot" and "single combo" but did so without accepting the examiner's position (which I have been informed is referred to as "electing with traverse"), as shown by the text below. *Id.* at 155.

Additional Species Election

The Examiner is requiring a species election.

A. Only one test lot of samples among: environmental lot, or pharmaceutical lot, or single-unit product lot as detailed in Claim 2; and

B. Only one lot selected from the group consisting of a single combo, single bin, single pallet, or a production assemblage as detailed in Claim 13.

Applicant herein elects "**single-unit product lot**" and "**single combo**", with traverse.

The basis of the traversal is that it would not require undue burden by the Office to search all the species.

Id. (highlighting added). In an Office Action issued on July 5, 2012, Examiner Srivastava withdrew the election requirements because IEH argued "the species are obvious variants." *Id.* at 91.

207. In the Office Action of July 5, 2012, the claims were rejected based on double patenting with respect to the '584 Patent because the claims of the '584 Patent and the claims of Application No. 12/360,796 were not considered patentably distinct from each other. *Id.* at 92–93.

208. On April 16, 2012, IEH filed an information disclosure statement to submit references of record in the reexamination such as Price. *Id.* at 113–15. On October 4, 2012, IEH filed an information disclosure statement to re-submit references of record in the reexamination that were not properly listed in the information disclosure statement filed on April 16, 2012. *Id.* at 80–83. On January 3, 2013, IEH filed another information disclosure statement to create a record of notification to the Office in Application No. 12/360,796 of Reexamination Control No. 95/001,294. *Id.* at 77–78. The relevant portion of the transmittal letter is shown below:

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicant wishes to make known to the Patent and Trademark Office the reference set forth on the submitted form PTO/SB/08. This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior Application No. 11/199,871, filed August 8, 2005, which claims benefit of Provisional Application No. 60/599,473, filed August 6, 2004.

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing one (1) reference to be considered by the Examiner. While Applicant's prior information disclosure statements in this case have already disclosed all alleged prior art submitted in inter partes reexamination number 95/001,294, corresponding to Applicant's issued underlying parent patent, the inter partes reexamination number 95/001,294 is included in the present information disclosure statement for completeness.

Id. at 77 (highlighting added).

209. Below is the form listing Reexamination Control No. 95/001,294.

PTO/SB/08A (07-06)
Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	12/360,796
Filing Date	January 27, 2009
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-008US1

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 95/001,294	04-05-2010	US- 7534584 B2	

Id. at 59 (highlighting added). However, no documents from the reexamination of the '584 Patent, including those from the Patent Office (e.g., Office Actions, Decisions, Orders, etc.), bioMérieux (e.g., Requests, Comments, etc.), or IEH (e.g., Responses, etc.), were submitted in Application No. 12/360,796. Nor is there any

evidence that Examiner Srivastava considered any reexamination documents from the Patent Office, bioMérieux, or IEH.

210. Also on January 3, 2013, IEH filed a response and a terminal disclaimer regarding the '584 Patent to overcome the double patenting rejection. *Id.* at 66–76.

211. A notice of allowance issued on January 17, 2013 with a section titled "Examiner's Comments and Reasons for Allowance" ("Reasons for Allowance"). *Id.* at 14–26. Examiner Srivastava provided a discussion of Price (Ex. 1017), Jarvis (Ex. 1027), Midura (Ex. 1024), FSIS Directive (Ex. 1023), and Skov in the Reasons for Allowance. *Id.* at 20–25. Each reference other than Price was characterized with the same phrase as not disclosing "re-testing individually each of the original specimens." *Id.* Examiner Srivastava incorrectly characterized Price 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 . . .)," as shown below:

> Price et al., teach a method to detect the presence of *Salmonella* in a food sample. Despite pre-enriching the composite lots of food sample (bottles shown in row 2 in Figure 1) and further biochemical testing (The rack of tubes at row 5 of Figure 1) of the isolated colonies from the petri plates (The rack of tubes at row 5 of Figure 1) from the samples plated on the petri plate (at row 4 of Figure 1); Price et al., do not teach 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 discussed in Claim 1(a)- 1(c) or 20 (a)- 20 (c) of the instantly claimed invention).

Id. at 24 (highlighting added).

212. The Examiner's incorrect characterization of Price contradicts the clear teaching of Figure 1 in Price, shown below, to subject the pre-enriched "retained samples" to "individual testing":

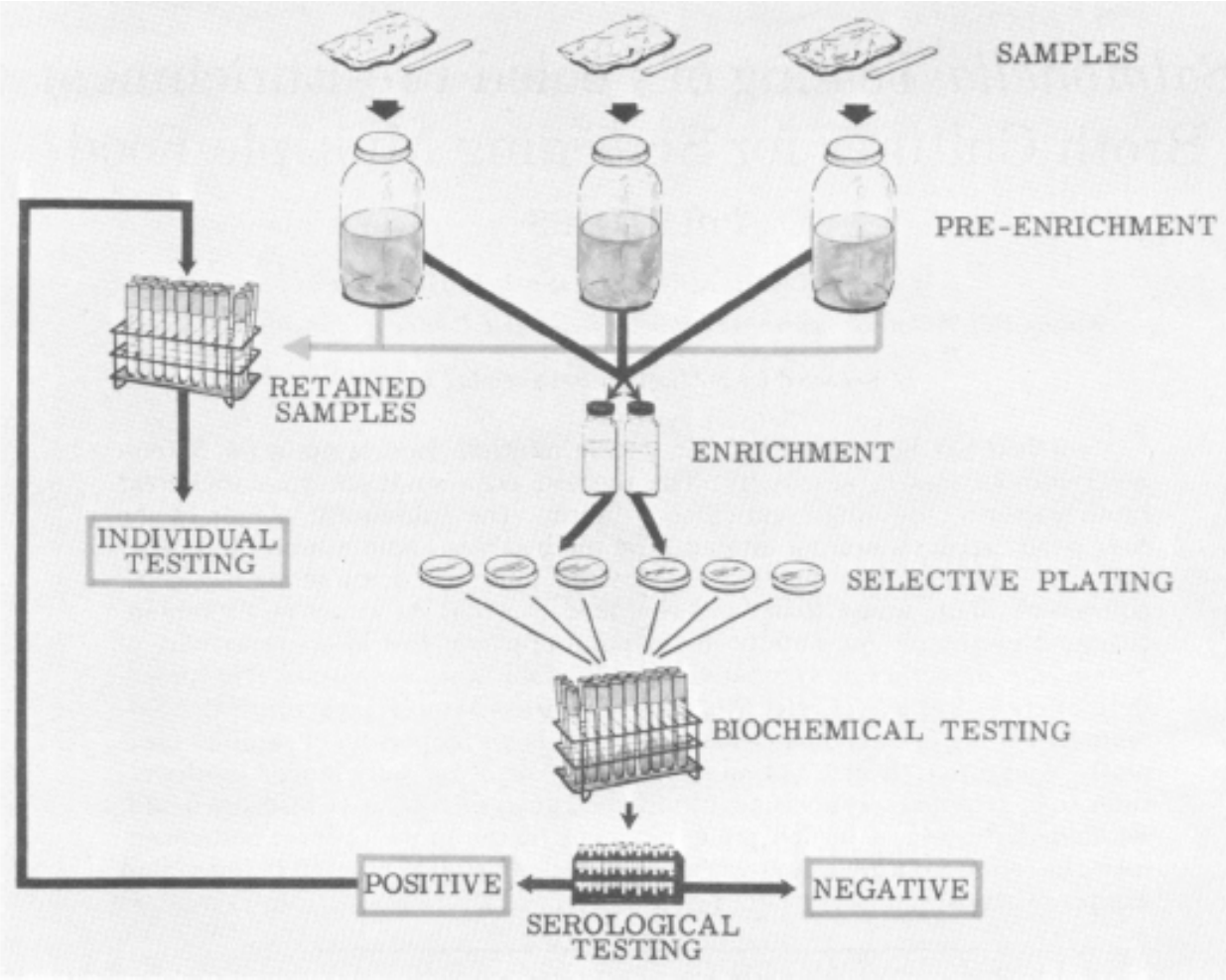


FIG. 1. *Salmonella testing of pooled pre-enrichment broths.*

Ex. 1017 at 680. The incorrect characterization also contradicts Price's statement that "[i]f the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool." *Id.* at 679. The same is true for Price's statement that "[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.* at 681.

213. The issue fee was paid on February 1, 2013 and a document titled "Comments on Statement of Reasons for Allowance" was simultaneously filed with the following comments regarding the reexamination of the '584 Patent:

> ***Comments on Statement of Reasons for Allowance***
>
> In addition or in combination with the Examiner's "Statement of Reasons for Allowance," Applicant's arguments of record for patentability in both the underlying parent application (U.S. Patent Application Serial No. 11/199,871; now U.S. Patent 7,534,584), and in the reexamination proceeding (95/001,294), are reasons for allowance of the presently allowed claims, and are herein incorporated into these Comments.

Ex. 1009 at 12 (highlighting added).

214. However, IEH's statement after examination was closed in the "Comments on Statement of Reasons for Allowance" was never supported by informing Examiner Srivastava regarding the status of Reexamination Control No. 95/001,294. When this statement was made on February 1, 2013, the claims of the '584 Patent had been analyzed and considered not to be patentable by the Office three times including by a first team of three examiners in an Order dated May 26, 2010 (*see* § VIII-C-2, *supra*) and an Action Closing Prosecution dated December 17, 2010 (*see* § VIII-C-5, *supra*) and by a second team of three examiners in a Right of Appeal Notice dated

February 8, 2012 (*see* § VIII-C-8, *supra*). Additionally, the parties had exchanged briefs in the related appeal. *See* § VIII-D-1 and § VIII-D-2, *supra*.

215. On February 4, 2013, IEH's patent attorney, Dr. Davison, and Examiner Srivastava had a telephone interview as summarized below by Examiner Srivastava:

> *Dr. Davison informed the Examiner that the telephone call is to clearly understand the reasons of allowance stated in the Notice of Allowability referenced supra. The Examiner explained that the closest reference is Price et al. Even the Price et al., reference does not teach to re-assess the sample constituting the composite. The last tube rack in Figure 1 of Price et al. is the battery of biochemical tests that are run to identify Salmonella. The Representative further informed the Examiner that the Applicant intends to file another application encompassing some of the subject matter that constituted the claims in the instant application and in the parent (i.e., USSN 11/199,871) of the instant application*

Ex. 1009 at 4 (emphasis added). With regard to the highlighted text, the Examiner's characterization is ambiguous. It is correct if the Examiner meant that Price does not teach retesting the composite, but it is incorrect if the Examiner meant that Price does not teach retesting the samples that were used to make the composite.

216. Regardless, the statement in the interview summary does not correct the Examiner's earlier incorrect statement in the Reasons for Allowance alleging that Price does not teach "re-testing of each of the three original pre-enrichment bottles." Considering that Price is only four-pages long, the clarity of Price's Figure 1 and related statements, the Examiner's statement that Price is "the closest reference" of record, and the knowledge that at least IEH's attorney had regarding Price from the reexamination, Examiner Srivastava's mischaracterization should have been corrected. A POSA would have clearly understood that Figure 1 referred to re-testing of the individual pre-enrichment samples.

217. The ’233 Patent issued on March 5, 2013. Because the Examiner’s misunderstanding about Price’s clear teachings was not corrected, the Examiner’s flawed view carried over into the prosecution of the applications that followed issuance of the ’233 Patent, the ’143 and ’771 Patents.

B. Prosecution History of ’143 Patent

218. The ’143 Patent issued from Application No. 13/784,606, which was filed on March 4, 2013. Ex. 1002.

219. An Office Action issued on December 17, 2013. Ex. 1010 at 52–58. The claims were rejected based on double patenting with respect to the ’584 Patent because the claims of the ’584 Patent and the claims of Application No. 13/784,606 were not patentably distinct from each other and the same applied regarding IEH’s U.S. Patent No. 8,389,233. *Id.* at 55–57.

220. On June 17, 2014, IEH filed terminal disclaimers and a response and amendment in which the claims were amended to the form in which the ’143 Patent issued. *Id.* at 83–96. The amendments were merely semantical revisions as shown below in IEH’s list of amendments:

Voluntary claim amendments

The claims have been amended to clarify the claimed subject matter.

Independent Claims 1 and 20 have been amended to recite:

"sample" in place of "portion" (support is found, for example, in the originally-filed specification at page 3, ll. 5-12, and replete throughout);

"microbe(s)" in place of "microbial agent or organism" (support is found, for example, in the originally-filed specification at page 5, line 20, and replete throughout);

"multiple" in place of "plurality" (English language equivalent; and support for analysis of multiple test lots by use of Applicant's presently claimed method is replete throughout the originally-filed specification);

"compositing" in place of "combining" (to emphasize that the physical act of compositing the samples collected in step a) is required) (support is found, for example, in the originally-filed specification at page 3, line 10 and 25; page 5, line 23; page 9, ll. 5-9; and replete throughout); and

"enriching" in place of "incubating" (in step c)); pooled modular composite sample in place of pooled modular composite sample (support is found, for example, in the originally-filed specification at page 31, line 6; and replete throughout).

Conforming amendments have been made to claims 2-3, 5-13, 15-19, 21-27, 29 and 32-34

Id. at 93–94. None of these amendments substantively altered the scope of the claims relative to the '584 Patent, as I discuss at § XI.

221. On June 19, 2014, IEH filed an information disclosure statement to submit references of record in the reexamination such as Price. *Id.* at 106–08. However, no documents filed by the parties or issued by the Office from the reexamination of the '584 Patent were included.

222. Also on June 19, 2014, IEH's patent attorney, Dr. Davison, conducted an interview with Examiner Srivastava. *Id.* at 166–168. They had a second interview on June 23, 2014 (*id.* at 177) and a third interview on July 10, 2014 (*id.* at 246).

None of the interview summaries indicate that the reexamination of the '584 Patent was discussed.

223. A notice of allowance issued on July 9, 2014. *Id.* at 169–76. As shown below, Examiner Srivastava provided a discussion of U.S. Patent Publication No. 2003/0225477 to Gilman et al., which is titled "Modular Equipment Apparatus and Method for Handling Labware":

> Publication referenced *supra* describes the concept of production lot sample assays for high throughput cell based assays(Page 1, Column 2, Paragraph 008, Lines 1- 13) to reduce sample numbers (Page 1, Column 2, Paragraph 008, Lines 39- 41) to be analyzed to screen for potential drug compounds derived from natural sources. Said method is for increasing test confidence for the positive individual analyses (Page 1, Column 2, Paragraph 008, Lines 39).
>
> The scope of said concept does not compromise the instantly claimed food Quality control method for microbial infestation because said method is not an analogous art reference.

Id. at 175. I have read U.S. Patent Publication No. 2003/0225477 and it does not relate to two-stage compositing.

224. No specific references are mentioned in any of the interview summaries other than a discussion in the third interview summary wherein Dr. Davison and Examiner Srivastava discussed a "inadvertent typographical error" (*id.* at 246) regarding U.S. Patent Publication No. 2003/0226477, which is titled "Coffee/Play Table," and mistakenly listed in the Notice of Allowance (*id.* at 175).

225. The issue fee was paid on July 15, 2014 and the ’143 Patent issued on September 2, 2014. *Id.* at 248, 256. When the issue fee was paid, no notification was provided regarding the reexamination of the ’584 Patent and, as mentioned above, no documents were included from the reexamination. Additionally, the appeal from the reexamination was proceeding and an Examiner’s Answer had been issued in which the Patent Office concluded for a fourth time that the claims of the ’584 Patent were not patentable. *See* § VIII-D-3, *supra*.

C. Prosecution History of ’771 Patent

226. The ’771 Patent issued from Application No. 14/472,144, which was filed on August 28, 2014. On the same date, the claims were amended in a preliminary amendment with nearly the same limitations entered on March 4, 2013 in Application No. 13/784,606, from which the ’143 Patent issued. Ex. 1011 at 1–13.

Voluntary claim amendments

The claims have been preliminarily amended to clarify the claimed subject matter.

Independent Claims 1 and 20 have been amended to recite:

"sample" in place of "portion" (support is found, for example, in the originally-filed specification at page 3, ll. 5-12, and replete throughout);

"microbe(s)" in place of "microbial agent or organism" (support is found, for example, in the originally-filed specification at page 5, line 20, and replete throughout);

"multiple" in place of "plurality" (English language equivalent; and support for analysis of multiple test lots by use of Applicant's presently claimed method is replete throughout the originally-filed specification);

"compositing" in place of "combining" (to emphasize that the physical act of compositing the samples collected in step a) is required) (support is found, for example, in the originally-filed specification at page 3, line 10 and 25; page 5, line 23; page 9, ll. 5-9; and replete throughout);

"enriching" in place of "incubating" (in step c)); pooled modular composite sample in place of pooled modular composite sample (support is found, for example, in the originally-filed specification at page 31, line 6; and replete throughout);

"lot" in place of "test lot" (where the "test" is redundant in view of the claims recitation that the lots are sampled for testing); and

in claim 20 reciting "single production lots" in place of "single-unit production lots" (where "-unit" is redundant).

Conforming amendments have been made to claims 2-3, 5-19, 21-27, 29 and 32-34

Id. at 11–12. The only difference between the amendments relates to the recitation of lots. For example, claim 1 in the '143 Patent recites "test lots" while claim 1 in the '771 Patent recites "lots," however that is a semantical distinction without a difference in meaning and scope.

227. On the same date the application was filed, IEH filed an information disclosure statement to submit references of record in the reexamination such as Price. *Id.* at 14–16. However, no documents filed by the USPTO, IEH, or

bioMérieux in the reexamination of the '584 Patent were included with that information disclosure statement.

228. Examiner Srivastava asked IEH on April 8, 2016 to restrict the claims to a single species by choosing between lots and production lots. *Id.* at 113–15. On June 8, 2016, IEH filed a response and elected to pursue claims reciting lots. *Id.* at 118–28. IEH argued the restriction was unnecessary and should be withdrawn, as provided by the text shown below. *Id.* at 127.

Group Election

Election of one of the following groups is requested:

Group I: Claims 1-19, 21, and 23-36: Drawn to a method to sample and test multiple lots for microbial contamination comprising collecting multiple independent samples from each of the multiple separate lots; or

Group II: Claims 20, 22, 37, and 38: Drawn to a method to sample and test lots for microbial contamination comprising separately collecting multiple independent samples from separate production lots.

Applicant herein elects **Group I (claims 1-19, 21, and 23-36)**, ***with traverse***.

The basis of Applicant's traversal is that a "single production lot" of claim 20 is a form/*species* of test "lot" of claim 1, and thus the same search would serve to examine both Groups of claims, placing no undue burden on the Office.

As noted above, Applicant hereby withdraws claims 20, 22, and 37-38 of Group II.

In view of the foregoing, reconsideration and withdrawal of the requirement for restriction is requested pursuant to 37 C.F.R. § 1.143.

Id. (highlighting added).

229. An Office Action issued on September 22, 2016. *Id.* at 133–40. The restriction requirement was withdrawn. *Id.* at 134. The claims were only rejected

based on double patenting with respect to the ’584, ’233, and ’143 Patents because their claims and the claims of Application No. 14/472,144 were not patentably distinct from each other. *Id.* at 136–39.

230. On October 14, 2016, IEH filed terminal disclaimers to ensure the patents terminate on the same date. *Id.* at 169–175. On the same date, IEH filed a response and amendment in which new dependent claims were added. *Id.* at 176–89. The claims as presented in the response and amendment correspond with those in ’771 Patent.

231. On November 8, 2016, IEH’s patent attorney, Dr. Davison, conducted an interview with Examiner Srivastava. *Id.* at 197. The summary does not indicate what specific art was discussed and it does not indicate that the reexamination of the ’584 Patent was discussed. By this time, the co-pending reexamination was almost complete. The Office had concluded for a fifth and sixth time that the claims of the ’584 Patent were not patentable in the First Board Decision issued on January 20, 2015 (*see* § VIII-D-5, *supra*) and another Examiner’s Answer issued on July 20, 2015 (*see* § VIII-D-8, *supra*).

232. A notice of allowance issued on January 13, 2017. *Id.* at 199–209. Examiner Srivastava indicated in the Reasons for Allowance that the closest prior art included the FSIS Directive (Ex. 1023) and Skov. *Id.* at 205–08. Examiner Srivastava’s analysis of FSIS Directive is provided below:

> FSIS teaches methods of sampling ground beef or poultry for *E. coli* 0157:H7 contamination, comprising aseptically collecting a plurality of pieces or samples and combining the pieces for a representative sample of a production lot from the current day's production (a production assemblage, see pages 4 and 27-28 in their entirety). FSIS further teaches follow-up sampling upon identification of contaminated lots and corrective or remedial measures (see the paragraph bridging pages 8-9).
>
> FSIS' teachings differ from the limitations of the steps 1(d) and 1e in the instant application **in not re-testing individually each of the original specimens** constituting any of the composites> FSIS, rather teaches follow-up sampling upon identification of a positive identification of a contaminated lot and corrective or remedial measures, not from the specimens/samples constituting the composite employed for testing that resulted in the positive identification of a target pathogenic organism. This is subsequent sampling which is an entirely different method than what constitutes the test method of the instantly presented invention.

Id. at 205.

233. Examiner Srivastava faulted the FSIS Directive, which focuses primarily on sampling, for not teaching retesting. *Id.* at 206. A POSA would have clearly understood that the FSIS Directive implied re-testing of the individual composite samples to determine the source of the positive result. For example, the FSIS Directive states that "[i]f inspection program personnel identify no significant problems . . . inspection program personnel are to contact OPHS . . . so a form can be sent for the collection of a follow-up verification sample." Ex. 1023 at 8 (Part V,

A-1); *see also id.* at 9 (Part V, A-4). Additionally, the FSIS Directive indicates that when suspension of an establishment is deferred, FSIS "will conduct follow-up sampling to verify that the corrective action taken by the establishment is appropriate and effective." *Id.* at 10 (Part V, A-7). Again, the Examiner failed to recognize that references had been submitted that teach further testing such as Price. Clearly, the Examiner did not analyze any documents filed by the parties or the Office in the reexamination otherwise the Examiner would have recognized that references such as Price teach retention and further testing.

234. For reasons that are unclear, Examiner Srivastava also attempted to distinguish the allowed claims of Application No. 14/472,144 from those of the '143 Patent. However, he incorrectly characterized the subject matter of step (b) of the independent claims of the '143 Patent as not reciting samples being combined/composited as shown by the highlighted text in the section shown below:

U.S. Patent 8,822,143 B2 issued to the inventor Samadpour.

> The instant application is a CON of U.S. provisional application **13/784,606 that resulted in to U.S. Patent** 8,822,143 B2. In claims of said application, the test lot is a composite mixture of individually taken multiple samples throughout a production run, wherein said individually taken multiple samples are not assemmblaged together to constitute a composite test lot.
>
> In contrast, in the method of Instant application first of all, sampling is multiple samples isolated during a production run wherein said multiple sampling is taken from one unit of material processed that is assemblage together rather than taking multiple sampling throughout the run constituted of multiple processed units, which is subsequently assenmblaged together. Thus, if the processed material is found to be tainted, only one unit would be discarded rather than discarding the entire production run which is defined a "test lot", rather than a "test lot" comprised of individual unit.

Ex. 1011 at 207 (highlighting added). Step (b) of the '143 Patent and the '177 Patent recite the same subject matter, so the above-highlighted statement is not correct. The issue fee was paid on March 23, 2017 (*id.* at 293) and the '771 Patent issued on May 2, 2017.

X. PRIOR ART REFERENCES

A. Ground References for Independent Claims

1. ICMSF

235. The International Commission on Microbiological Specifications for Foods ("ICMSF" or "the Commission") is a non-governmental organization that sets general specifications for foods. The Commission publishes a multi-chaptered series of books titled "Microorganisms in Foods," referred to in the industry as the ICMSF guidelines and recognized as international standards.

236. Before the priority date, a POSA would have been very familiar with the ICMSF guidelines because it is a well-known resource, one of the main guidelines for the food testing industry, and is commonly taught in academic classes on food microbiology. IEH failed to cite any ICMSF guideline even though AAPA #6 describes sampling plans and refers to ICMSF guidelines. *See* § V-A-6, *supra*.

237. The ICMSF guidelines are typically referenced by their series number. Exhibit 1012 includes Chapters 6, 10, 12, and 15–17 of ICMSF 7, which was published in 2002. ICMSF 7 is referred to herein simply as ICMSF for brevity. A portion of ICMSF 2, which was published in 1986, is also included herein as Exhibit 1013.

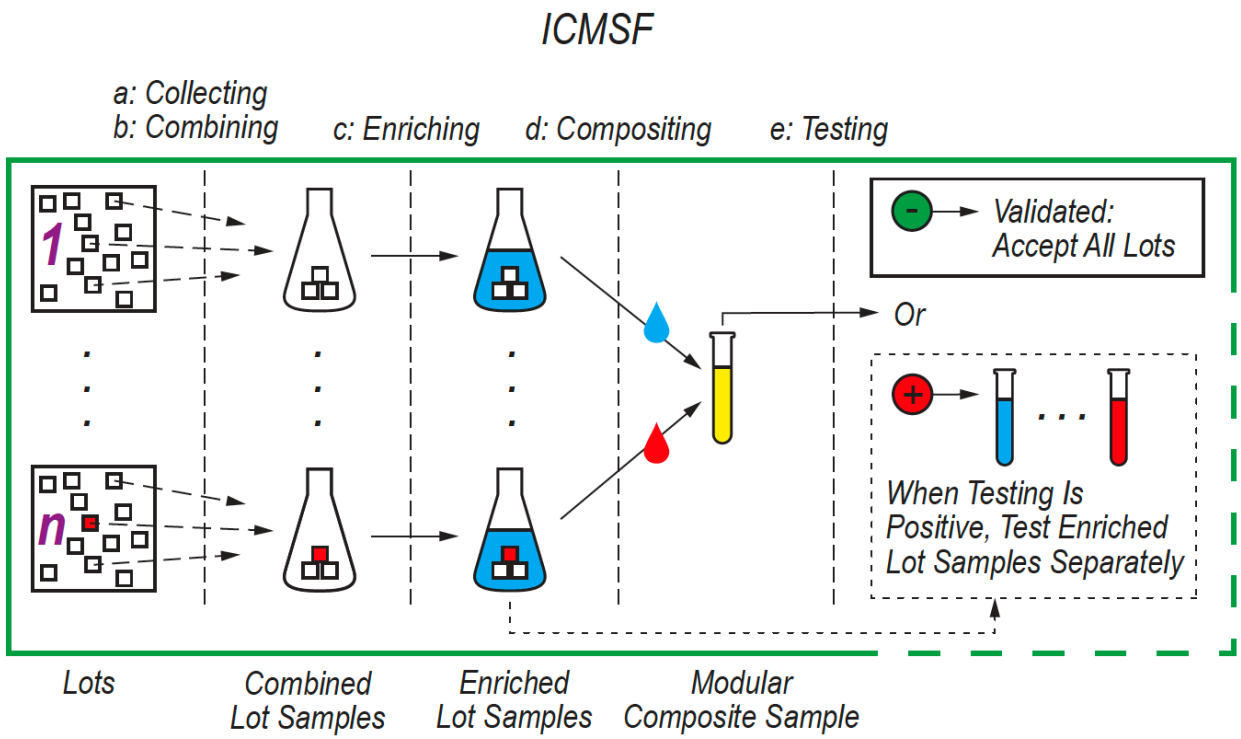
238. The ICMSF publications vary considerably between each publication such that the different publications are not considered different editions. Rather, each

publication stands on its own and reflects different but related objectives. For example, in the period between the respective publication dates of ICMSF 1 in 1978 and ICMSF 7 in 2002, the content of ICMSF changed from simply testing to prevention with content regarding tracking a consignment of lots and use of composited enrichments. In contrast, the FDA's BAM and the USDA's MLG tend to carry over more content from earlier publications such that each update is a different edition.

239. Exhibit 1012, ICMSF, is mainly cited herein for the teachings of Chapters 6, 10, and 12. Chapter 6 is titled "Concepts of Probability and Principles of Sampling." Ex. 1012 at 113–21. Chapter 10 is titled "Experience in the Use of Two-Class Attributes Plans for Lot Acceptance." *Id.* at 183–97. Chapter 12 is titled "Sampling, Sample Handling, and Sample Analysis." *Id.* at 225–236. Chapters 15–17 respectively focus on *Salmonella*, *Listeria*, and *E. coli*. *Id.* at 273–332.

240. Chapters 6, 10, and 12 are the primary sources cited herein for describing: (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. *Id.* at 113–21, 183–97, 225–36. Based on these teachings, ICMSF

is depicted below as disclosing every aspect of steps (a)–(d) of the independent claims and most of step (e) too:



The above diagram accurately reflects the teachings of ICMSF, as summarized herein. The green rectangle in the above diagram of ICMSF indicates that ICMSF either explicitly teaches the listed step, as indicated by the solid line, or only implicitly teaches the listed step, as indicated by the broken line. ICMSF discloses tracking lots with a coding system for traceability. *Id.* at 119 (§ 6.10), 227 (§ 12.2.1). This teaching implicitly indicates utilization of the common practice of retaining portions for further testing after a positive test. However, because ICMSF does not explicitly teach further testing after a positive test, the corresponding portion of the rectangle in the above diagram is shown with a dotted line.

2. Gombas

241. Gombas is an article titled "Survey of *Listeria monocytogenes* in Ready-to-Eat Foods." Ex. 1014 at 559. Gombas describes the steps involved in the testing method of the survey and depicts the method in a diagram, referred to as Figure 1, which depicts "[t]he general scheme for sample testing." *Id.* at 563. Figure 1 is reproduced below:

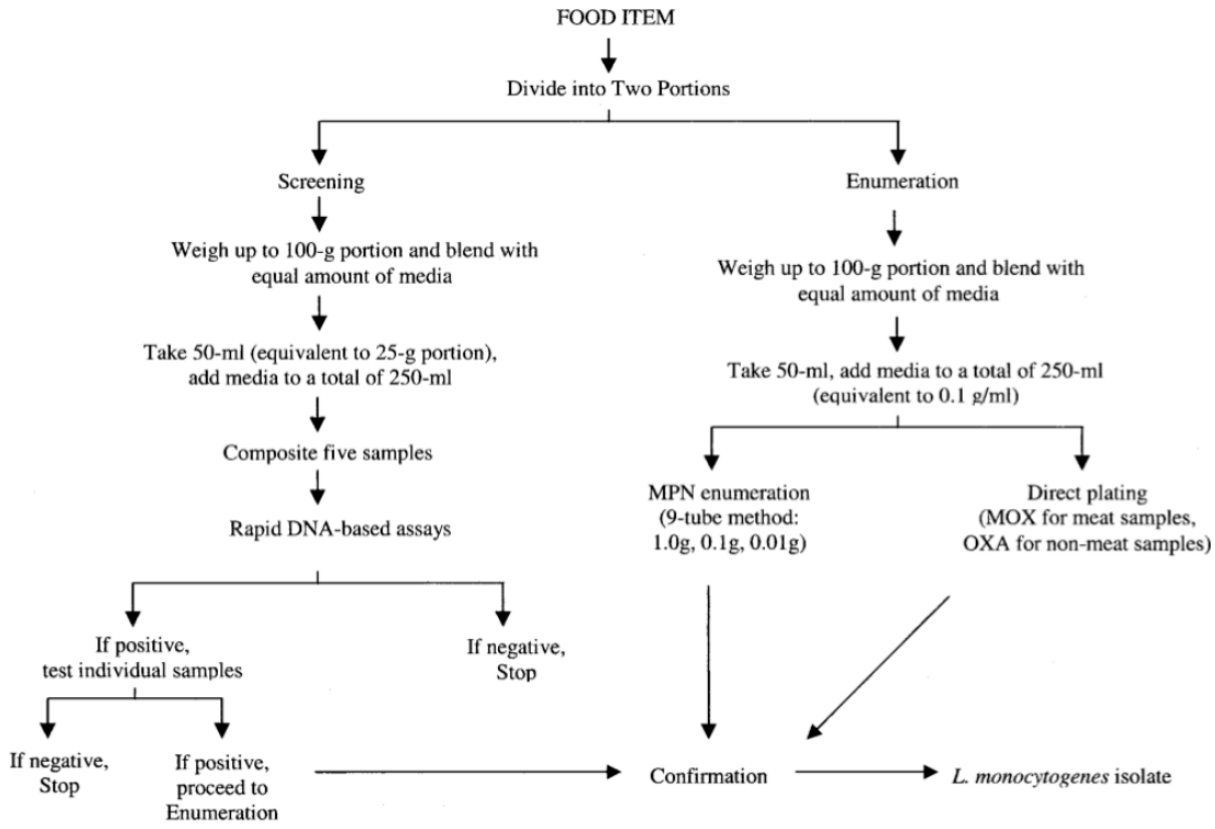
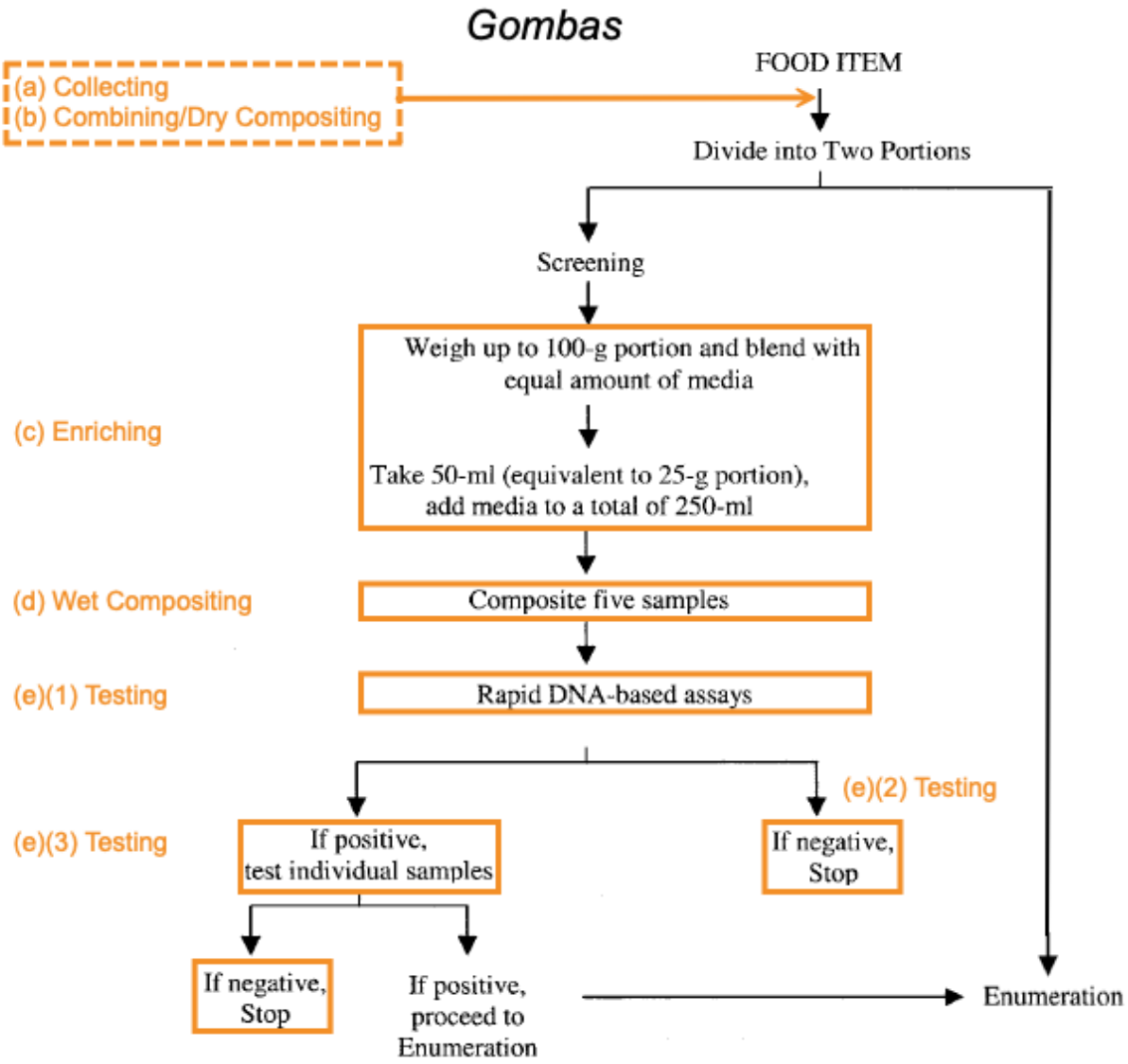


FIGURE 1. *Detection and enumeration of* L. monocytogenes *in RTE food samples.*

Id. Petitioner prepared an annotated version of Figure 1 limited to the content relevant to the IEH Patents and with added text and boxes in orange to correlate the

steps of the method in Gombas to the steps of the independent claims of the IEH Patents as shown below:



Id.

242. Gombas states that Chapter 8 of the revised 1998 version of the USDA's Microbiology Laboratory Guidebook (MLG) was adapted for meat products. *Id.* at 563, 569; *see also* Ex. 1029. Gombas further discloses sampling of meat products,

such as ready-to-eat beef bologna, and therefore at least implicitly teaches collecting and combining such samples. *Id.* at 561–62.

243. Gombas describes the use of tracking codes and recording product information to identify a source when a composited sample tests positive. *Id.* at 563. The annotated version of Figure 1 depicts a step identified as correlating with enriching. Gombas describes this step as using selective enrichment and mixing the sub-samples of the meat samples for homogeneous distribution of any *Listeria monocytogenes*. *Id.* Gombas also discloses incubation of the enrichment broth. *Id.* at 564.

244. As shown in the annotated version of Figure 1, Gombas depicts a step identified as correlating with wet compositing. In the text of Gombas, it states that "up to five like-product samples were composited." *Id.* This wet compositing step occurs after enrichment and incubation. *Id.* After compositing, "the 5-mL composite was tested by the BAX assay according to the manufacturer's procedures." *Id.*

245. Gombas further describes its testing method as depicted in the annotated version of Figure 1 as being complete after a negative test result:

> If a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay with the PBS from the second mLCA plate or by the BAX assay with the secondary enrichment broths. Individual samples that tested negative were not tested further.

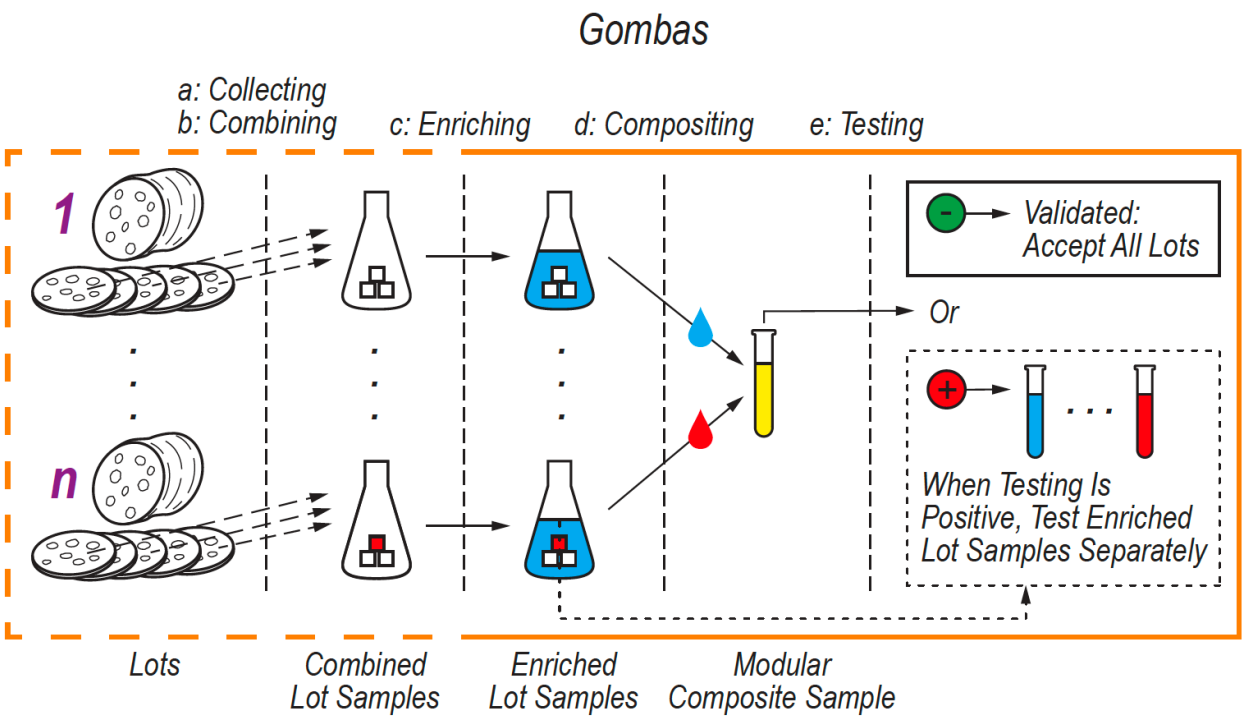
Id. (highlighting added).

246. Because portions of the enrichment cultures are retained, they are available to be further tested after a positive test of a composite sample by the BAX assay:

> If a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay with the PBS from the second mLCA plate or by the BAX assay with the secondary enrichment broths. Individual samples that tested negative were not tested further.

Id. (highlighting added).

247. Below is another diagram of Gombas prepared by Petitioner that is styled like Petitioner's diagram of the steps of the independent claims of the IEH Patents.



248. The above diagram accurately reflects the teachings of Gombas, as summarized above. The orange rectangle in the above diagram indicates that Gombas either explicitly teaches the listed step, as indicated by the solid line, or only implicitly teaches the listed step, as indicated by the broken line. Steps (a) and (b) are shown with a dotted line. With regard to step (a), Gombas at least implicitly teaches collecting sub-samples or sample units of RTE foods such as the beef bologna that is depicted. Furthermore, with regard to step (b), Gombas at least implicitly teaches combining those sub-samples or sample units. Because the text of Gombas at least implicitly teaches these steps, the corresponding portion of the rectangle in the above diagram is shown with a dotted line.

249. At the time of the publication of Gombas in 2003, it was well-known to composite either after pre-enrichment or selective enrichment and to retain a portion for subsequent testing in the event of a positive result. It is not surprising that use of selective enrichment followed by wet compositing with retention of portions of the selective enrichment is described in Gombas in a manner indicating that it was just conventional practice because that is exactly what it was.

3. Hughes

250. Hughes reports on a study conducted to compare an enrichment procedure for various food types. The food types analyzed in the United States included milk chocolate, dried egg, and raw turkey. Ex. 1015 at 634. Thirty-eight collaborators participated in the study and the enrichment procedure was adopted by AOAC International. *Id.*

251. Hughes has a section titled "Preparation of Sample," which describes compositing portions of two enriched samples to form a composite sample, retention of the enriched samples "for culture confirmation of any samples that test positive in an enzyme immunoassay ("EIA"). *Id.* at 636, 638. Shown below is the section in Hughes titled "Preparation of Sample," with some text highlighted. This reproduction is followed by a discussion of the primary concepts disclosed in this section.

F. Preparation of Sample

(a) *Pre-enrichment.*—Pre-enrich product in noninhibitory broth to initiate growth of *Salmonella* spp. Methods used may vary with product and should be performed as indicated in **967.26A** or BAM, 7th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, chapter 5, section C. Pre-enrichment broths should be incubated at 35°–37°C.

(b) *Selective enrichment.*—Transfer 0.1 mL incubated pre-enrichment mixtures to Rappaport-Vassiliadis R10 broth (9.9 mL) and 1 mL to TT broth (9 mL). For all foods other than raw foods or foods having a high microbial load, incubate 6–8 h at 41°–43°C. Selective enrichments of raw foods or foods having a high microbial load must be incubated 16–20 h at 41°–43°C. An air incubator is suitable for this purpose.

(c) *Post-enrichment.*—Remove selective broths from incubation and mix by hand or by Vortex mixer. Remove 1 mL from TT tube and transfer to separate tube of sterile M broth (10 mL) that has been warmed to 35°–37°C. Also remove 1 mL from Rappaport-Vassiliadis R10 tube and transfer to a separate tube of prewarmed M broth (10 mL). For all foods other than raw foods or foods having a high microbial load, incubate M broth tubes 16–20 h at 35°–37°C and return selective enrichment broth tubes to 41°–43°C incubator and incubate for additional 16–18 h. For raw foods or foods having a high microbial load, incubate M broth tubes 6 h at 35°–37°C and return selective enrichment broth tubes to 41°–43°C and incubate for an additional 6 h.

(d) *Preparation of sample for EIA analysis.*—Remove M broth tubes from incubation and mix tubes by hand or Vortex mixer. Combine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube and heat in boiling H_2O bath or in flowing steam 15 min. Refrigerate (2°–8°C) remaining M broth and TT and Rappaport-Vassiliadis R10 tubes from (c) for culture confirmation of any EIA-positive samples (*see* **967.26B, 967.26C, 967.27** and **967.28**). Cool heated M broths to 25°–37°C prior to analysis.

Id. (highlighting added).

National Beef Ex. 1041

252. The "Preparation of Sample" section shown above, identifies four phases including (a) pre-enrichment, (b) selective enrichment, (c) post-enrichment, and (d) preparation of sample for enzyme immunoassay ("EIA"). *Id.* These phases are discussed below.

253. (a) *Pre-enrichment*. "Pre-enrich product in noninhibitory broth to initiate growth of *Salmonella* spp." *Id.* at 636. Hughes indicates that methods "may vary with product." *Id.* Hughes indicates in this section that methods should be performed as indicated in chapter 5 of BAM, 7th Ed., which is titled "*Salmonella*."

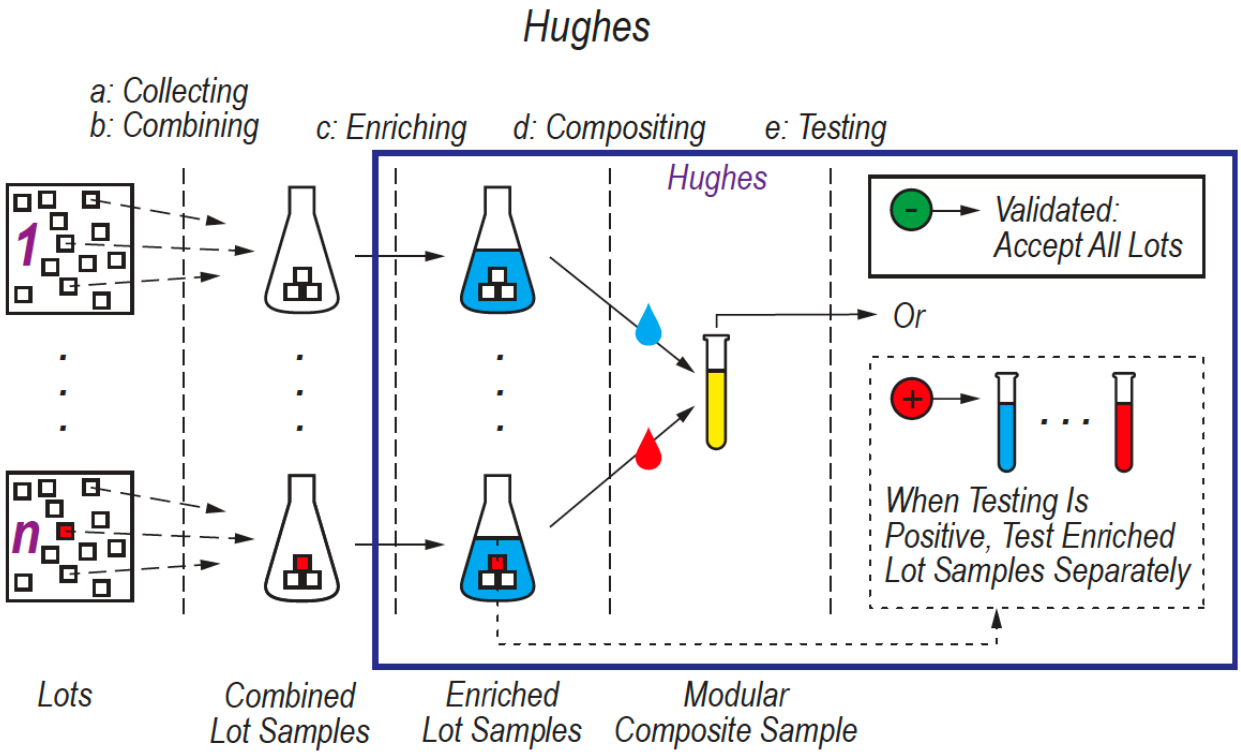
254. (b) *Selective enrichment*. Transfer portions of the incubated pre-enrichment mixtures to two different selective enrichment broths, Rappaport-Vassiliadis R10 broth and TT broth. *Id.*

255. (c) *Post-enrichment*. Remove the selective broths from incubation, mix each by hand or by Vortex mixer, and then transfer a 1 mL portion from the TT tube and a 1 mL from the Rappaport-Vassiliadis R10 tube to separate, sterile M broth tubes. *Id.* at 636, 638.

256. (d) *Preparation of sample for EIA analysis*. "Remove M broth tubes from incubation and mix tubes by hand or Vortex mixer" then "[c]ombine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube." *Id.* at 638. The composite sample is then assayed. *Id.* Hughes retained and refrigerated the

"remaining M broth and TT and Rappaport-Vassiliadis R10 tubes from (c) for culture confirmation of any EIA-positive samples." *Id.*

257. Below is a diagram of Hughes prepared by Petitioner that is styled like Petitioner's diagram of the steps of the independent claims of the IEH Patents. These steps described in the "Preparation of Sample" section disclose steps (c)–(e) of the independent claims, as depicted below.



258. The above diagram accurately reflects the teachings of Hughes summarized above. The purple rectangle in the above diagram correlates to the explicit teachings of Hughes with steps (c)–(e) of the independent claims of the IEH Patents.

259. At the time of the publication of Hughes, in 1999, wet compositing following pre-enrichment may have been more common, however, it was not uncommon to composite enrichments and to retain portions for subsequent testing in the event of a positive result. Like Gombas, Hughes discloses use of enrichment as merely a part of a routine procedure. Again, it is not surprising this is described in Hughes in a manner indicating that it was just conventional practice because that is exactly what it was in 1999.

260. An additional publication followed Hughes in 2003, which is referred to herein as Hughes 2003. Ex. 1016. Hughes 2003 references the pooled enrichments discussed in the earlier 1999 publication, Hughes, but analyzes use of single enrichment broths. *Id.* at 775–76.

4. Price

261. Price is a paper published in the historical context of the National Academy of Science report entitled "An Evaluation of the *Salmonella* Problem." At that time, there was considerable discussion on the appropriate methodology to analyze food samples for *Salmonella*, including but not limited to the number of samples to be collected and the actual laboratory procedures. Also, at that time, laboratory methods for the detection of *Salmonella* were time consuming and labor intensive involving multiple steps and incubations. Briefly, the method incorporated a pre-enrichment (non-selective enrichment) to revive injured bacterial cells, a second

enrichment with two different media (selective enrichment) to enhance the growth of *Salmonella* while suppressing the growth of other bacteria and a detection method which involved streaking the selective enrichment for isolation onto multiple selective media petri dishes. The presumptive *Salmonella* colonies were subsequently identified by standard bacteriological methods.

262. Below is the abstract from Price:

Salmonella Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples

W. R. PRICE, R. A. OLSEN, AND J. E. HUNTER

Winton Hill Technical Center, The Procter & Gamble Company, Cincinnati, Ohio

Received for publication 10 December 1971

A method has been described for testing multiple food samples for *Salmonella* without loss in sensitivity. The method pools multiple pre-enrichment broth cultures into single enrichment broths. The subsequent stages of the *Salmonella* analysis are not altered. The method was found applicable to several dry food materials including nonfat dry milk, dried egg albumin, cocoa, cottonseed flour, wheat flour, and shredded coconut. As many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis. The procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found. *Salmonella* testing of pooled pre-enrichment broths provides increased consumer protection for a given amount of analytical effort as compared to individual sample analysis.

Ex. 1017 at 679 (highlighting added).

263. As indicated in the Abstract, the intent of the authors was to demonstrate a practical and more efficient method of handling large numbers of samples in the

analytical laboratory without compromising the sensitivity of the method. *Id.* The method reported by Price involved combining or pooling aliquots (sub-samples) from the pre-enrichment step from multiple samples into a single selective enrichment step. *Id.* In practice with many foods, the majority of the samples are routinely negative for *Salmonella*, so the modified method presented in this paper reduced both the time and labor required to analyze a large number of samples, as indicated by the highlighted text below:

> **Positive test results are relatively rare among the many samples of food ingredients and products which are analyzed for *Salmonella*. Therefore, 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. These studies support the conclusion that *Salmonella* pre-enrichment broths can be pooled for analysis without loss in sensitivity to *Salmonella* in the individual samples.**

Id. (highlighting added).

264. Price also retained a portion of the pre-enrichment samples so that if the combined selective enrichment sample was positive for *Salmonella*, the individual samples could be tested to determine which individual sample was positive, as indicated by the highlighted text below:

MATERIALS AND METHODS

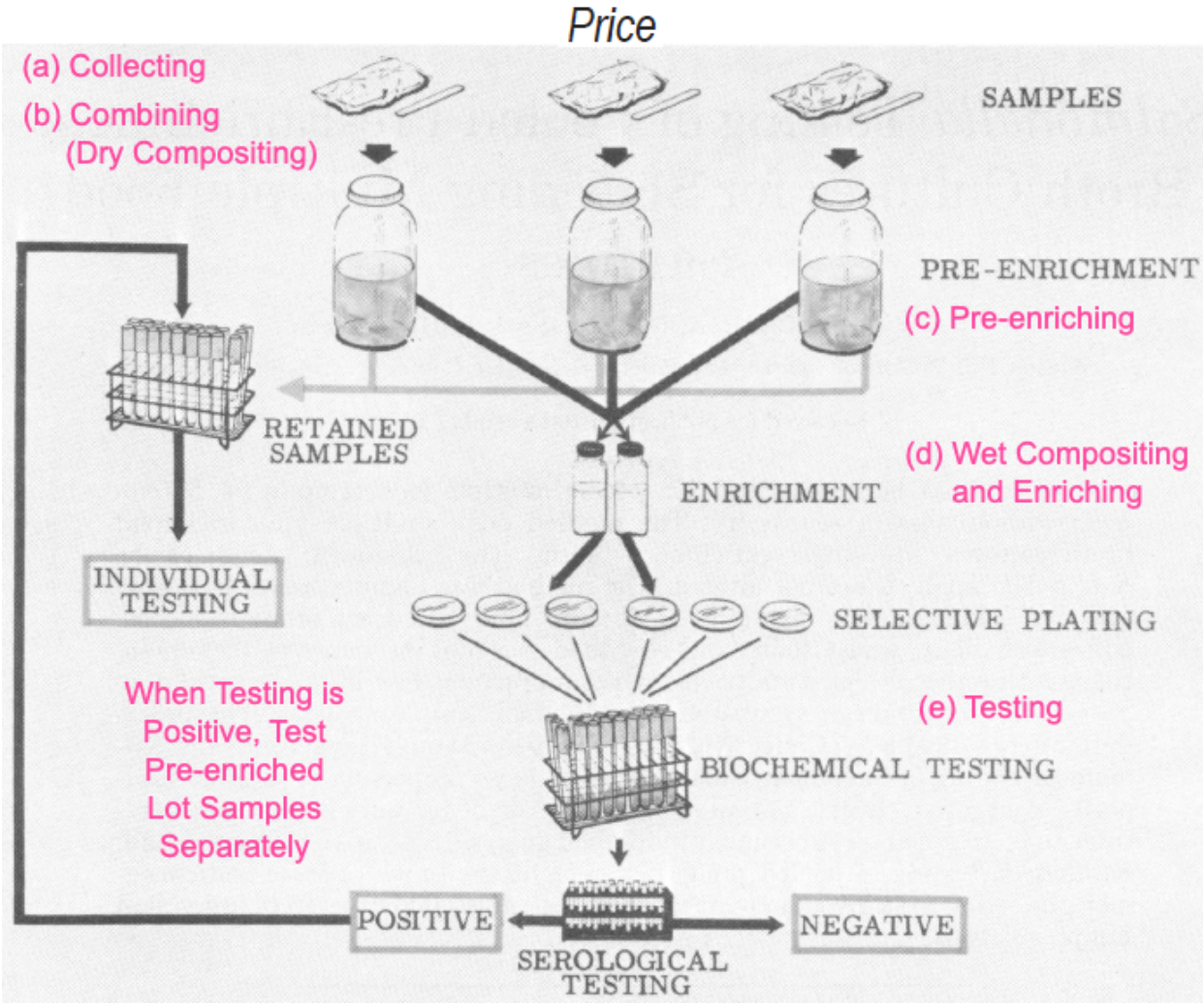
Salmonella analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths described in the following paragraph.

The procedure for *Salmonella* testing of pooled pre-enrichment broths is illustrated in Fig. 1. Samples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage. During pooling, a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4 C for later reference to the individual samples. If the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.

Id. (highlighting added).

265. The results of this research demonstrated that there was no loss in sensitivity by using the modified method, i.e., combining pre-enrichments into a single selectively enriched sample. *Id.* To demonstrate this, the authors combined a single known-positive sample with equal amounts of up to 9 negative samples. *Id.* at 681. In this case, the method used 25-gram samples, so there was one positive 25-gram sample combined with 9 negative 25-gram samples. *Id.* At varying concentrations of *Salmonella* there was no difference in the sensitivity of the method, whether one individual sample was analyzed or if 10 samples were analyzed. *Id.*

266. Price also depicted the analytical method in a diagram identified as Figure 1, which is reproduced below.



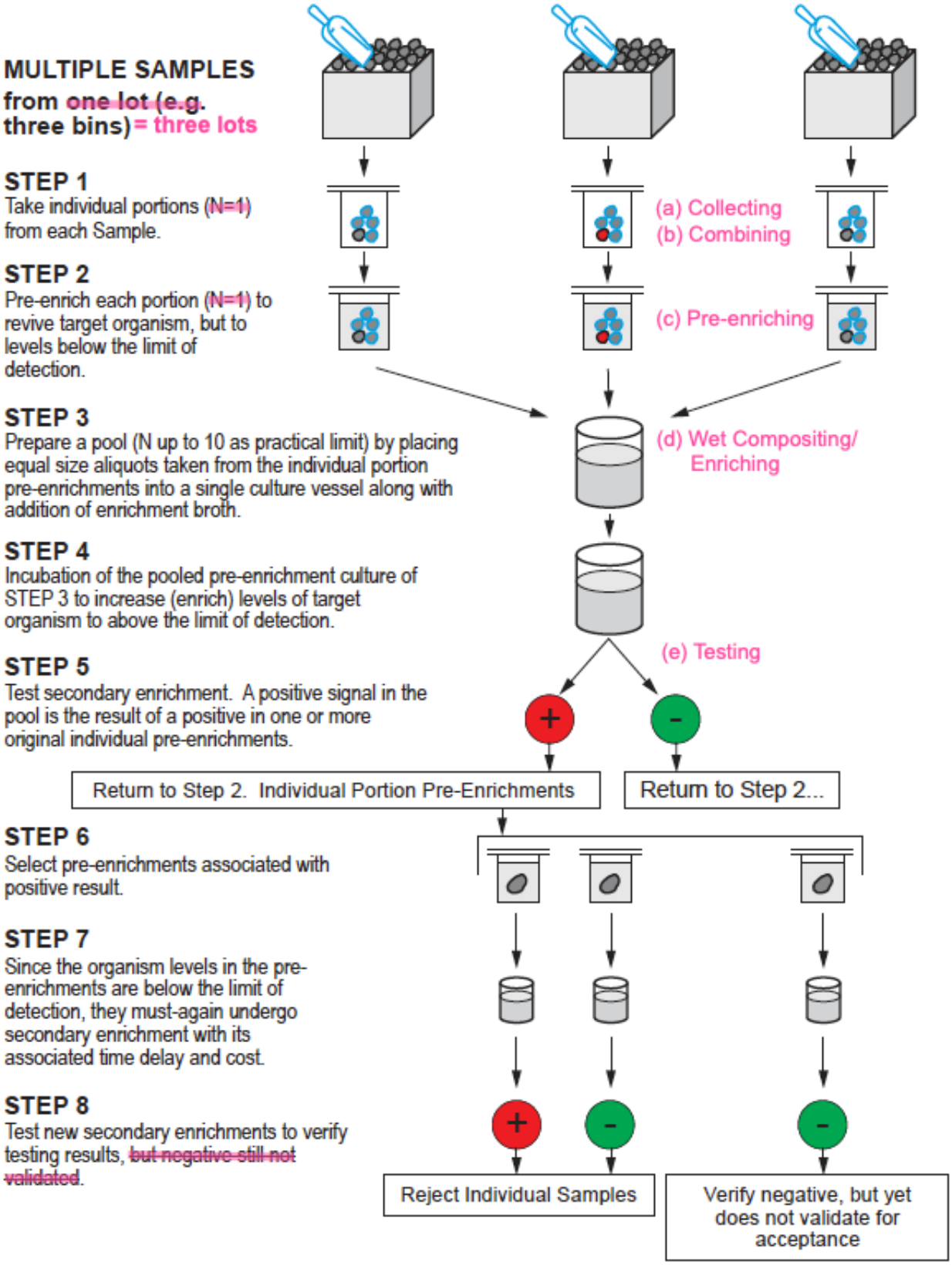
Id. at 680 (Figure 1 (annotated)). Price's diagram is annotated to list the steps of the independent claims of IEH's Patents such that they are correlated to Price's steps.

267. While Price is focused on laboratory methods, the intent is clearly that of production application in the food industry. The authors all worked for The Procter & Gamble Company, and while the paper focused on laboratory methods, the actual method would have been implemented and applied to the processing and production of foods. *Id.* at 679. Additionally, although not explicitly stated, the method would

have been applied to foods produced by The Procter & Gamble Company, which had a vested interest in assuring the safety of its food products.

268. In the reexamination, IEH provided a diagram of Price identified as Figure 3. The annotated version of IEH's diagram, which is provided below, more accurately reflects Price's teachings. The depiction in IEH's version of the Figure 3 diagram of Price is actually a simplification of Price's disclosure, as Price teaches the collection of multiple portions/samples combined into multiple groups. *Id.* at 679–81.

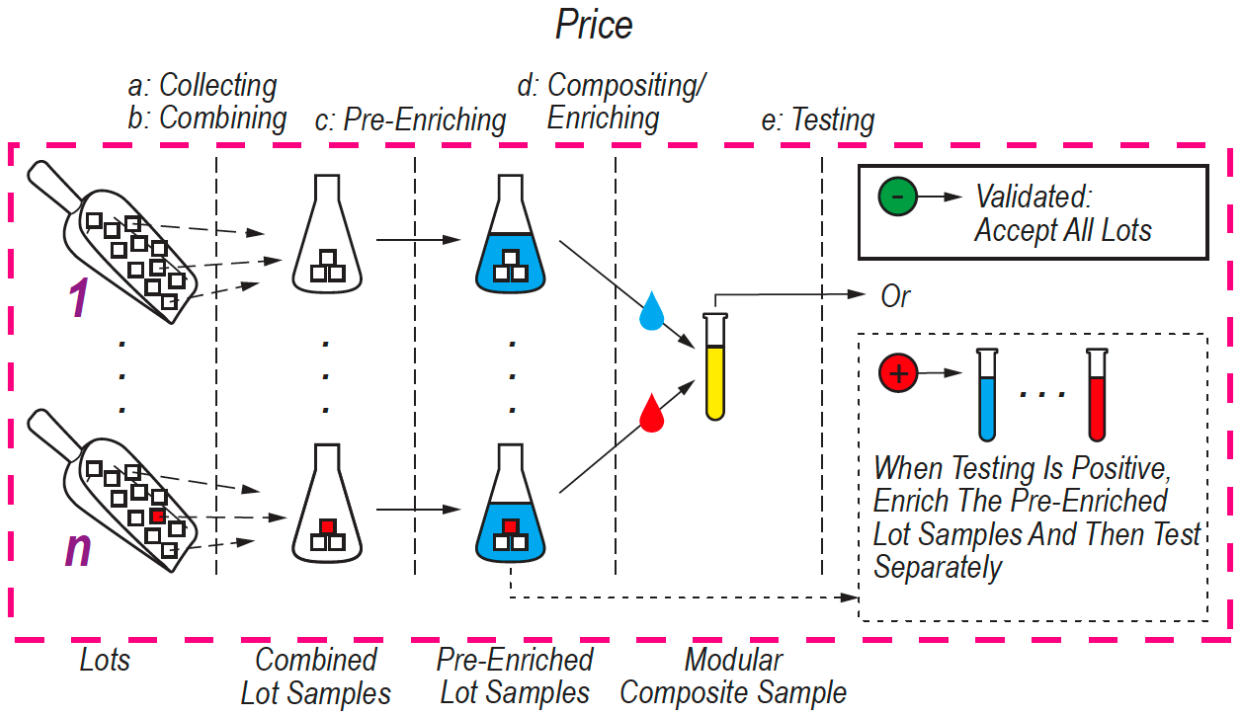
Figure 3: CITED PRIOR ART (PRICE et al, 1972)



Ex. 1007 at 298 (annotated). I agree with the annotations to IEH's Figure 3 diagram of Price shown above. I disagree with the content IEH presented as step 8 in the above diagram because the general practice in food safety is that a negative test result is sufficient to validate a food product.

269. IEH's Figure 3 diagram of Price indicates the method starts by obtaining samples. Because Price tests dry food materials, in the annotated version of Figure 3, scoops are depicted for removing the materials from the depicted bins.

270. Below is a diagram of Price that mirrors the information in the annotated version of IEH's Figure 3 diagram of Price and is styled like the diagram of the independent claim steps. The below diagram is an accurate depiction of the teachings of Price.



As depicted above, Price discloses the independent claim steps except that: (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.

B. Ground References for Dependent Claims

271. Stewart (Ex. 1018), Fratamico (Ex. 1019), D'Haese (Ex. 1020), and D'Aoust (Ex. 1021) are relied on in several grounds to challenge several dependent claims including claims 3, 5, 6, and 28–30 of the '584 Patent; claims 4, 6, 7, and 30–32 of the '143 Patent; and claims 5 and 7–11 of the '771 Patent, as discussed at § XII-D-2 to § XII-D-5, *infra*.

1. Stewart — Incubation after Enrichment

272. Exhibit 1018 is referred to herein as "Stewart" and corresponds to the following reference:

> Diana Stewart et al., "Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water," J. AOAC Int'l, vol. 85, no. 2, pages 395–403 (Mar./Apr. 2002).

273. The intent of this manuscript was to compare three rapid methods for the detection of *Salmonella* with the traditional cultural method, considered to be the "gold standard." Ex. 1018 at 395. The methods were the Assurance Gold

Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP methods of analysis. *Id.* The Assurance Gold is a visual immunoprecipitate assay, while the BAX and GENE-TRAK assays are based on nucleic acid methods. *Id.* All three methods were commercially available during the years prior to the publication of the manuscript in 2002. *Id.*

274. All three rapid methods were performed in a manner consistent with the manufacturer's instructions. *Id.* at 398–400. The procedure for the Assurance Gold Salmonella EIA involves a pre-enrichment in buffered peptone water followed by a selective enrichment in Rappaport-Vassiliadis (RV) broth and tetrathionate (TT) broth. *Id.* at 398. Following the selective enrichment in RV and TT broths, the two selective enrichments were combined into a single sample for further incubation and analysis. *Id.* The text states:

> post-enrichment by transfer and combination of 0.5 mL RV and 1 mL TT **into a single tube** containing 10 mL prewarmed trypticase soy broth supplemented with novobiocin (TSB + n) at 10 μg/mL **with incubation for 16–20 h at 42°C.**

Id. (emphasis added).

275. The authors of this manuscript were all employees of the U.S. Food and Drug Administration, and the paper was published in the Journal of AOAC International. *Id.* at 395. The methods described in this Journal are recognized and accepted as official methods by many different countries.

2. Fratamico — Concentration of Bacteria

276. Exhibit 1019 is referred to herein as "Fratamico" and corresponds to the following reference:

> Pina Fratamico et al., "Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method," Food Microbiol., vol. 9, no. 2, pages 105–113 (June 1992).

277. As the title indicates, this reference discusses the rapid isolation of a target microorganism using an immunomagnetic separation method. Ex. 1019 at 105.

278. More specifically, Fratamico developed "[a] method employing immunomagnetic beads" to concentrate and thereby improve the isolation and detection of *E. coli*. *Id.* For example, Fratamico was able to use immunomagnetic beads to isolate *E. coli* strains from enrichment cultures of raw ground beef "when the initial inoculum level was 1 cfu g^{-1}." *Id.* at 109.

279. Fratamico further teaches that "[t]he percentage of bacteria recovered increased with increasing amounts of beads." *Id.* at 108. Consequently, Fratamico "demonstrates that immunomagnetic separation [using immunomagnetic beads] is a simple and rapid technique" for concentrating a microbe for isolation and detection. *Id.* at 109.

280. It is significant that this reference appears in the journal Food Microbiology as that is a publication that disseminates original research articles, short research communications, and review papers dealing with all aspects of the microbiology of

foods, including methods for the detection, identification, and enumeration of foodborne microorganisms and microbial toxins.

3. D'Haese — Culture Method is Gold Standard

281. Exhibit 1020 is referred to herein as "D'Haese" and corresponds to the following reference:

> 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).

282. The intent of this manuscript was to describe a new and more rapid method for the detection of *Mycobacterium paratuberculosis* in milk. Ex. 1020 at 979. However, the significance of this manuscript is the statement in the introduction, which states: "Conventional culturing still remains the gold standard, as the demonstration or enumeration of target bacteria in a liquid broth or on solid agar media is unmistakable proof of their viability, defined here as their ability to multiply." *Id.*

283. This paper was published in the Journal of AOAC International. *Id.* The methods described in this Journal are recognized and accepted as official methods by many different countries.

4. D'Aoust — Pre-enrichment and Enrichment

284. Exhibit 1021 is referred to herein as "D'Aoust" and corresponds to the following reference:

> Jean-Yves D'Aoust, "Update on Preenrichment and Selective Enrichment Conditions for Detection of *Salmonella* in Foods," J. Food Prot., vol. 44, no. 5, pages 369–374, 393 (May 1981).

285. *Salmonella* methods of analysis have undergone many revisions over time. One of the earliest revisions included the concept of enrichment when it was determined that *Salmonella* could be present in very low populations and that the bacteria may have been stressed or injured by food processing. D'Aoust describes this in the introduction to the paper:

> Preenrichment in a non-selective broth medium provides for the non-inhibited growth of indigenous bacterial flora and the resuscitation and proliferation of stressed or injured salmonellae to detectable levels (35). Selective enrichment inhibits growth of non-salmonellae and facilitates isolation of *Salmonella* on differential plating media (17).

Ex. 1021 at 369.

286. D'Aoust did extensive research and published on *Salmonella* during his employment with the Health Protection Branch of the Canadian Government. This reference is an example of the knowledge which was publicly available well before

the priority date regarding preenrichment and enrichment methods for the detection of foodborne pathogenic bacteria.

C. State of the Art References for Sampling and Combining

1. BAM

287. The Bacteriological Analytical Manual ("BAM"), from the FDA, provides the official methods of microbiological analysis for foods and cosmetics. The FDA has regulatory authority over most foods with the exception of meat and poultry, liquid eggs, and Siluriformes (catfish). However, as the FDA has regulatory authority over pet and animal foods, some of the methods are applicable to meat or poultry containing products. Earlier editions of the BAM were published as physical copies in a three-ring binder but transitioned to electronic and online in approximately 2000 (*see* https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam). The analytical methods described in the BAM must meet stringent scientific criteria such that the results are considered valid in legal matters. In addition, as part of the United States participation in the World Trade Organization, the methods must be made available to our trading partners as the U.S. established standards or guidelines for imported products. The BAM provides guidance on collecting and transporting samples of different types and categories of foods. The number of samples to be collected are based on scientific studies and statistical analysis from the late 1960s and early 1970s, with additional guidance from the

International Commission on Microbiological Specifications for Foods (i.e., the ICMSF).

288. Exhibit 1022 includes the Table of Contents, Introduction, About the Bacteriological Analytical Manual, and Chapters 1, 5, and 10 of the version of the BAM published in 2003, referred to herein as "BAM 2003" or simply "BAM." Chapter 1 is titled "Food Sampling and Preparation of Sample Homogenate." Ex. 1022 at 10. Chapter 5 is titled "*Salmonella*." *Id.* at 20. Chapter 10 is titled "Detection and Enumeration of *Listeria monocytogenes* in Foods." *Id.* at 40. Chapter 1 of BAM 2003 was submitted by bioMérieux in the reexamination. Ex. 1007 at 142. IEH cited a version of BAM but only included Chapters 4 and 4A, which relate to *E. coli*. Ex. 1006 at 195, 241.

289. Chapter 1 describes, at Section A, use of sampling plans to obtain a representative sample such as 60 analytical units for foods in Food Category I, which includes meat. Ex. 1022 at 11. Chapter 1, at Section E, describes mixing to overcome non-uniform distribution of microorganisms, which is the expected state of a food sample. *Id.* at 17–18.

290. Chapter 5, at Section C-15, describes steps to prepare a sample of meat for isolation of *Salmonella*, which includes placing the sample in a blender with a lactose broth. *Id.* at 27. At Section D of Chapter 5, the steps are described for isolating *Salmonella*. *Id.* at 28–31.

291. Chapter 10 describes, at Section C, collecting sub-samples to obtain a representative sample, combining the sub-samples, blending in *Listeria* enrichment broth to obtain an enriched, pooled composite sample, and then incubating. *Id.* at 43–45. Chapter 10 also describes, at Sections D and E, an isolation procedure and an identification procedure. *Id.* at 45–48.

2. FSIS Directive

292. The FSIS Directive states that its purpose is to provide:

> Food Safety and Inspective Service (FSIS) inspection program personnel, program investigators, and import inspection personnel **instructions for sampling raw beef products** as part of verification testing for *Escherichia coli* O157:H7 (*E. coli* O157:H7) **to ensure the protection of public health**. . . . [and] outlines actions FSIS will take when a raw ground beef product sample, raw ground beef component sample, raw ground beef component sample, or raw beef patty component sample is found to be positive for *E. coli* O157:H7.

Ex. 1023 at 1 (emphasis added). The FSIS Directive also states that "FSIS may **sample and test beef manufacturing trimmings** and other raw ground beef and beef patty components at a supplying establishment when that establishment has supplied product to grinders that tested positive for *E. coli* O157:H7 after it was ground." *Id.* at 21 (emphasis added). The FSIS Directive describes factors to be

considered when "developing a **sampling plan** based on risk." *Id.* (emphasis added).

293. The FSIS Directive indicates that "[i]nspection program personnel may be instructed to collect **more than one sample per lot** in certain circumstances." *Id.* at 4. Additionally, the FSIS Directive teaches that the samples are to be collected from the "current day's production" (*id.*) and then further clarifies that "**[r]andomized or [r]epresentative [s]ampling**" should be conducted by either varying time or location. *Id.* at 27 (emphasis added). Thus, FSIS Directive states:

> 1. **Time**: Throughout the production lot, as defined by the establishment, as **boxes or combo bins** are filled, collect samples **at random times**. Use standard procedures for identifying "random times".
> 2. **Space**: . . . Use a standard random number procedure to select which containers to sample. Select **representative samples** from the top of the filled boxes or **combo bins**. These pieces should have collected representative bacteria from the product contact surfaces during the course of production.

Id. (emphasis added).

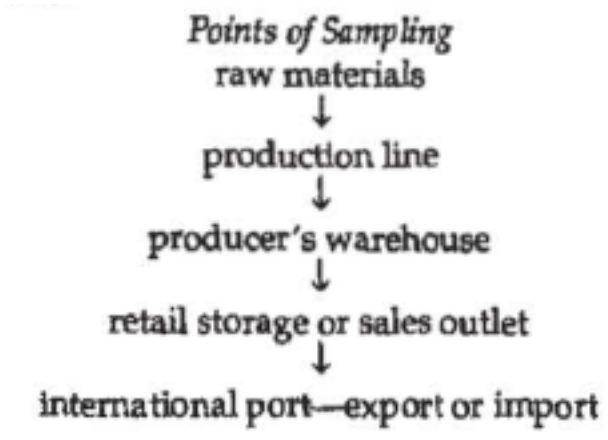
294. A more specific example of such collecting and sampling raw ground beef components is described in the FSIS Directive's Attachment 2. For example, it states:

> [f]rom each of the designated containers (or during the day) "Grab sample" pieces with the hook. From each piece, slice a thumb to palm-sized piece of surface, no thicker than ½ inch (or 1 cm). Place the samples into the sterile sample bag, using the hook or laboratory-supplied tongs.

Id. at 28. The FSIS Directive also indicates that "[i]f the establishment's confirmation testing finds the sample **negative** for the pathogen, that product **may be shipped in commerce** under normal procedures." *Id.* at 3 (emphasis added).

3. Midura

295. Midura is Chapter 2 from the Compendium of Methods for the Microbiological Examination of Foods and is titled "Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis." Ex. 1024 at 13. Midura indicates that "[t]ypical points of sampling where sampling plans may be applied are shown in the following chart:"



Id. at 14. Midura presents sampling plans for various types of food including raw and processed meat. *Id.* at 18. Midura states that sampling plans are best understood when certain basic concepts are clarified:

> First, the **lot to be sampled must be defined**. When a given quantity of product is surveyed and units or portions of this lot are taken for examination (including microbiological analyses), the procedure is called "sampling." **Sampling can be applied in a way that ensures that results obtained will be statistically valid**. In this case, a "**sampling plan**" is developed, where selection of samples taken from a lot is carried out in a manner that ensures that each sample has the same chance of being chosen. For example, assume that a lot defined as "1000 packages in a warehouse" is to be sampled. Each package is assigned a number. If the 1000 items are stacked equally in 10 rows, then 1 to 100 would be assigned to the units in the first row, 101 to 200 to the second, and so on until all packages are numbered. A random number table is used to choose the required numbered containers for sampling. In this example, if we select five as the required number of packages, then five typical random numbers (lot size being 1000) could be 586, 973, 99, 838, and 737. In addition to random sample selection, a sampling plan will also contain instructions that specify the number of packages to be taken and the

> basis for accepting or rejecting the lot. Thus, **a sampling plan as employed in this context states the number of units required to be randomly collected from a lot and lists the acceptance and rejection criteria**. Before using a sampling plan, it is usually prudent to consult a professional statistician to ascertain that the lot of food to be sampled meets the criteria required by that particular sampling plan.

Id. at 14 (footnotes omitted and emphasis added).

D. State of the Art References for Enriching, Wet Compositing, and Testing Portions of Retained Composites

1. Silliker and Gabis

296. In Section 10.4, ICMSF 2002 discusses Silliker & Gabis (1973), which is Exhibit 1025 and referred to herein as "Silliker", and Gabis & Silliker (1974), which is Exhibit 1026 and referred to herein as "Gabis." Ex. 1012 at 187. At the time of the publication of these papers, Silliker Laboratories, Inc., which was founded by Dr. Silliker, was one of the preeminent contract testing laboratories for the food industry and would have had extensive knowledge of the current practices and procedures in the industry.

297. The Silliker and Gabis papers were published in the historical context of the National Academy of Science report cited below:

National Academy of Sciences, National Research Council, Committee on *Salmonella*. "An Evaluation of the *Salmonella* Problem." In Nat. Acad. Sci. 1969.

At that time, there was considerable discussion on the appropriate methodology to analyze food samples for *Salmonella*, including but not limited to the number of samples to be collected and the actual laboratory procedures. Laboratory methods during this time period for the detection of *Salmonella* were time consuming and labor intensive involving multiple steps and incubations.

298. The sampling protocol from the 1969 NRC report suggested that sixty, 25-gram samples be analyzed to determine if a food product was contaminated with *Salmonella*. Analyzing 60 samples for each food product required an extensive amount of resources, including labor, materials, and space in the laboratory. The intent of these studies was to determine if combining individual samples from foods into a fewer number of larger samples would result in the same sensitivity as analyzing the samples individually. To test this, Silliker looked at various combinations of samples from low moisture foods, including 60 individual 25-gram samples, combining the 25-gram samples into 15 100-gram samples, and finally combining the individual samples into three 500-gram samples. Ex. 1025 at 475. The laboratory results for *Salmonella* were compared for all types of samples. *Id.* at 477–78.

299. The results of this research demonstrated that there was no loss in sensitivity of the method by combining the samples, and the authors noted "[r]outine surveillance requires collection and examination of large numbers of samples, especially in a large plant producing many products. If the samples from individual lots can be lumped as described here, the monetary and time savings are obvious." *Id.* at 479.

300. In the Gabis paper, the experiment described previously was repeated with some modifications for high moisture foods. Ex. 1026 at 663. The high moisture food products were sampled to result in 13 individual 25-gram samples, three samples of 108.3 grams, a single 325-gram sample consisting of 13 individual samples or a 500-gram sample. *Id.* at 663–64. As with the low-moisture foods, there was no loss in sensitivity when the individual samples were combined into larger (and fewer) samples for analysis. *Id.* at 663, 668.

301. Silliker and Gabis are papers on laboratory methods, but the intent is clearly that of application in the food industry. While these papers focused on laboratory methods, the actual method would have been applied to the processing and production of foods. The concern was that the burden of analyzing large numbers of individual samples, rather than a smaller number of composite samples would take resources that could be better employed in testing more products.

302. Of particular relevance to the IEH Patents, the Silliker paper indicates that two-stage compositing was known because the paper states that:

> Compositing of multiple subsamples (lumping) and wet compositing of pre-enrichment cultures have been tested as economical approaches to *Salmonella* control. Both approaches are being used widely by the food industry in the United States, but little has been published on the efficacy of either technique.

Ex. 1025 at 475.

Silliker acknowledged that their research built on Price, which "reported that as many as 25 pre-enrichment broth cultures could be pooled without apparent loss in sensitivity." *Id.* at 476. As explained below, Silliker also taught two-stage compositing including dry compositing and wet compositing followed by a testing step. *Id.* at 476–79. Like Price, the combined samples are only pre-enriched prior to wet compositing. *Id.* at 476.

303. Silliker describes grinding samples of dried products in a grinder followed by collecting subsamples. *Id.* After the resulting mixed products were sampled then they were added to a pre-enrichment broth, as indicated below:

Sampling

In tests 1–21 the mixed products were sampled directly, i.e., sixty 25-g, fifteen 100-g, and three 500-g subsamples were weighed directly into the pre-enrichment broth. In tests 22–26, 180 25-g subsamples were weighed into 180 sterile sample bottles. Sixty of the 180 subsamples were randomly selected for the 25-g subsamples. The 100-g subsamples were prepared by randomly pooling four 25-g subsamples to form 15 groups. The 500-g subsamples were prepared by randomly pooling groups of twenty 25-g subsamples.

Id. (highlighting added).

304. Silliker also discloses enriching the samples, as shown below:

Subculturing of Pre-enrichment Cultures

All pre-enrichment cultures were incubated for 24 h at 35C. After incubation, 1 ml from each of the cultures was introduced into 9 ml selenite–cystine broth (Difco) and 9 ml tetrathionate broth containing brilliant green dye (Difco) (4).

Sixty 25-g pre-enrichment cultures were randomly assigned to 12 groups of five. Each of these groups was used to prepare wet composites as follows: 1 ml from each of the five pre-enrichment cultures was introduced both into 45 ml selenite broth and 45 ml tetrathionate broth. Similarly, the fifteen 100-g pre-enrichment cultures were randomized and assigned to three groups of five. Wet composites of the 100-g pre-enrichment cultures were prepared in the same manner as described above. The selenite and tetrathionate subcultures were incubated 24 h at 35C.

Id. (highlighting added).

305. Silliker states that the wet composites were then tested for the presence of *Salmonella* using "conventional biochemical and serological procedures." *Id.* at 477. Like Price, Silliker employed common laboratory practices of retaining pre-enrichment cultures for subsequent re-testing. *Id.* at 476.

306. The systems compared in Silliker included "sixty 25-g subsamples." *Id.* at 478. The co-authors concluded that "[p]ooling sixty 25-g or fifteen 100-g pre-enrichment cultures into groups of five (wet compositing) followed by selective enrichment of the composites apparently results in the same assurance of detection of positive lots as analysis of individual samples." *Id.*

307. The co-authors continued their research and published their 1974 article, referred to herein as "Gabis," in which they discussed their techniques used for dried foods as applied to "high-moisture foods, such as meats, poultry, and eggs." Ex. 1026 at 663. Thus, when meat and poultry samples were analyzed in Gabis, the co-authors built on their research reported in Silliker. *Id.* Gabis states that the "[t]he economic advantage of lumping samples is obvious; indeed, this approach makes statistical quality control over the *Salmonella* defect economically feasible, particularly for high-risk foods where analysis of as many as sixty 25-g subsamples has been recommended." *Id.*

308. Gabis indicated that testing such high-moisture foods is more problematic than dried foods because meats and poultry "are apt to contain large numbers of competing microorganisms." *Id.* at 663–64. Thus, Gabis investigated "the efficacy of lumping subsamples . . . in conjunction with the influence of preenrichment as compared to direct selective enrichment." *Id.* at 664.

309. The authors concluded that "[t]he results clearly indicate that lumping of 25-g subsamples to produce larger samples for analysis is as sensitive for the detection of positive samples as is the analysis of individual 25-g subsamples." *Id.* at 668. Thus, Gabis built upon the work of Silliker which built upon the work of Price, thereby furthering the adoption and evolution of food safety testing techniques that employ compositing.

310. Gabis describes grinding samples of meat products:

> *Sample Preparation*
>
> Meat, poultry, and casing samples were passed once through a meat grinder with a plate containing holes 8 mm in diameter. The samples were then hand mixed and reground twice through the meat grinder with a plate containing holes 3 mm in diameter. Egg samples were mixed thoroughly by hand in a 20-liter can using a large ladle. Mixing of the samples was a preliminary step to analysis to promote even distribution of contaminating organisms within the samples as received.
>
> Twenty-five-gram subsamples were then weighed from each mixed sample in sufficient number for analysis. The 25-g subsamples were randomly selected to form lumped samples as described below.

Id. at 664 (highlighting added).

311. The next step in the method of Gabis involves lumping, which is a synonym for combining and compositing, as provided in the paragraph below:

Sampling

The acceptance criteria for category III products in the NRC report (5) was followed. Products in this category are accepted if thirteen 25-g subsamples are analyzed for *Salmonella* and found negative. Accordingly, 13 of the 25-g units were used for analysis as individual subsamples. Three lumped subsamples of 108.3 g each were prepared by combining four 25-g units and weighing an additional 8.3-g subsample from one of the 25-g units. A 325-g lumped subsample was prepared by combining thirteen 25-g units. In addition, a 500-g subsample was included in view of our previous experience with the analysis of 500-g dry food samples (7). Thus for each analytical procedure, thirteen 25-g, three 108.3-g, one 325-g, and one 500-g subsamples were analyzed.

Id. (highlighting added).

312. The sampling and lumping steps described by Gabis equate to steps (a) and (b) of the IEH Patents.

313. The next step described by Gabis is pre-enrichment and direct enrichment, as provided below:

Enrichment Procedures

All samples for non-selective preenrichment were introduced into sufficient volumes of lactose broth containing 1% (v/v) Tergitol Anionic 7 (sodium heptadecyl sulfate, Union Carbide, Chicago) to obtain a 1:10 dilution of the sample (7). For direct selective enrichment, the samples were introduced into appropriate volumes of tetrathionate broth containing brilliant green dye and selenite cystine broth (7, 10). All media were obtained from Difco, Detroit, Michigan. Preenrichment and direct enrichment cultures were incubated 24 h at 35C.

Id. (highlighting added).

314. Portions of preenrichment cultures were then transferred to enrichment broths, incubated, and then tested, as provided below:

Subculturing of Enrichment Cultures

One-milliliter portions of the lactose preenrichment cultures were transferred to 9 ml of tetrathionate broth and 9 ml of selenite cystine broth, and these cultures were incubated 24 h at 35C. After incubation, the selective enrichment cultures, originating both from lactose preenrichment cultures and direct enrichment, were streaked onto brilliant green (BG), *Salmonella-Shigella* (SS), and bismuth sulfite (BS) agar plates which were then incubated at 35C. The BS and SS plates were examined after 24 h and the BS plates after 48 h.

Id. (highlighting added).

315. The pre-enrichment, wet compositing, and testing described by Gabis correspond to the main aspects of steps (c)–(e) of the IEH Patents, except that the wet compositing in Gabis involves pre-enrichment portions, not selectively enriched portions. It would be expected to preserve the pre-enriched cultures for retesting as such is common laboratory practice.

2. Jarvis

316. Jarvis discloses various methods of sampling and testing foods using composite samples for testing and teaches that composite samples "reduce the work load on the laboratory" in Section 8.4.2.1. Ex. 1027 at 141. Section 8.4.2.1 is shown below:

8.4.2.1 Compositing of samples. When a number of samples is to be tested it is sometimes recommended that the samples be composited in order to reduce the work load on the laboratory. Several methods of compositing can be undertaken:

(1) Combine all samples at pre-enrichment stage; i.e. for 10 x 25 g samples inoculate all 250 g directly into 2250 ml of pre-enrichment medium. After incubation, carry out tests on the same basis as for a single sample (i.e. inoculate 10 ml into 100 ml enrichment medium).

(2) Prepare 10 pre-enrichment series (i.e. one for each 25 g sample) and after incubation composite equal volumes of each pre-enrichment medium (e.g. 10 x 1 ml) to inoculate the 100 ml enrichment broth.

(3) A combination of (1) and (2) above where, say, 5 samples are composited at pre-enrichment stage and aliquots of the duplicate pre-enrichment media are composited at the stage of inoculating the enrichment medium.

(4) Composite all 10 samples and then test one (or rarely two) 25 g aliquots from the bulk composited samples.

Methods (1), (2) and (3) provide the same degree of statistical confidence as would be attained by testing the 10 samples separately, in so far as a negative result indicates no sample contamination and therefore < 11 organisms/kg (at $P = 0.95$). However, if a positive result is obtained, it is not possible to estimate (even approximately) the degree of contamination. Method (2), at least in theory, permits the tests to be repeated on stored pre-enrichment cultures so that some indication of the proportion of contaminated samples can be obtained. Method (3) is a compromise between Methods (1) and (2).

Method (4) is based on a fallacious concept, since by compositing the original sample and testing only one aliquot of the composite sample, the results will provide no more information about the lot than would testing of a single sample of, say, 25 g. It is totally incorrect to interpret a negative result as indicating (at $P = 0.95$) a maximum contamination level of 11 organisms/kg, which would have been given by 10 negative results.

Id.

317. According to method (2) in Section 8.4.2.1 above "[p]repare 10 pre-enrichment series (i.e. one for each 25 g sample) and after incubation composite equal volumes of each pre-enrichment medium (e.g. 10 x 1 ml to inoculate the 100

ml enrichment broth." *Id.* Jarvis concludes that the method provides "the same degree of statistical confidence as would be attained by testing the 10 samples separately." *Id.* Jarvis identifies the advantage of this method as permitting "the tests to be repeated on stored pre-enrichment cultures so that some indication of the proportion of contaminated samples can be obtained." *Id.* at 141–42. Thus, Jarvis teaches that a negative test result on the wet composite validates all of the samples and re-testing of the separate samples in the event of a positive test result for the wet composite. Accordingly, Jarvis taught the elements of steps (d) and (e) of the IEH Patents but with pre-enrichments not selective enrichments.

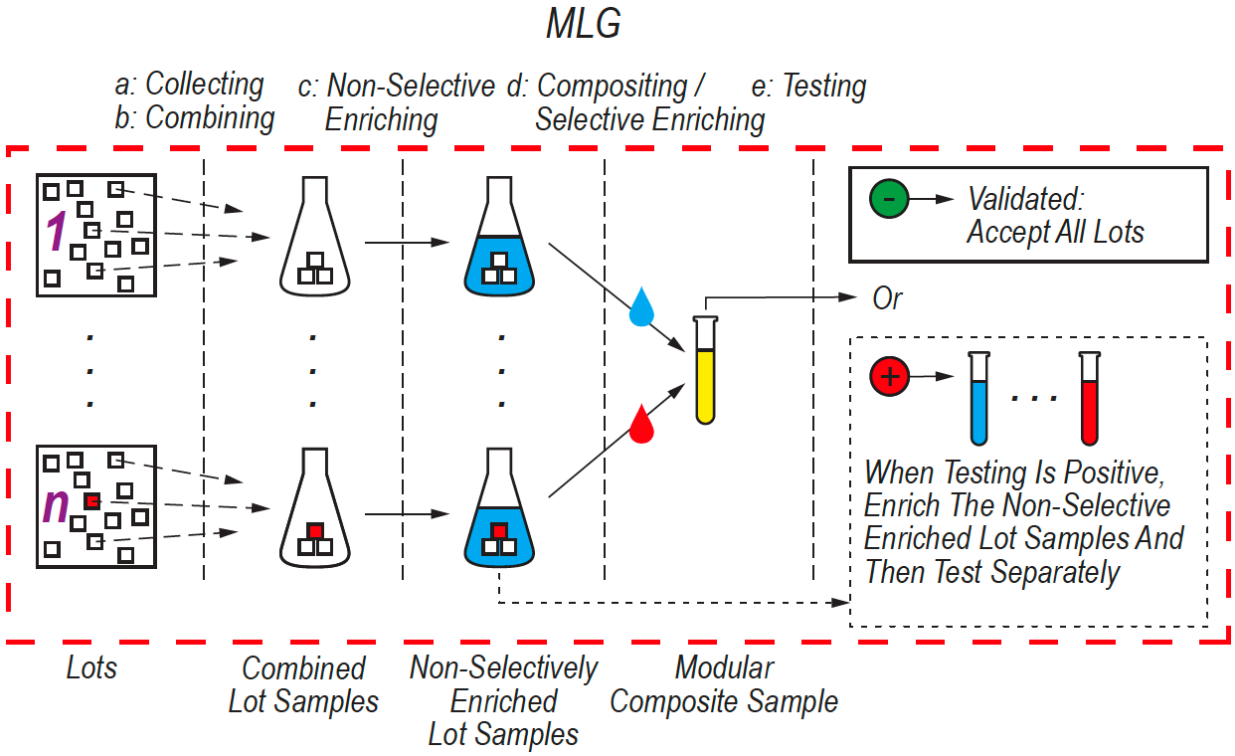
3. MLG

318. The Microbiology Laboratory Guidebook ("MLG") "contains protocols for analytical tests required by FSIS regulatory activities on meat and poultry products. Specifically, microbiological methods are presented for sample preparation, isolation and identification of the major foodborne pathogenic microorganisms." Ex. 1028 at 1. The MLG is a multi-chaptered document that is the FSIS's equivalent to the FDA's Bacteriological Analytical Manual ("BAM").

319. Even though AAPA #1, #2, and #6 describe sampling plans in FSIS guidelines, which is MLG, IEH failed to cite any MLG content during prosecution. *See* §§ V-A-1-a, V-A-1-b, and V-A-1-f, *supra*. IEH included Chapter 5.03 as an

appendix to the Second Samadpour Declaration during reexamination. Ex. 1007 at 660–674.

320. Exhibit 1028 consists of portions of a 2003 version of MLG, referred to herein as "MLG 2003" or simply "MLG," including chapters 4.02, 5.03, and 8.03, which respectively relate to *Salmonella*, *E. coli*, and *Listeria*. As shown below MLG 2003 provides a framework for two-stage compositing but does so with pre-enrichments not selective enrichments. *See, e.g.,* Ex. 1028 at 14–15. However, the description of two-stage compositing in a widely used guidebook such as MLG indicates that two-stage compositing had industry acceptance before the priority date.



a. Chapter 4.02 — *Salmonella*

321. Chapter 4.02 includes a description of procedures for *Salmonella* detection in various types of foods including ready-to-eat (RTE) foods at Section 4.5.3 and raw meat at Section 4.5.5. Both sections are reproduced below in their entirety:

> **4.5.3 Ready-to-Eat Foods**
>
> Follow program requirements for preparing sample and sub-sample composites. Outbreak investigation requirements may differ, in which case, follow the client specifications for those samples.
>
> a. Weigh 325 g of the composite sample into a Stomacher bag (or sterile blender jar if required by the client or sample type).
>
> b. Add approximately one third to half of 2925 ml of ambient temperature sterile buffered peptone water. Blend or stomach approximately 2 minutes, and then add the remainder of the 2925 ml of BPW.
>
> c. Incubate at 35 ± 1°C for 20-24 h.
>
> d. Transfer 0.5 ± 0.05 ml of incubated broth into 10 ml TT and 0.1 ± 0.02 ml into 10 ml of mRV broth.
>
> e. Incubate the enrichment broths at 42 ± 0.5°C for 22-24 h, or in a water bath at 42 ± 0.5°C for 18-24 h.
>
> f. Streak above enrichments on BGS and either DMLIA or XLT4 agar plates. Use one 10-microliter loopful for each plate. Do not subdivide plates for streaking multiple samples; streak the entire agar plate with a single sample enrichment.
>
> g. Incubate at 35 ± 1°C.
>
> h. Examine in 18-24 h. Select colonies. Refer to Section 4.6 et seq.
>
> i. Re-incubate all plates for an additional 18-24 h. Reexamine initially negative plates and pick colonies as above. Reserve, under refrigeration, all plates from which colonies were picked. If suspect *Salmonella* colonies do not confirm, reexamine the plates from which they were picked, and if appropriate, re-pick colonies for confirmation. See Section 4.6.1.b.

Id. at 15–16 (highlighting added).

4.5.5 Raw Meat

If the sample is not already ground, in some cases it may be best to mince it with scissors or leave it whole (e.g. chicken wings) to avoid jamming blender blades with skin or connective tissue. Whirl-Pak™ bags can be used in culturing these samples.

a. Weigh 25 ± 0.5g of meat into a sterile blender jar, other sterile jar or a Whirl-Pak™ or Stomacher™ bag. HACCP program samples collected using a sampling ring are allowed a weight range of 25 ± 2.5 g.

b. Add 225 ml of BPW. Stomach or blend, as required, for approximately two minutes or shake thoroughly.

c. Incubate at 35 ± 1°C for 20-24 h.

d. Transfer 0.5 ± 0.05 ml into 10 ml TT broth and 0.1 ± 0.02 ml into 10 ml mRV broth.

e. Incubate at 42 ± 0.5°C for 22-24 h.

f. Streak on DMLIA or XLT4 and BGS agar plates. Use one loopful of inoculum for each plate. Do not subdivide plates for streaking multiple samples; streak the entire agar plate with a single sample enrichment.

g. Incubate at 35 ± 1°C.

h. Examine in 18-24 h. Select colonies. See Section 4.6 et seq.

i. Re-incubate all plates for an additional 18-24 h. Reexamine initially negative plates and pick colonies as above. Reserve, under refrigeration, all plates from which colonies were picked. If suspect *Salmonella* colonies do not confirm, reexamine the plates from which they were picked, and if appropriate, re-pick colonies for confirmation. See Section 4.6.1.b.

Id. at 17 (highlighting added).

322. Both sections describe forming a composite sample; adding buffered peptone water ("BPW") as a non-selective enrichment and incubating; transferring the incubated broth into TT broth and modified Rappaport Vassiliadis ("mRV") broth, which are selective enrichment broths then incubating; and testing the enrichments by streaking on agar plates. *Id.* at 15–17.

323. The entirety of MLG's Section 4.5.1, which is titled "Sample Pooling," is provided here:

> **4.5 Isolation Procedures**
>
> **4.5.1 Sample Pooling**
>
> NOTE: Follow sample pooling instructions in specific program protocols. Otherwise, do not use sample pooling.
>
> When examining products that are expected to be *Salmonella*-free, sample pooling can save valuable time, labor and materials. There are several ways this can be done. Pooling at the non-selective enrichment step is appropriate when the likelihood of finding *Salmonella* is unlikely or when, if a positive is found, it is not important to know which particular sample contained the organism.
>
> a. Those samples that are to be examined only for *Salmonella* may be pooled in the blenders. Up to 30 samples may be combined, depending on the capacity of the blenders and culture flasks. The proportions of sample volume to BPW must be maintained at the 1 to 10 ratio (1 part sample to 9 parts BPW). The BPW should be pre-warmed to the temperature of incubation.
>
> b. When food homogenates (Section 4.5.9) are pooled, the culture flask should be warmed in a water bath to bring the contents up to incubation temperature before placing it in the incubator.
>
> c. Incubation of large pools should be prolonged to two days if growth is not apparent in one day. Subculture 5 ± 0.5 ml of the incubated non-selective broth pool into 100 ±1 ml of TT (Hajna), 1 ± 0.1 ml into 100 ± 1 ml of mRV, and proceed as usual.
>
> In cases in which it is important to identify particular samples that may contain *Salmonellae*, it is still possible to take advantage of labor-saving by pooling. In such cases, the samples may be started in the usual way in non-selective broth. After incubation, up to ten of these cultures may be pooled in selective enrichment broth. Maintain the 0.5 to 10 ratio for inoculation of TT broth and the 0.1 to 10 ratio for inoculation of mRV broth. The remaining non-selective broths (or portions of them) are refrigerated. The total volume of selective enrichment broth used will be the same, but the number of plates to be streaked is reduced. If a positive pool is found, all the pooled samples are started individually in selective enrichment broth by going back to the refrigerated non-selective broths.

Id. at 14–15 (highlighting added).

324. Section 4.5.1 extols the benefits of sample pooling as "sav[ing] valuable time, labor, and materials." *Id.* at 14. It also guides users to retain a portion of "[t]he **remaining** non-selective broths" such that "[i]f a **positive** pool is found, all the

pooled samples **are started individually in selective enrichment broth** by going back to the refrigerated non-selective broths." *Id.* at 15 (emphasis added).

b. Chapter 5.03 — *E. Coli*

325. Chapter 5.03 includes a description of procedures for *E. coli* detection in various types of foods including raw beef. Section 5.5 titled "Detection Procedure" is shown below in its entirety:

5.5 Detection Procedure

a. Sample Preparation

i. Raw ground beef microbiological testing programs.
Randomly collect five 65 ± 2 g sub-samples (total of 325 ± 10 g) that are representative of the entire sample. Place each 65 ± 2 g sub-sample in a sterile Strainer Stomacher™ bag. Add 585 ml mEC+n broth and pummel for two minutes in a Stomacher™.

b. Incubate all bags (static) with their contents for 20 to 24 h at 35 ± 2°C. Include a positive, negative, and uninoculated medium control for each group of samples tested. Use the fluorescent *E. coli* O157:H7 strain (FSIS culture # EC 465-97) as a positive control and *E. coli* ATCC strain 25922 as the negative control.

c. From the enrichment cultures in the Stomacher™ bags, perform the screening test for *E. coli* O157:H7/NM following the manufacturer's instructions. The enrichment culture may be analyzed immediately upon removal from the incubator without waiting for tempering to room temperature. To prevent clogging the pipette tip, be sure to collect the appropriate size sample from the enrichment culture outside the inner strainer bag.

d. Samples negative by the screening test can be reported as negative for *E. coli* O157:H7/NM and discarded.

e. Samples positive by the screening test should be reported as potential positives. Begin isolation procedures from the enrichment culture in the Stomacher™ bag.

Id. at 31–32 (highlighting added). Section 5.5 describes collecting sub-samples that are representative of the entire sample of beef. *Id.* at 31. The sub-samples are

uniformly dispersed in a non-selective broth pool, modified EC broth with novobiocin ("mEC+n") and incubated. *Id.* at 31–32. From the enrichment cultures, a screening test is conducted. *Id.* at 32.

326. Chapter 5.03 includes detailed information about steps to be taken to confirm a positive sample, as summarized in Section 5.1 as shown below:

> **5.1 Introduction**
>
> **5.1.1 General**
>
> The following method is used for the analysis of raw and ready-to-eat meat products for *Escherichia coli* O157:H7 and O157:NM (O157:H7/NM). The method is based on enrichment in a selective broth medium, application of a rapid screening test, immunomagnetic separation (IMS) in paramagnetic columns, and plating on a highly selective medium.
>
> The following definitions are used for reporting purposes. A potential positive sample causes a positive reaction on the screen test kit. A presumptive positive sample has typical colonies, observed on Rainbow Agar, and reacts specifically with O157 antiserum. A sample is a confirmed positive sample for E.coli O157:H7 or E. coli O157:NM when the isolate is confirmed biochemically and serologically, and the presence of Shiga toxin(s) or Shiga toxin gene(s) is demonstrated.

Id. at 27 (highlighting added).

c. Chapter 8.03 — *Listeria*

327. Chapter 8.03 includes a description of procedures for *Listeria* detection in various types of foods including chicken and beef. Section 8.5.1 titled "Sample Preparation" is shown below in its entirety:

8.5.1 Sample preparation

a. Meat, poultry and egg products: A 25 ± 1.0 g portion is used for raw and processed red meat, poultry and egg product testing. The test portion should be a composite representative of the entire sample or available samples common to a specific lot.

i. Intact retail packages must be disinfected at the incision sites immediately prior to incision for sampling. Appropriate disinfectants include but are not limited to ca. 3% hydrogen peroxide, ca. 70% ethanol or ca. 70% isopropanol. If the package does not appear to be clean, scrub gently using soapy water and rinse thoroughly prior to disinfection. A sterile scalpel may be helpful for cutting the packaging. Aseptically pull the packaging away to expose the product for sampling.

ii. Using a sterile scalpel, knife, spoon, chisel or other tool cut small pieces from representative sites on the sample and/or a variety of same-lot samples to prepare a composite sample.

iii. Place 25 ± 1.0 g of the composite sample in a sterile Stomacher™ bag (i.e. filter bag recommended). If necessary, double-bag with a non-filter bag prior to stomaching (e.g. zip-lock bag).

iv. If analysis of the test portion is not to be initiated within 1 h, store at ≤ -10°C. Do not dilute the sample until ready to initiate analysis.

v. For analysis, proceed to Section 8.5.2.

b. Outbreak/recall samples: Some samples or sample lots, particularly those implicated in foodborne illness outbreaks, may require analysis of up to thirteen 25 g test portions. The test portion should be a composite representative of the entire sample or available samples common to a specific lot. The need for multiple subsample analyses must be determined on a case-by-case basis, or by client requirements.

Id. at 46–47 (highlighting added).

328. After collecting sub-samples from a specific lot and combining the subsamples, the lot samples are dispersed in a non-selective broth pool, modified

University of Vermont broth ("UVM"), and then incubated to yield a homogenate as described at Section 8.5.2 shown below:

8.5.2 Primary Enrichment in UVM broth

a. For all meat, poultry and egg product samples (including outbreak/recall samples):

To the 25 ± 1.0 g test portion, dispense 225 ± 5 ml (or 225 ± 5 g) of UVM broth. Stomach or blend for 2 ± 0.2 minutes. If blended, aseptically transfer the homogenate to an appropriate sterile container. Incubate the homogenate at 30 ± 2°C for 22 ± 2 h. Proceed to Section 8.5.3.

Id. at 47–48 (highlighting added).

329. The UVM enrichment is then transferred to a selective enrichment broth, Fraser broth ("FB"), as described at Section 8.5.3, which is as shown below in the highlighted text here:

8.5.3 Secondary Enrichment in FB and Direct Plating of UVM

a. Transfer 0.1 ± 0.02 ml of the UVM enrichment to 10 ± 0.5 ml of FB. As per media preparation instructions, be sure that appropriate supplements have been added to the FB prior to inoculation. Incubate inoculated FB tubes at 35 ± 2°C for 26 ± 2 h.

b. Streak a MOX plate. Streak a loopful or a drop approximating 0.1 ml of the UVM over the surface of the plate. Alternatively, dip a sterile cotton-tipped applicator or equivalent into the UVM and swab 25-50% of the surface of a MOX plate. Use a loop to streak for isolation from the swabbed area onto the remainder of the plate. Incubate the MOX at 35 ± 2°C for 26 ± 2 h.

Id. at 48–49 (highlighting added). After selective enrichment, testing is performed for *Listeria*. *Id.* at 49–57.

XI. CLAIM CONSTRUCTION

A. Standard

330. In my analysis below, I apply the standard discussed *supra* at III-A to the words and phrases of the claims of the IEH Patents, unless otherwise stated. I also offer my opinions on some of the terms used in these claims. My opinions are provided for the purposes of these petitions only.

B. Construed Terms

1. Lots

331. Step (a) of each of independent claims of the IEH Patents recites "collecting" from "lots" as presented by the tables below.

Step (a) of the First Independent Claims		
Claim 1 of the '584 Patent	Claim 1 of the '143 Patent	Claim 1 of the '771 Patent
collecting a plurality of portions from each of a plurality of	separately **collecting** multiple independent samples from each of multiple	
separate operationally-linked **test lots** of beef,	separate **test lots**,	separate **lots**,

Step (a) of the Second Independent Claims		
Claim 17 of the '584 Patent	Claim 35 of the '143 Patent	Claim 37 of the '771 Patent
collecting a plurality of portions from each of a plurality of	separately **collecting** multiple independent samples from each of multiple	
operationally-linked **single-unit production lots** of meat or poultry,	**single-unit production lots**	**single production lots**

332. The above tables show that the IEH Patents use various terms to describe "lots" including test lots, single production lots, and single-unit production lots. Test lots, single production lots, and single-unit production lots are all types of "lots."

333. The IEH Patents define the term "test lot" as provided below:

> Definitions
>
> The term "test lot" or "reportable lot" as used herein to refer to an assemblage of one or more specimens of a medium or process (e.g., assemblage of specimens of air, water, solids, or of products of a production process, etc.), where such assemblage can be sampled by taking portions of the one or more specimens thereof, and where the one or more specimens of the assemblage are operationally linked in a manner (e.g., proximity, time, process step, etc.) whereby information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot. In particular instances, portions are synonymous with specimens.

Ex. 1001 at 5:21–32; Ex. 1002 at 5:34–45; Ex. 1003 at 5:43–54 (highlighting added). Based on the quoted section, a test lot is "as an assemblage of one or more specimens" that are "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 test lot." This same definition applies to a "lot" because there is no difference between a lot and a test lot.

334. This definition corresponds with the definition that the Board previously used in the reexamination, as shown below:

The following selected claim terms are defined as follows in the '584 patent disclosure:

Test lot or reportable lot: an assemblage of one or more specimens of an operationally linked medium or process (column 5, lines 21-32).

Product portion: piece, aliquot or weight of a product (column 5, lines 38-49).

Test lot sample (or single-unit production lot sample or single production unit lot sample): a sample formed by combining multiple product portions from a test lot (column 5, line 57, through column 6, line 6).

Enrichment: incubating a test lot sample under conditions suitable to allow levels of a target agent or organism to reach detectable levels (see column 6, lines 7-16).

Enrichment medium: mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism (column 6, lines 17-35).

Modular composite sample: a larger sample formed from combining equal portions of a plurality of enriched single-unit production lot samples (column 6, lines 57-61).

Validation: determining that a particular sample tests negative using a detection assay (column 7, lines 1-10). When a modular composite sample tests negative, all single unit production lot samples are validated.

Ex. 1007 at 184 (Office Action dated May 26, 2010 at 5).

335. During reexamination, claims 1 and 17 of the '584 Patent were amended to recite that lots are "operationally-linked." IEH stated that these amendments were made to "clarify that the test lots, while separate, are nonetheless operationally-linked during a production run." *Id.* at 1686 (Patent Owner's Response of February 20, 2015 at 9). However, the addition of the term "operationally-linked" does not change the meaning because the term is included in the definition of "test lots."

336. As shown in the above tables, in addition to the terms "lots" and "test lots," the independent claims of the IEH Patents also recite "single production lots" and "single-unit production lots." However, the IEH Patents indicate that "single

production lots" and "single-unit production lots" are examples of test lots as shown by the highlighted text in the two excerpts reproduced below:

> The term "single production unit" or "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") rather than, as in the prior art, to a composite comprised of multiple, non-operationally linked single production units (production sublots).

Ex. 1001 at 5:33–38; Ex. 1002 at 5:46–51; Ex. 1003 at 5:55–60 (highlighting added).

> Therefore, according to particular aspects, 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.), or a single environmental sample (e.g., single air sample, single water and wastewater sample, etc.), rather than, as in the prior art, as a composite of multiple production units or environmental samples.

Ex. 1001 at 7:28–36; Ex. 1002 at 7:42–50; Ex. 1003 at 7:54–63 (highlighting added).

337. These quotes reflect the way these terms are commonly used to refer to types of "test lots" or more generically, "lots."

338. Based on the above quotes, examples of a single production lot and a single-unit production lots, which are examples of a test lot, include "for beef trim a 'combo,' or for almonds a 'bin.'" Ex. 1001 at 5:35, 36; Ex. 1002 at 5:48, 49; Ex. 1003 at 5:57, 58. Other examples, include "a single combo, bin, pallet, or segment of production, etc.)." Ex. 1001 at 7:31–33; Ex. 1002 at 7:46, 47; Ex. 1003 at 7:58, 59.

339. An additional example is provided in the highlighted text of the excerpt reproduced below:

> According to particular aspects of the present invention the producer of RTE meat or poultry products collects samples from individual single-unit production lots. Preferably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), 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.

Ex. 1001 at 12:49–55; Ex. 1002 at 12:57–61; Ex. 1003 at 13:17–22 (highlighting added). In this example, the lot includes "the product produced by a particular production line," or various subsets based on time, volume, and/or location. These subsets include the product "produced by a particular production line in a particular period of time" and "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." *Id.*

340. The excerpt reproduced in the preceding paragraph includes a statement indicating that "the producer defines and produces these single-unit lots." Ex. 1001 at 12:46–47; Ex. 1002 at 12:52–53; Ex. 1003 at 13:13.

> According to particular aspects of the present invention the producer of RTE meat or poultry products collects samples from individual single-unit production lots. Preferably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), 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.

Ex. 1001 at 12:44–55; Ex. 1002 at 12:50–61; Ex. 1003 at 13:10–23 (highlighting added). The IEH Patents reflect the common self-management approach accepted in the industry of allowing producers to define the scope and content of a lot for reporting, accounting, and traceability purposes. In other words, a producer defines what is a lot and what is the size of the lot.

2. Separately Sampled

341. Step (a) of each of the IEH Patents recites "collecting" from "lots" that are "separately sampled," as presented by the tables below.

<table>
<tr><th colspan="3">Step (a) of the First Independent Claims</th></tr>
<tr><th>Claim 1 of the '584 Patent</th><th>Claim 1 of the '143 Patent</th><th>Claim 1 of the '771 Patent</th></tr>
<tr><td>collecting a plurality of portions from each of a plurality of</td><td colspan="2">separately collecting multiple independent samples from each of multiple</td></tr>
<tr><td>separate operationally-linked test lots of beef, . . . ,</td><td>separate test lots,</td><td>separate lots,</td></tr>
</table>

wherein each test lot	wherein each separate test lot	wherein each separate lot
is **separately sampled** . . . ;		

Step (a) of the Second Independent Claims		
Claim 17 of the ’584 Patent	Claim 35 of the ’143 Patent	Claim 37 of the ’771 Patent
collecting a plurality of portions from each of a plurality of	separately **collecting** multiple independent samples from each of multiple	
operationally-linked **single-unit production lots** of meat or poultry, . . . ,	separate **single-unit production lots,**	separate **single production lots**
wherein each single-unit production lot	wherein each separate single-unit production lot	wherein each separate single production lot
is **separately sampled** . . . ;		

342. These phrases from the claims indicate, especially when viewed in the context of other claim limitations that clearly require traceability or attributability such that a contaminated lot is easily identified, that when collecting the portions from the lots, it is done so such that each lot is separately sampled.

343. This interpretation is also supported by the specification as shown by the highlighted text in the two excerpts shown below:

> Particular aspect provide a method of sampling, testing and validating test lots, comprising: separately collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more operationally-linked specimens, wherein the assemblage can be sampled by taking portions thereof; combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot;

Ex. 1001 at 9:7–16; Ex. 1002 at 9:21–29; Ex. 1003 at 9:36–45 (highlighting added).

> Definitions
>
> The term "test lot" or "reportable lot" as used herein to refer to an assemblage of one or more specimens of a medium or process (e.g., assemblage of specimens of air, water, solids, or of products of a production process, etc.), where such assemblage can be sampled by taking portions of the one or more specimens thereof, and where the one or more specimens of the assemblage are operationally linked in a manner (e.g., proximity, time, process step, etc.) whereby information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot. In particular instances, portions are synonymous with specimens.

Ex. 1001 at 5:21–32; Ex. 1002 at 5:34–45; Ex. 1003 at 5:43–54 (highlighting added). These quotes establish that traceability to a lot is critical such that information from a test lot sample may be attributed to a particular lot. On this basis, the specification also indicates that in addition to collecting the portions from lots, it is done so such that each lot is separately sampled.

344. It is a well understood principle that when collecting sub-sample units (i.e., portions/samples) from a lot, the sampling is conducted such that the resulting test

lot sample is representative of the lot being sampled. Thus, the excerpt reproduced below includes a statement indicating that "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." Ex. 1001 at 5:52–56; Ex. 1002 at 5:65–6:2; Ex. 1003 at 6:7–11.

> The term "compositing" as used herein refers to combining a number of single product portions to form one larger sample. In preferred embodiments, 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.

Ex. 1001 at 5:50–56; Ex. 1002 at 5:63–6:2; Ex. 1003 at 6:5–11 (highlighting added). Based on the foregoing, "collecting such that a lot is separately sampled" necessarily means that collecting results in the test lot sample being representative of the lot being sampled.

345. Another well understood principle is that randomly collecting the sub-sample units (i.e., portions/samples) from a lot ensures a test lot sample is representative of the lot being sampled. Randomness may be achieved by varying time, location, or both for collecting sub-sample units as respectively exemplified by Examples III, I, and II of the specification of the IEH Patents.

346. Example III obtains a representative sample by collecting sub-sample units at random times over a production shift, as indicated by the excerpt shown below:

> In such embodiments, final almond products of each type are collected at random times over a production shift. The producer defines and establishes individual single-unit production lots as the amount of product produced during a production shift (from 'cleanup to cleanup'), or as some smaller production unit (e.g., a 'truckload'), provided that one sample was collected from each such single-unit production lot. The single-unit production lot samples are combined to form a corresponding composite sample,

Ex. 1001 at 13:49–62; Ex. 1002 at 13:56–14:2; Ex. 1003 at 14:12–30 (highlighting added).

347. Example I describes a typical production lot of beef that includes five combos, each weighing about 2,000 pounds, as indicated by the excerpt shown below:

> At present, the standard size 'production lot' for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five combos, where each combo represents a single production unit and weighs approximately 2,000 pounds.

Ex. 1001 at 11:12–16; Ex. 1002 at 11:18–22; Ex. 1003 at 11:37–41 (highlighting added). While Example I does not specifically mention collecting sub-sample units from different locations of a lot, that was the well-known practice at the time of the priority date. Of course, it was also known to avoid collecting samples from the same location because the sampling needs to be representative of the lot.

348. Example II obtains a representative sample using randomness of two variables—time and location, because it states "samples are collected at random

times over a production shift (e.g., from 'cleanup to cleanup'), and from several product lines," as indicated by the highlighted text in the excerpt shown below:

> Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may adapt an 'end product' sampling program as verification that their product is free of the pathogen *Listeria monocytogenes*. The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (e.g., from 'cleanup to cleanup'), and from several product lines.

Ex. 1001 at 12:28–38; Ex. 1002 at 12:35–44; Ex. 1003 at 12:62–13:4 (highlighting added).

349. It should also be noted that step 1(a) of the '584 Patent explicitly states that test lots comprise "an assemblage of one or more specimens" from which "a plurality of portions" are "separately sampled." The specification states that "[i]n particular instances, portions are synonymous with specimens"; however, this statement does not apply to step 1(a) of the '584 Patent because step 1(a) recites "specimens from which the portions are collected." Thus, all "portions" are "specimens," but in the context of step 1(a) of the '584 Patent not all "specimens" are "portions."

3. Combining/Compositing

350. Step (b) of each of the IEH Patents recites "combining"/"compositing" "portions"/"samples" to provide a corresponding set of separate "lot samples," as shown by the tables below.

Step (b) of the First Independent Claims		
Claim 1 of the ’584 Patent	Claim 1 of the ’143 Patent	Claim 1 of the ’771 Patent
combining the collected conforming plurality of portions corresponding to	separately **compositing** the collected multiple independent samples from	
each of the separate		
test lots		lots
to provide a corresponding set of separate		
test lot samples . . . ;	composited test lot samples . . . ;	composited lot samples . . . ;

Step (b) of the Second Independent Claims		
Claim 17 of the ’584 Patent	Claim 35 of the ’143 Patent	Claim 37 of the ’771 Patent
combining the collected conforming plurality of product portions corresponding to	separately **compositing** the collected multiple independent samples from	
each of the separate		
single-unit production lots	test lots	lots
to provide a corresponding set of separate		
single-unit production lot samples . . . ;	composited single-unit production lot samples . . . ;	composited single production lot samples . . . ;

351. The IEH Patents state that “compositing” refers to “combining a number of single product portions to form one larger sample.” Ex. 1001 at 5:50–52; Ex. 1002 at 5:63–65; Ex. 1003 at 6:5–7. Based on the foregoing, step (b) of the claims use “combining” and “compositing” interchangeably as synonyms. The same is true for “portions” and “samples” in step (b) across the IEH Patents—they mean the same

thing because they are both ultimately combined/composited to provide corresponding "lot samples."

4. Enrichment/Enriching

352. Step (c) of the '584 Patent recites "enriched." Step (c) of the Continuation Patents recites "enriching." The term "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. 1001 at 6:7–12; Ex. 1002 at 6:21–26; Ex. 1003 at 6:30–36. A similar definition was used in the reexamination, as shown below:

> The following selected claim terms are defined as follows in the '584 patent disclosure:
>
> Test lot or reportable lot: an assemblage of one or more specimens of an operationally linked medium or process (column 5, lines 21-32).
>
> Product portion: piece, aliquot or weight of a product (column 5, lines 38-49).
>
> Test lot sample (or single-unit production lot sample or single production unit lot sample): a sample formed by combining multiple product portions from a test lot (column 5, line 57, through column 6, line 6).
>
> Enrichment: incubating a test lot sample under conditions suitable to allow levels of a target agent or organism to reach detectable levels (see column 6, lines 7-16).
>
> Enrichment medium: mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism (column 6, lines 17-35).
>
> Modular composite sample: a larger sample formed from combining equal portions of a plurality of enriched single-unit production lot samples (column 6, lines 57-61).
>
> Validation: determining that a particular sample tests negative using a detection assay (column 7, lines 1-10). When a modular composite sample tests negative, all single unit production lot samples are validated.

Ex. 1007 at 184 (Office Action dated May 26, 2010 at 5) (highlighting added).

5. Validated

353. Step (e) of each of the independent claims of the IEH Patents recites "validated." The term "validation" is defined as "determining that a particular sample tests negative using the detection assay." Ex. 1001 at 7:1–3; Ex. 1002 at 7:15–17; Ex. 1003 at 7:27–29. A similar definition was utilized in the reexamination, as shown below:

> The following selected claim terms are defined as follows in the '584 patent disclosure:
>
> Test lot or reportable lot: an assemblage of one or more specimens of an operationally linked medium or process (column 5, lines 21-32).
>
> Product portion: piece, aliquot or weight of a product (column 5, lines 38-49).
>
> Test lot sample (or single-unit production lot sample or single production unit lot sample): a sample formed by combining multiple product portions from a test lot (column 5, line 57, through column 6, line 6).
>
> Enrichment: incubating a test lot sample under conditions suitable to allow levels of a target agent or organism to reach detectable levels (see column 6, lines 7-16).
>
> Enrichment medium: mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism (column 6, lines 17-35).
>
> Modular composite sample: a larger sample formed from combining equal portions of a plurality of enriched single-unit production lot samples (column 6, lines 57-61).
>
> Validation: determining that a particular sample tests negative using a detection assay (column 7, lines 1-10). When a modular composite sample tests negative, all single unit production lot samples are validated.

Ex. 1007 at 184 (Office Action dated May 26, 2010 at 5) (highlighting added).

354. In the reexamination, the phrase "releasing into commerce" was "not considered to limit the claim," as indicated by the excerpt below:

Validated for release into commerce

Step e) of claims 1 and 17 involve testing using a suitable detection assay, and "when such testing is negative all of said separate single-unit production lot samples are validated for release into commerce." Because the '584 patent does not define "validate" to require a physical or manipulative step, but rather only involves a "determin[ation] that a particular sample tests negative using the detection assay" ('584 patent, col. 7, ll. 1-10), we construe it broadly to encompass a mental step or process that does not limit the claim because it is not translated into a physical act in the claim. Appreciating that such samples may be released into commerce does not change how the claim is carried out and is thus not considered to limit the claim. See *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377–79 (Fed. Cir. 2005).

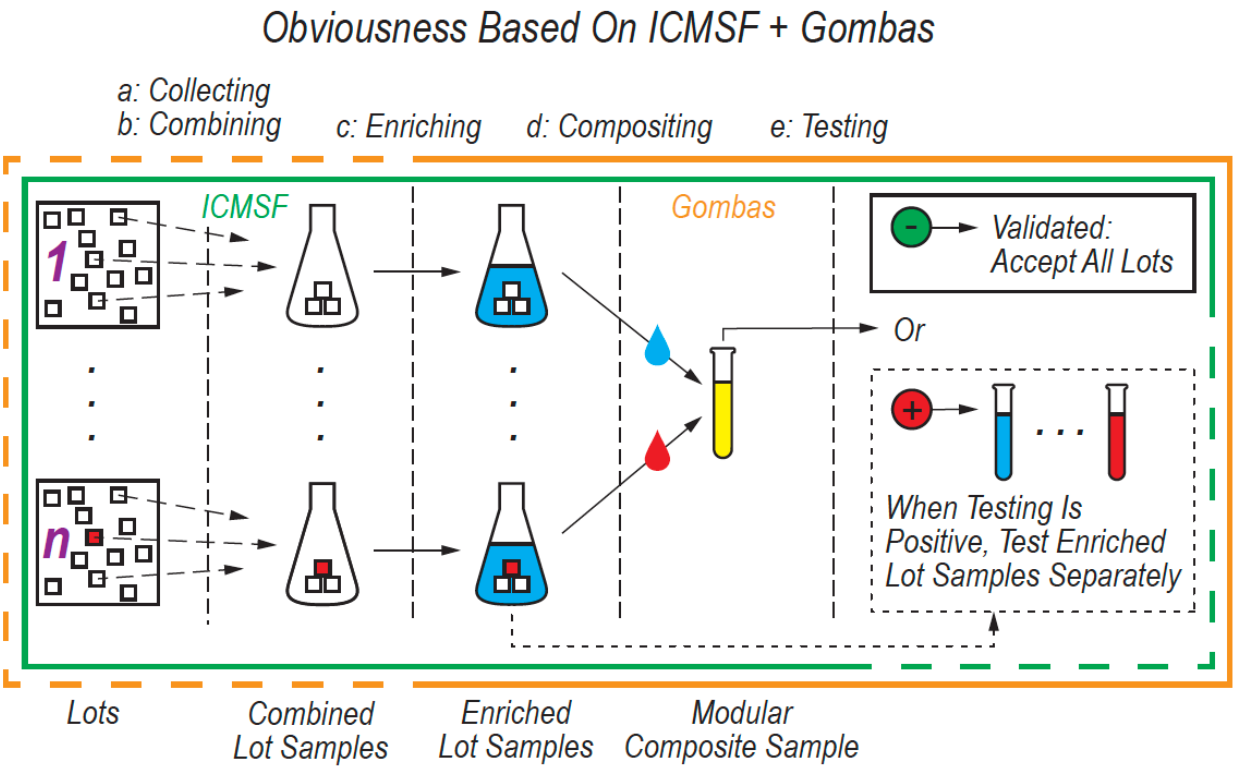
Ex. 1007 at 1568–69 (First Board Decision at 9–10) (highlighting added).

XII. PATENTABILITY

355. In my analysis below, I apply the standard discussed above at III-E to the words and phrases of the claims of the IEH Patents, unless otherwise stated. My opinions are provided for the purposes of these petitions only.

A. Ground 1 Combination of ICMSF and Gombas

356. ICMSF discloses the same procedure claimed in IEH's independent claims but lacks an explicit teaching for testing retained samples after a positive test even though such would have been well-understood by a POSA. Gombas is relied on primarily for disclosing steps (c)–(e) but a POSA would understand it to disclose more. The combination of ICMSF and Gombas is depicted below.



1. Independent Claims

a. Preamble

357. Each preamble for claim 1 for each of the IEH Patents is listed below.

Preambles of the First Independent Claims		
Claim 1 of '584 Pat.	Claim 1 of '143 Pat.	Claim 1 of '771 Pat.
A method of sampling, testing and validating a plurality of operationally-linked	A method of sampling and testing	A method of sampling and testing
	for microbes in multiple separate	products for microbes in multiple separate
test lots of beef for release into commerce,	test lots,	lots,
comprising:		

358. Each preamble for the second independent claims in each of the IEH Patents is listed below.

Preambles of the Second Independent Claims		
Claim 17 of ’584 Pat.	Claim 35 of’143 Pat.	Claim 37 of ’771 Pat.
A method of sampling, testing and validating a plurality of operationally-linked	A method of sampling, and	A method of sampling and
	testing for microbe(s) in multiple separate	testing products for microbe(s) in multiple separate
test lots of meat or poultry for release into commerce,	test lots,	lots,
comprising:		

359. Every aspect of these preambles is taught by the combination of ICMSF and Gombas as described below. To avoid repetition, the teachings related to the preambles are discussed below with reference to claim steps (a) and steps (e)(1)–(e)(4). *See* §§ XII-A-1-b and XII-A-1-f to XII-A-1-i *infra*.

b. Step (a) — Collecting

360. Each step (a) for claim 1 for each of the IEH Patents is listed below.

Step (a) of the First Independent Claims		
Claim 1 of the ’584 Patent	Claim 1 of’143 Pat.	Claim 1 of’771 Pat.
collecting a plurality of portions	separately collecting multiple independent samples	
from each of a plurality of separate	from each of multiple separate	
operationally-linked test lots of beef,	test lots,	lots,

each to be validated for release into commerce, the test lots each comprising an assemblage of one or more specimens from which the portions are collected,		
wherein each test lot	wherein each separate test lot	wherein each separate lot
is separately sampled		
to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the test lot into commerce;	by taking said multiple independent samples thereof;	

361. Each step (a) for the second independent claim of each of the IEH Patents is listed below.

Step (a) of the Second Independent Claims		
Claim 17 of the ’584 Pat.	Claim 35 of ’143 Pat.	Claim 37 of ’771 Pat.
collecting a plurality of portions	separately collecting multiple independent samples	
from each of a plurality of	from each of multiple separate	
operationally-linked single-unit production lots of meat or poultry,	single-unit production lots	single production lots
the single-unit production lots each comprising an assemblage of one or more production specimens from which the portions are collected,		
wherein each		

single-unit production lot	separate single-unit production lot	separate single production lot
is separately sampled		
to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the single-unit production lot into commerce;	by taking said multiple independent samples thereof;	

362. The various versions of step (a) do not recite anything that was not already known and readily understood by a POSA. The different versions of step (a) include separately collecting portions or samples, which in the context of step (a), are synonyms. ICMSF states that "[a] sample unit is a small portion of the lot." Ex. 1012 at 225 (§ 12.1). ICMSF also refers to samples and sample units interchangeably. *Id.* Like the IEH Patents, ICMSF shows that portions or samples are used as synonyms. Specimen is another synonym. For example, BAM refers to "the sample or specimen received for examination" that "are representative of the sampled lot." Ex. 1022 at 10 (Chapter 1 at 1). Additionally, MLG uses "sub-sample" and "portion" as synonyms. Ex. 1028 at 15–16, 31–32, 46–47 (§§ 4.5.3, 5.5, 8.5.1). Thus, samples, portions, specimens, sample units, and sub-samples are used in the art as synonyms.

363. Chapter 12 of ICMSF is titled "Sampling, Sample Handling, and Sample Analysis" and its § 12.1, reproduced below, describes collecting sample units from lots or consignments:

> **12.1 INTRODUCTION**
>
> Many different types of samples are collected and submitted to the laboratory for analysis. Some are sample units from lots or consignments of foods or ingredients for lot acceptance determination. Others may be for investigational purposes to assess control of the environment, investigate the source of a problem, or validate a process. Some may have legal implications relative to a lawsuit or for regulatory compliance. This chapter briefly discusses some of the major factors that should be considered when collecting sample units, shipping them to a laboratory, preparing them for analysis, and analyzing them.
>
> 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. This requirement is only completely fulfilled when the food and processing conditions result in a homogeneous distribution of microorganisms. This only occurs in well-agitated fluid products. In general, the distribution of microorganisms is presumed to be random.

Ex. 1012 at 225 (highlighting added).

364. ICMSF also describes randomly collecting sample units from lots to draw a representative sample. Chapter 6 is titled "Concepts of Probability and Principles of Sampling," and its § 6.11 asks "What is a Representative Sample?" followed by a detailed explanation as reproduced below:

6.11 WHAT IS A REPRESENTATIVE SAMPLE?

A *representative sample* reflects, as far as is possible, the composition of the lot from which it is drawn.

How then should a representative sample be drawn? It is important to avoid bias and to draw a sufficient number of sample units to confidently make a judgment about a lot. Sampling at random is the universally recognized way of avoiding bias and is more reliable than consciously trying to draw the sample units from the various parts of a lot. The units (cartons or containers, particular weights of solid, or volumes of liquid) are drawn by using random numbers. There is, of course, no guarantee that a random sample has characteristics identical with those of the lot, but the randomness of sampling is the basis for calculation of the probability that a sample will give a biased result.

It is also possible, and may be desirable, to use a *stratified random sampling* approach, drawing a random sample of a given number of sample units from each *stratum* (e.g., each sublot or carton). The distribution of sample units on strata should correspond to the distribution of lot units on strata. This means that if each stratum contains the same quantity as every other one, the number of sample units per stratum should be the same. Otherwise, they should differ just as the proportions of the lot contained in the strata differ. Stratification is a device for handling known sources of variation and may be used where one has prior knowledge that the consignment is potentially not of uniform quality. A consignment might not be of uniform quality if portions of it are shipped in different vehicles or in different holds of a vessel, or if it is known that it is really composed of several lots representing, for example, different days of production from the same plant or different plants of the same company. The results for different strata should be assessed separately and then pooled if they appear to be homogeneous.

The calculation of acceptance probabilities is based on the assumption that random samples have been drawn and analyzed. Where physical or practical constraints prevent random sampling, such calculated probabilities may not be valid. Their reliability depends on how close reality approaches the ideal situation of random sampling. This fact should be borne in mind when subsequently interpreting results.

Id. at 119–20 (highlighting added). The above section also describes a consignment as comprising several lots.

365. Section 6.10 of ICMSF asks "What is a Lot?" and then provides a detailed explanation as reproduced below:

6.10 WHAT IS A LOT?

Ideally, a lot is a quantity of food or food units produced and handled under uniform conditions. Under certain circumstances, it has been shown that the logarithms of the counts from a batch of food are likely to be normally distributed (Baird-Parker, 1980; Kilsby & Baird-Parker, 1983 [their Table 2]; Ingram & Roberts, 1976). The implication is that there is homogeneity within a lot, which, when considering microbial levels and distributions, rarely occurs in practice. In most instances, the distribution of microorganisms within lots of food is heterogeneous. Even in food factories, this heterogeneity makes the interpretation of sample results difficult, and it becomes even more so in circumstances where a lot is less well defined, such as in a consignment of a very large quantity of food.

It is therefore helpful if suppliers can be persuaded 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).

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.

A lot should be composed of food produced with as little variation as possible for a given process or commodity. Because of the uncertainties in identifying a lot commercially, however, the use of the word *lot* in this book is usually in its statistical sense, as a collection of units of a product, the acceptability of which is determined by examining a sample drawn from it.

Ex. 1012 at 118–19 (highlighting added). This section of ICMSF shows it was well known to separately collect a plurality of sample units from separate lots and track the lots in a consignment for release into commerce to minimize waste.

366. ICMSF also includes a more succinct description of a lot with a quote to an earlier version of ICMSF:

The ICMSF has defined a lot as follows:

> In the commercial sense, a lot is a quantity of food supposedly produced under identical conditions, all packages of which 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 (ICMSF, 1986).

In this example, the maximum size of a lot consists of all the ground beef produced on common equipment from cleanup to cleanup. Smaller lots could be established (e.g., hourly).

Id. at 327 (§ 17.5.3.2) (highlighting added). This definition also reflects the common practice referred to in the IEH Patents at Example II, wherein "[p]referably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available." Ex. 1001 at 12:46–48, Ex. 1002 at 12:52–54, and Ex. 1003 at 13:13–15.

367. ICMSF describes collecting portions/samples from lots in a consignment wherein the lots equate to "operationally-linked test lots" and "operationally-linked single-unit production lots" as recited in the '584 Patent, "separate test lots" and "separate single-unit production lots" as recited in the '143 Patent, and "separate lots" and "separate single production lots" as recited in the '771 Patent. For example, such lots in a consignment are described in § 6.10, which titled "What is a Lot?" as reproduced below:

It is therefore helpful if suppliers can be persuaded 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).

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.

Id. at 119 (§ 6.10) (highlighting added).

368. The portions of ICMSF discussed above show that it was known to separately collect a plurality of portions from separate operationally-linked test lots, such as those during a particular time interval. The same also shows that ICMSF discloses operationally-linked single-unit production lots because Example II of the IEH Patents (AAPA #4) defines "an individual single-unit production lot" as "all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), 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." Ex. 1001 at 12:49–55; Ex. 1002 at 12:55–61; and Ex. 1003 at 13:16–23.

369. Based on the foregoing, there is nothing new recited in step (a) of the Continuation Patents. The next several paragraphs address the additional language for step (a) in the '584 Patent.

370. ICMSF also indicates it was well known to separately collect samples randomly from separate lots according to statistical-based sampling plans to identify lots testing negative for a target organism for safe release into commerce, as indicated in ICMSF at § 6.5, reproduced below:

6.5 THE SAMPLING PLAN

The sample units so drawn will, after examination, yield results that will be compared with certain criteria to reach a decision as to whether the entire lot should be accepted or rejected (see section 6.9 for explanation of rejection). The particular choice of sampling procedure and the decision criteria make up the *sampling plan*. Proper drawing of samples is essential if the decision making criteria of the sampling plan are to give unbiased results. By sampling randomly, we are able to reduce the risk of making biased decisions.

A simple example of a sampling plan follows. Take 10 sample units of a food from a lot and subject them to appropriate laboratory procedure to test for the presence or absence of a microorganism. If two or fewer of the 10 sample units show presence of the organism, that is, give a positive result, then the whole lot of food is acceptable (relative to this organism). But if three or more give a positive result, the whole lot is to be rejected. This plan is described by the use of two terms $n = 10$ and $c = 2$, where n is the number of sample units chosen separately and independently, and where c is the maximum allowable number of sample units yielding a positive result.

Ex. 1012 at 115 (highlighting added). These sampling plans are necessarily statistically based as exemplified by the discussion above for a formula in which "*n* is the number of sample units chosen separately and independently, and . . . *c* is the maximum allowable number of sample units yielding a positive result." *Id.* at 115. There is no doubt that such sampling plans are statistically based sampling plans because ICMSF uses that exact phrase in the introduction section of Chapter 6:

6.1 INTRODUCTION

It is important to recognize that the management of food safety using the approaches outlined in the first five chapters, based on controlling hazards through Good Hygienic Practices (GHP) and Hazard Analysis Critical Control Point (HACCP), is much more effective than trying to ensure safety by lot acceptance through end-product testing. This chapter discusses the concepts of probability and sampling that determine the limitations of end-product testing. Those concepts form the basis of the design of statistically based sampling plans (Chapter 7) and the establishment of cases (Chapter 8).

In Chapters 6 and 7, it is assumed that the microbiological test will give an absolutely accurate result, with no false positives or false negatives. This is not a realistic assumption, and problems arising from sampling, sample transport and preparation for analysis, and the imprecision of microbiological methods are addressed in Chapters 10 and 12 and elsewhere in the text.

Id. at 113 (highlighting added). *See also id.* at 115–21 (§§ 6.4–6.13), 319–20 (§ 17.2.3.3), and 326–30 (§§ 17.5.3.1–17.6).

371. ICMSF additionally reflects the common practice of collecting 60 portions/samples/sample units of beef and poultry as indicated at § 10.6, reproduced below:

10.6 RELATION TO COMMERCIAL PRACTICE

Stringent sampling plans like those just suggested represent an ideal not yet attainable for products such as poultry or carcass meats, which are found to be contaminated by *Salmonella* when specially sensitive methods of detection are used. At present, it is often recommended to use procedures such as rinsing or swabbing of the whole carcass, where in effect the analytical unit is most of the carcass surface and internal cavity, and a positive may correspond to levels of contamination on the order of one *Salmonella* cell per 2 kg for poultry or even one per 100 kg for carcass meats. Using such criteria, one finds slaughter lines producing contaminated carcasses with a frequency of 10% or more. For lots with 10% defectives, the relations shown in Section a of Table 10–2 are valid. The sampling plan $n = 60$, $c = 0$ would reject virtually all such material; $n = 5$, $c = 0$ would reject one-third of it (Table 10–2). Even the plan $n = 5$, $c = 1$ would reject one in twelve lots, a commercially severe rate of rejection. If, as a result of rejections on the basis of $n = 5$, $c = 1$, the quality of lots improved to the point where only 2% instead of 10% of carcasses were found to be contaminated, the relations would be as in Section b of Table 10–2. If 2% of carcasses are contaminated, the indicated average concentration of *Salmonella* cells is on the order of one per 50 kg for poultry, and one per 5000 kg or more for beef. If a 2% frequency of contamination was still thought to be too great, a similar pressure for further improvement (rejecting about 1 in 10 such contaminated lots) could be reintroduced by changing the sampling plan from $n = 5$, $c = 1$ to $n = 5$, $c = 0$.

Id. at 189 (highlighting added); *see also id.* at 184 (§ 10.2). ICMSF discusses the number of portions to be taken sufficient for validation of a particular microorganism including *Salmonella* (*id.* at 276 (§ 15.3.3); *see also id.* at 282 (§ 15.6.3)); *Listeria* (*id.* at 309 (§ 16.6.3)), and *E. coli* (*id.* at 318–21 (§§ 17.2.3.2–17.2.3.4), 326 (§ 17.5.3.1)).

372. Like § 10.6, ICMSF includes many other references to testing lots of beef or poultry, two of the most common types of meat in commerce. *Id.* at 114 (§ 6.3), 184–191 (§§ 10.2–10.6), 225–226 (§ 12.1), 285 (§ 16.1), 313–330 (Chapter 17). ICMSF is relevant to any kind of food product including beef or poultry.

373. The purpose of ICMSF was to collect together information for a quick reference manual that is in a form that could be assessed easily by food industry personnel to assist in making judgments and to improve food safety. Of course, the purpose of testing is to ensure that food sources such as particular lots have been validated so the food may be released into commerce and ultimately safely consumed. ICMSF teaches that this is achieved by tracking lots in a consignment for validation and release into commerce, as discussed above with reference to ICMSF at 118–19 (§ 6.10). *See id.* at 184–89 (§§ 10.2–10.6).

374. It is also noteworthy that Gombas describes sampling from RTE products ("[a]ll products were to be sliced (either presliced by manufacturers or sliced by the retail stores")) including beef bologna and "products made from pork or poultry."

Ex. 1014 at 559 (abstract), 562. Gombas discloses a testing method that overlaps with many of the teachings of ICMSF. For example, the RTE products of Gombas would be considered "lots" if this survey was being conducted in a processing/production environment. Additionally, Gombas discloses sampling according to a sampling plan for testing for *Listeria*. *Id.* at 563. As explained regarding step (d) (*see* § XII-A-1-e *infra*) a POSA reading Gombas would recognize that Gombas collected a plurality of portions/samples from five lots.

c. Step (b) — Combining/Dry Compositing

375. Each step (b) for claim 1 for each of the IEH Patents is listed below.

<table>
<tr><th colspan="3">Step (b) of the First Independent Claims</th></tr>
<tr><th>Claim 1 of '584 Pat.</th><th>Claim 1 of '143 Pat.</th><th>Claim 1 of '771 Pat.</th></tr>
<tr><td>combining the collected conforming plurality of portions corresponding to</td><td colspan="2">separately compositing the collected multiple independent samples from</td></tr>
<tr><td colspan="3">each of the separate</td></tr>
<tr><td colspan="2">test lots</td><td>lots</td></tr>
<tr><td colspan="3">to provide a corresponding set of separate</td></tr>
<tr><td>test lot samples,</td><td>composited test lot samples,</td><td>composited lot samples,</td></tr>
<tr><td>wherein each separate test lot sample</td><td>wherein each of the separate composited test lot samples</td><td>wherein each of the separate composited lot samples</td></tr>
<tr><td colspan="3">is attributed to a particular corresponding separate</td></tr>
<tr><td colspan="2">test lot;</td><td>lot;</td></tr>
</table>

376. Each step (b) for the second independent claim of each of the IEH Patents is listed below.

Step (b) of the Second Independent Claims		
Claim 17 of '584 Pat.	Claim 35 of '143 Pat.	Claim 37 of '771 Pat.
combining the collected conforming plurality of product portions corresponding to	separately compositing the collected multiple independent samples from	
each of the separate		
single-unit production lots	test lots	lots
to provide a corresponding set of separate		
single-unit production lot samples,	composited single-unit production lot samples,	composited single production lot samples,
wherein each separate single-unit production lot sample	wherein each of the separate composited single-unit production lot samples	wherein each of the separate composited single production lot samples
is attributed to a particular corresponding separate		
single-unit production lot;		single production lot;

377. As described at § X-D-1 *supra*, ICSMF cites to Silliker (Ex. 1025) and Gabis (Ex. 1026) which describe two-stage compositing. The first compositing step, referred to as lumping, equates to combining/compositing the collected portions/samples as recited in step (b). For example, § 10.4 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. A laboratory investigation undertaken for ICMSF (Silliker & Gabis, 1973) indicated that different sized analytical units drawn from a single well-mixed sample unit of dried food give very similar results. A subsequent investigation (Gabis & Silliker, 1974) using foods of high moisture content (including eggs, poultry meat, meat, and meat products) showed comparable reliability in the use of composite analytical units; for example, examination of three composites of 20 × 25 g analytical units gave the same result as examination of all 60 analytical units individually (the total amount examined being 1500 g in both instances). This finding suggests that considerable reductions may be made in the cost of laboratory analyses by compositing (pooling) analytical units. Such compositing offers the prospect of large increases in the number of analytical units, *n*, with corresponding increase in the stringency of examination, without correspondingly increasing laboratory effort.

Id. at 187 (§ 10.4) (highlighting added).

378. Silliker notes that "[c]ompositing of multiple samples (lumping) and wet compositing of pre-enrichment cultures have been tested as economical approaches to *Salmonella* control." Ex. 1025 at 475. Silliker further notes that "**[b]oth approaches are being used widely by the food industry** in the United States." *Id.* (emphasis added). For example, ICMSF's Section 10.5.1 states:

10.5.1 Conceivable Alternative Plans

As indicated above, for an infectious agent such as *Salmonella*, there are strong reasons for adopting sampling plans in which $c = 0$:

1. It is philosophically objectionable to some people to accept a lot containing a recognized pathogen, regardless of how the food is to be used in a manufacturing process or by the consumer.
2. There is the very great technical advantage of combining many analytical units for bacteriological examination in systems with $c = 0$, because a single positive decides the outcome.
3. The plan with $c = 1$ (or more) would always require the examination of (many) more analytical units, for equal probability of acceptance, than a plan with $c = 0$.
4. Even if the indicated probabilities of plans with $c = 0$ versus $c = 1$ are the same, their implications are not. For example, when a lot is accepted with the plan $n = 60$, $c = 0$, it is possible (though not certain) that the lot may not be contaminated at all. But using the plan $n = 95$, $c = 1$ and accepting one positive, it is known that the lot certainly is contaminated (though the probability that a lot with 5% of analytical units contaminated would be accepted is in both instances $P_a = 0.05$).

Id. at 188 (§ 10.5.1) (highlighting added). ICMSF also provides an example of "[u]sing a sampling plan involving n = 15 (25 g analytical units) and a composite of 375 g." *Id.* at 195 (§ 10.7.2). ICMSF also states "[f]or qualitative analyses, 25 g analytical units are frequently analyzed individually or as composites of 100 g, 200 g, or more." *Id.* at 232 (§ 12.5.2).

379. ICMSF states that "[a]ll steps up to the analysis must be controlled . . . to allow reliable traceability." Ex. 1012 at 227 (§ 12.2.1). ICMSF also describes lot samples that are traceable to a particular corresponding lot:

It is therefore helpful if suppliers can be persuaded 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).

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.

Id. at 119 (§ 6.10) (highlighting added).

380. Gombas also discloses that each of the separate composited lot samples is attributed to a particular corresponding separate lot. Gombas discloses that "[s]amples were assigned codes" and product information was recorded for the luncheon meats including "sampling location." Ex. 1014 at 563. These codes were tracked for the composited samples as evidenced by the process described below for testing individual samples when composited samples test positive. *See id.* at 563, 564.

d. Step (c) — Enriching

381. Each step (c) for claim 1 for each of the IEH Patents is listed below.

Step (c) of the First Independent Claims		
Claim 1 of ’584 Pat.	Claim 1 of ’143 Pat.	Claim 1 of ’771 Pat.
incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples,	enriching each of the separate composited test lot samples	enriching each of the separate composited lot samples
to provide a set of separate		
test lot samples	composited test lot samples	composited lot samples
enriched for the target microbial agent or organism;	enriched for the target microbe(s);	

382. Each step (c) for each second independent claim is listed below.

Step (c) of the Second Independent Claims		
Claim 17 of’584 Pat.	Claim 35 of ’143 Pat.	Claim 37 of ’771 Pat.
incubating the set of separate single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate single-unit production lot samples,	enriching of the separate composited single-unit production lot samples	enriching of the separate composited single production lot samples
to provide a set of separate		
single-unit production lot samples	composited single-unit production lot samples	composited single production lot samples
enriched for the target microbial agent or organism;	enriched for the target microbe(s);	

National Beef Ex. 1041

383. It was well known long before the priority date to use non-selective enrichments after dry compositing and prior to wet compositing as evidenced by Price (Ex. 1017), Silliker (Ex. 1025), Gabis (Ex. 1026), and MLG (Ex. 1028). It was also known long before the priority date to use selective enrichments after dry compositing and prior to wet compositing as disclosed by ICMSF (Ex. 1012) and Gombas (Ex. 1014).

384. For example, 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 at 187 (§ 10.4) (highlighting added).

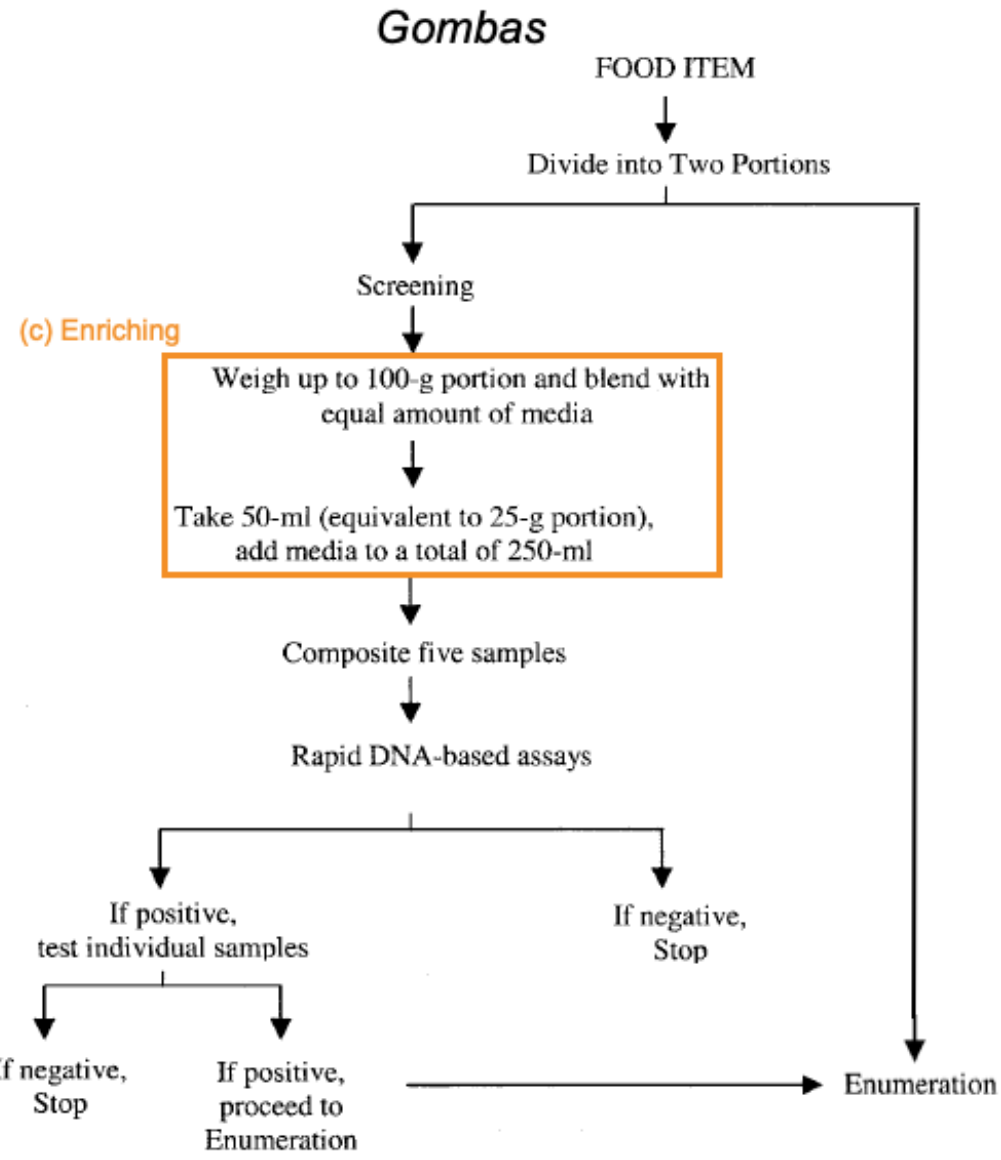
385. ICMSF describes analyzing composites of analytical units diluted "for qualitative (enrichment)" analysis. *Id.* at 232 (§ 12.5.2). In particular, ICMSF states:

> For practical reasons, however, analytical units of 10 g up to 50 g are typical for quantitative methods and are diluted 1:10. For qualitative analyses, 25 g analytical units are frequently analyzed individually or as composites of 100 g, 200 g, or more.
>
> . . .
>
> Preparation of the first dilution, either for qualitative (enrichment) or quantitative (direct) analyses, can have a marked impact on the microbial population in the sample. This is often due to changes in the physico-chemical characteristics of the suspension as compared to the food matrix. Where the food does not confer protection, the composition of the diluent is important to prevent or minimize shock/injury to the microorganisms that can result from rapid changes in the ionic concentrations.

Id. (highlighting added). ICMSF also describes strategic use of non-selective enrichment to resuscitate microorganisms and selective enrichments for growing microorganisms. *Id.* at 232–33 (§ 12.6). The same section describes optimizing the

incubation period. *Id.* It was a well-known, standard practice before the priority date to rely on incubation for microorganisms to become at least substantially uniform in the selective enrichment broth to be detectable and avoid incorrect analytical results. D'Aoust reflects this common practice when stating "standard methodology recommends incubation of selective enrichment broths." Ex. 1021 at 372.

386. Gombas clearly discloses use of selective enrichments after dry compositing and prior to wet compositing as shown in its diagram, reproduced below with an orange highlighted box:



Ex. 1014 at 563 (Figure 1 (annotated)).

387. Gombas also describes use of selective enrichments after dry compositing and prior to wet compositing as provided below:

> **Sample screening.** Each sample was divided into two portions for screening and enumeration. For screening, approximately half (up to 100 g) of a sample was aseptically transferred to a sterile stomacher bag and blended with an equal amount of enrichment broth. For Maryland samples, University of Vermont broth 2 (UVM-2 broth) was used as the enrichment broth for luncheon meats, smoked seafood, and seafood salads; phosphate-buffered *Listeria* enrichment broth was used for the other product types. 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.

Id. at 563 (highlighting added).

388. Gombas further indicates that:

> After incubation, individual Maryland sample enrichments were swabbed onto two plates of modified lithium chloride-ceftazidime agar (mLCA), which were incubated at 35°C for 24 ± 2 h. Cell growth was collected from one of the plates with a cotton swab for composite screening with Gene-Trak, and the other plate was held for individual screening if needed. 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. at 564 (highlighting added). Gombas utilized conventional steps to avoid a "potential heterogeneous distribution." *Id.* at 563. Blending a sample in a stomacher bag as done by Gombas enables vigorous mixing of the sample and the enrichment broth and achieves a homogenous mixture referred to as a homogenate. *Id.* Note

that stomachers became available in the early 1970s and quickly replaced blenders in food microbiology laboratories as the standard method for homogenizing samples. This mixing ensures the target microbial agent or organism is at least substantially uniform in the homogenate. *See id.*

389. Additionally, Gombas indicates that "[a]fter blending, 50 g of the homogenate was added to 200 ml of enrichment broth and stomached for 1 min." *Id.* at 563. Then, "[t]he 250-ml enrichment was incubated at 35°C for 24 ± 2 h." *Id.* Gombas further indicates that "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." *Id.* at 564 (emphasis added). Gombas notes that the "procedure resulted in a detection sensitivity equivalent to that of current regulatory methods." *Id.* at 563.

390. Because the procedure in Gombas resulted in equivalent detection sensitivity, the procedure necessarily equates to incubating under conditions suitable to allow levels of the target microbial agent or organism to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate samples. A POSA would have been motivated by Gombas to apply this procedure to the teachings of ICSMF to enrich a set of separate lot samples, as recited in step (c).

e. Step (d) — Wet Compositing

391. Each step (d) for claim 1 for each of the IEH Patents is listed below.

<table>
<tr><th colspan="3">Step (d) of the First Independent Claims</th></tr>
<tr><th>Claim 1 of ’584 Pat.</th><th>Claim 1 of ’143 Pat.</th><th>Claim 1 of ’771 Pat.</th></tr>
<tr><td colspan="3">removing portions of each</td></tr>
<tr><td>enriched separate test</td><td>separate enriched composited test</td><td>separate enriched composited</td></tr>
<tr><td colspan="3">lot sample,</td></tr>
<tr><td colspan="3">and combining the removed portions to provide a</td></tr>
<tr><td></td><td colspan="2">pooled</td></tr>
<tr><td colspan="3">modular composite sample; and</td></tr>
</table>

392. Each step (d) for the second independent claim of each of the IEH Patents is listed below.

<table>
<tr><th colspan="3">Step (d) of the Second Independent Claims</th></tr>
<tr><th>Claim 17 of the ’584 Pat.</th><th>Claim 35 of ’143 Pat.</th><th>Claim 37 of ’771 Pat.</th></tr>
<tr><td>removing portions of each,</td><td colspan="2">removing portions of each</td></tr>
<tr><td>enriched separate single-unit production</td><td>separate enriched composited single-unit production</td><td>separate enriched composited single production</td></tr>
<tr><td colspan="3">lot sample,</td></tr>
<tr><td colspan="3">and combining the removed portions to provide a</td></tr>
<tr><td></td><td colspan="2">pooled</td></tr>
<tr><td colspan="3">modular composite sample; and</td></tr>
</table>

393. Compositing after enrichment is sometimes referred to as wet compositing or pooling. Before the priority date, compositing enriched lot samples was conventional as described by ICMSF:

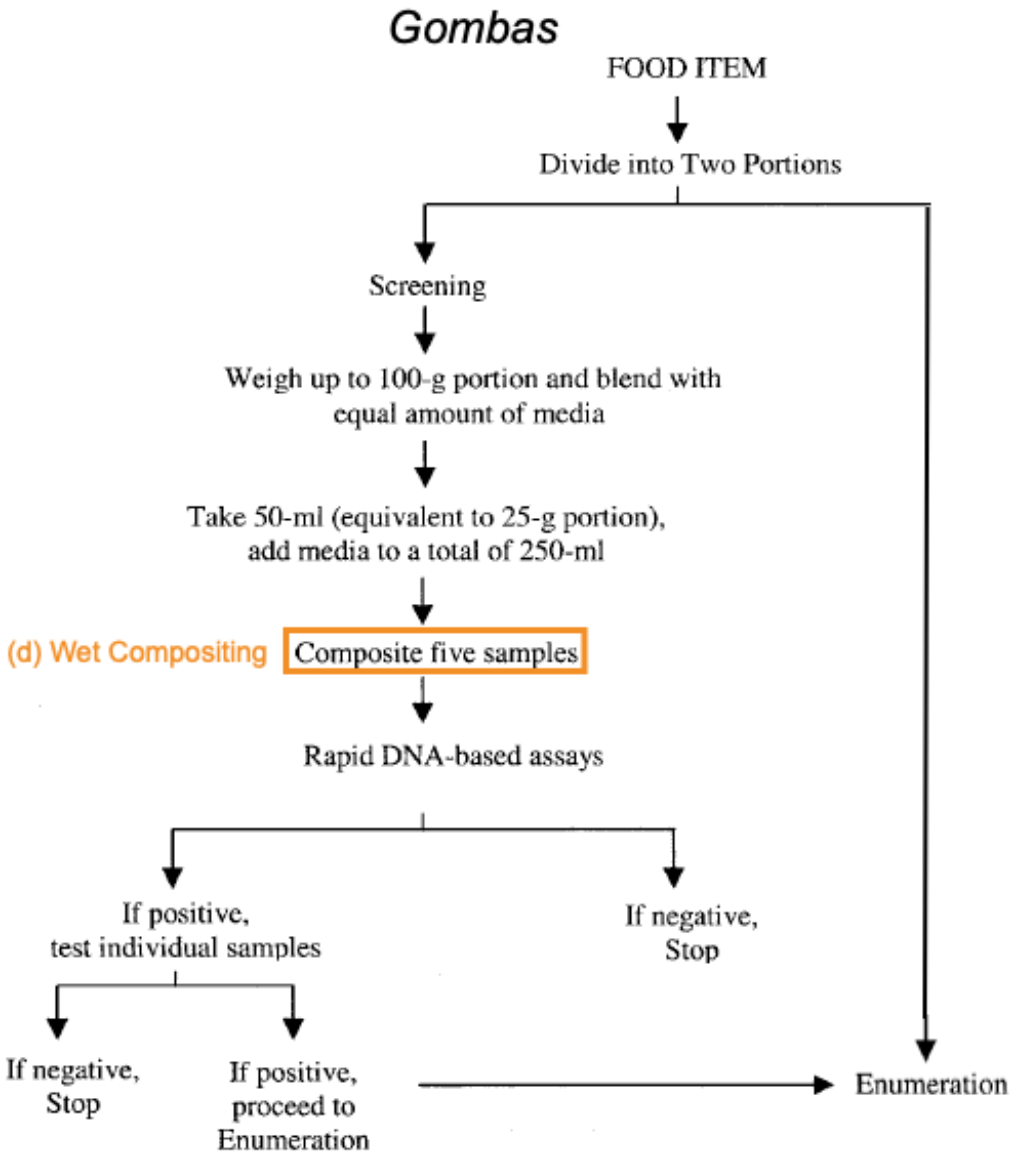
To reduce laboratory effort while maintaining the stringency of the sampling plan, it would be helpful to combine either groups of analytical units or the enrichment cultures therefrom, using plans in which the presence of a single positive rejects the consignment. A laboratory investigation undertaken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

Ex. 1012 at 187 (§ 10.4) (highlighting added).

394. Gombas also discloses conventional compositing of enriched samples:

> Up to five like-product samples were composited and screened. For Maryland samples, cells from five cotton swabs (representing five samples) were suspended in 5 ml of phosphate-buffered saline (PBS, pH 7.5). The suspension was centrifuged at 3,000 × *g* for 10 min; the cell pellet was resuspended in 1 ml of PBS and tested by the Gene-Trak assay according to the manufacturer's procedures. For California samples, five 1-ml samples of secondary enrichment broths were composited, and the 5-ml composite was tested by the BAX assay according to the manufacturer's procedures.

Ex. 1014 at 564 (highlighting added). Gombas also depicts compositing as a conventional step in its procedure as shown below:



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

f. Step (e)(1) —Testing

395. Each step (e)(1) of the independent claims for the IEH Patents is listed below.

Step (e)(1) of the First and Second Independent Claims		
Claims 1 and 17 of '584 Pat.	Claims 1 and 35 of '143 Pat.	Claims 1 and 37 of '771 Pat.
testing of the		
	pooled	
modular composite sample,		
using a suitable detection assay,		
for the target microbial agent or organism,	for the target microbe(s),	

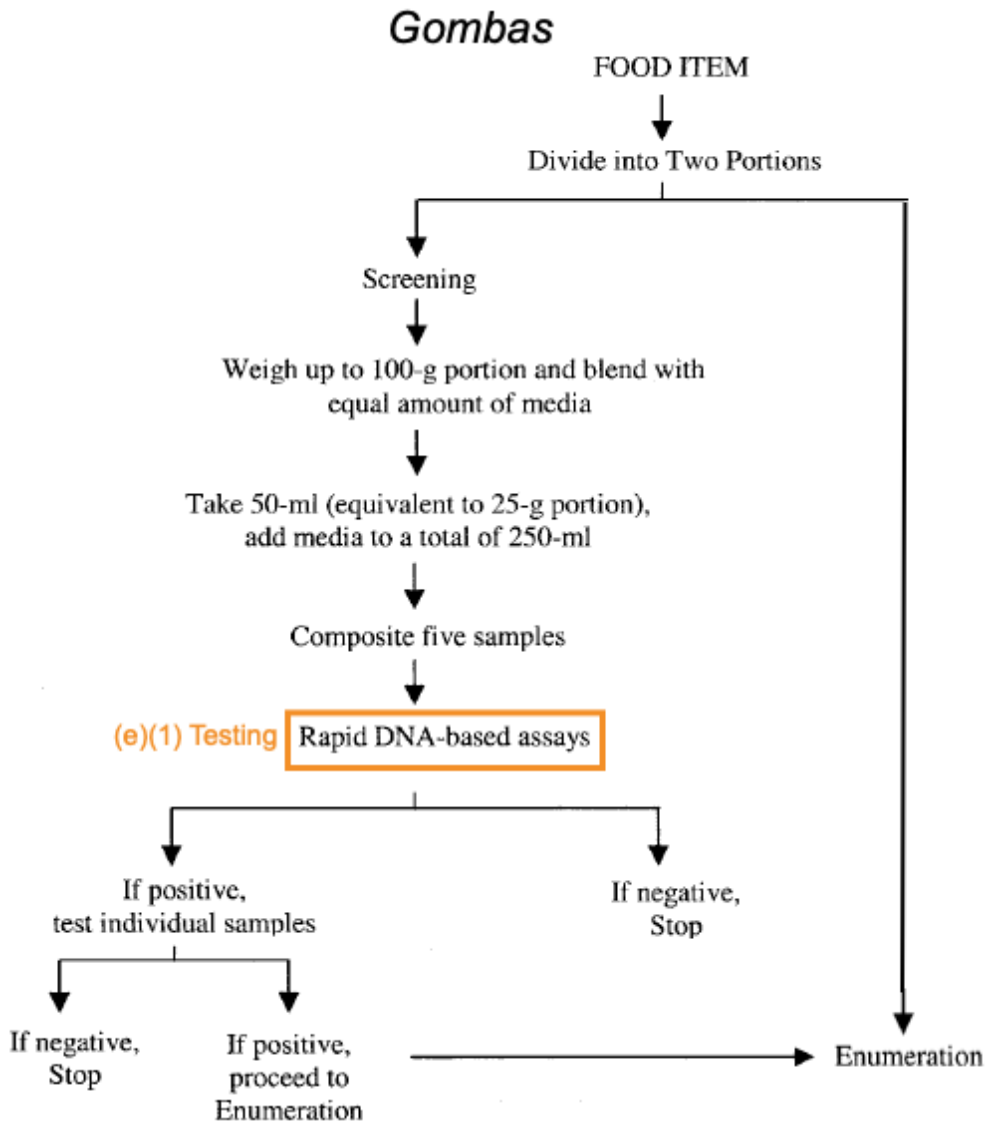
396. A specific type of detection assay is not mentioned in ICMSF, however, step (e)(1) just requires that the detection assay is suitable, which was established by the investigations of Silliker (Ex. 1025) and Gabis (Ex. 1026), as discussed in ICSMF. Ex. 1012 at 187 (§ 10.4 (citing to Silliker and Gabis). Additionally, ICMSF mentions that assays used for "qualitative methods" include "presence/absence tests." *Id.* at 233 (§ 12.7). However, testing methodologies, particularly detection assays, are not the focus of ICMSF because of the differences in methodologies and regulations between different countries and the wide variety of foods and microbes of interest.

397. To identify or use a suitable detection assay, a POSA would look to a reference such as Gombas, which provides more details regarding testing. For example, Gombas states:

> For California samples, five 1-ml samples of secondary enrichment broths were composited, and the 5-ml composite was tested by the BAX assay according to the manufacturer's procedures.

Ex. 1014 at 564 (highlighting added). This same BAX assay is used by Gombas in step (e)(3) when further testing after a positive test. *Id.*

398. Gombas also depicts testing using a suitable detection assay as shown below:



Ex. 1014 at 563 (Figure 1 (annotated)).

g. Step (e)(2) —Tested Negative

399. Each step (e)(2) for claim 1 for each of the IEH Patents is listed below.

<table>
<tr><th colspan="3">Step (e)(2) of the First Independent Claims</th></tr>
<tr><th>Claim 1 of ’584 Pat.</th><th>Claim 1 of ’143 Pat.</th><th>Claim 1 of ’771 Pat.</th></tr>
<tr><td colspan="3">wherein when such testing is negative all of said</td></tr>
<tr><td></td><td colspan="2">samples that were composited to form the separate composited</td></tr>
<tr><td></td><td>test lot samples</td><td>lot samples</td></tr>
<tr><td rowspan="3">separate test lots are validated for release into commerce, and</td><td colspan="2">are deemed negative for the target microbe(s) and each of the multiple separate</td></tr>
<tr><td>test lots</td><td>lots</td></tr>
<tr><td colspan="2">is validated, and</td></tr>
</table>

400. Each step (e)(2) for the second independent claim of each of the IEH Patents is listed below.

<table>
<tr><th colspan="3">Step (e)(2) of the Second Independent Claims</th></tr>
<tr><th>Claim 17 of ’584 Pat.</th><th>Claim 35 of ’143 Pat.</th><th>Claim 37 of ’771 Pat.</th></tr>
<tr><td colspan="3">wherein when such testing is negative all of said</td></tr>
<tr><td></td><td colspan="2">samples that were composited to form the separate composited</td></tr>
<tr><td></td><td>single-unit production lot samples</td><td>single production lot samples</td></tr>
<tr><td rowspan="3">separate single-unit production lot samples are validated for release into commerce,</td><td colspan="2">are deemed negative for the target microbe(s) and each of the multiple separate</td></tr>
<tr><td>single-unit production lots</td><td>single production lots</td></tr>
<tr><td colspan="2">is validated, and</td></tr>
</table>

401. ICMSF's § 6.10, which is reproduced below, describes correlating lots in a consignment with lot samples such that a negative or positive test result enables a lot to be validated or rejected:

6.10 WHAT IS A LOT?

Ideally, a lot is a quantity of food or food units produced and handled under uniform conditions. Under certain circumstances, it has been shown that the logarithms of the counts from a batch of food are likely to be normally distributed (Baird-Parker, 1980; Kilsby & Baird-Parker, 1983 [their Table 2]; Ingram & Roberts, 1976). The implication is that there is homogeneity within a lot, which, when considering microbial levels and distributions, rarely occurs in practice. In most instances, the distribution of microorganisms within lots of food is heterogeneous. Even in food factories, this heterogeneity makes the interpretation of sample results difficult, and it becomes even more so in circumstances where a lot is less well defined, such as in a consignment of a very large quantity of food.

It is therefore helpful if suppliers can be persuaded 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).

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.

A lot should be composed of food produced with as little variation as possible for a given process or commodity. Because of the uncertainties in identifying a lot commercially, however, the use of the word *lot* in this book is usually in its statistical sense, as a collection of units of a product, the acceptability of which is determined by examining a sample drawn from it.

Ex. 1012 at 118–19 (§ 6.10) (highlighting added). This section of ICMSF shows it was well known to separately collect a plurality of sample units from separate lots and track the lots in a consignment for release into commerce to minimize waste.

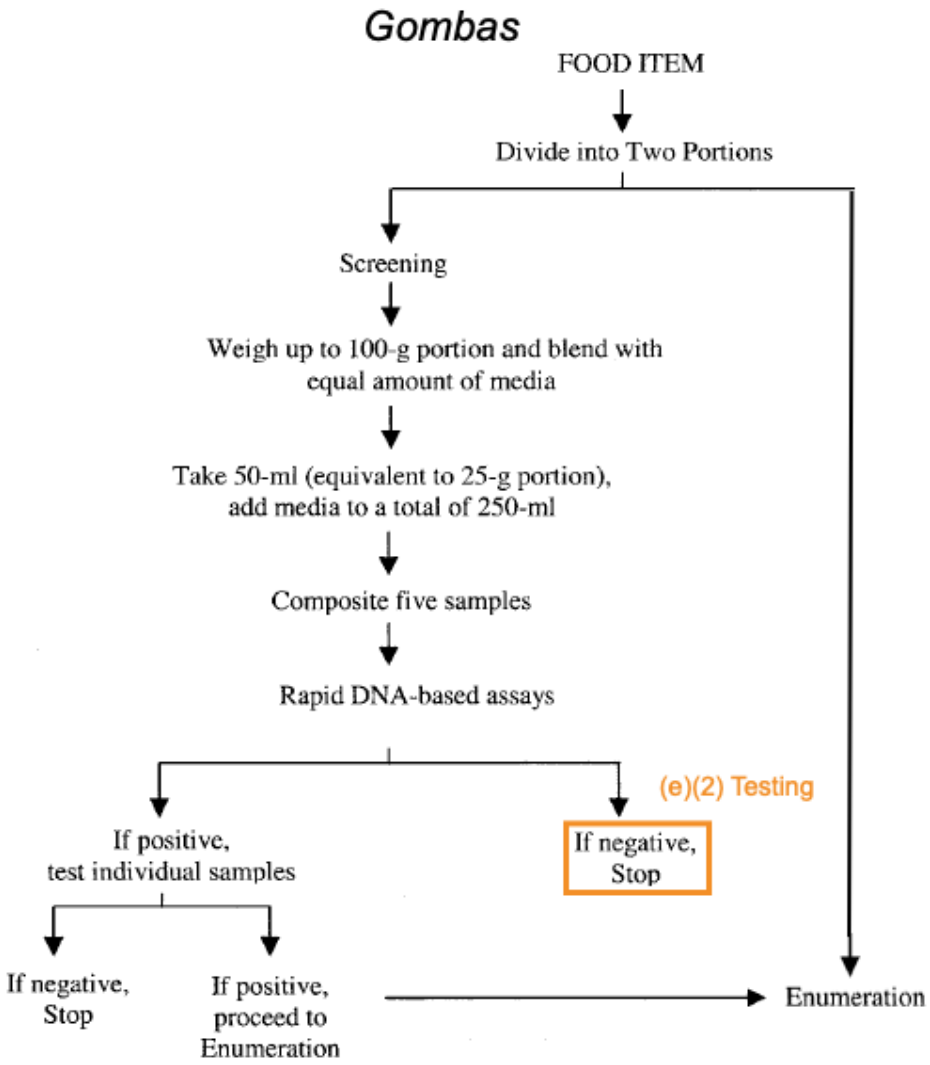
402. A negative result indicating that meat is not contaminated and is safe for consumption is the expected and desired outcome of food testing. Unsurprisingly, ICMSF includes references to sampling plans in which "*c* is the maximum allowable number of sample units yielding a positive result" and requires c = 0, which means only negative results are acceptable. *Id.* at 113–15 (§§ 6.3–6.6), 118 (§ 6.8), 183–90 (§§ 10.1–10.6), 309 (§§ 16.6.3), 325–26 (§§ 17.5.3–17.5.3.1). A negative test result indicates a lot has been validated and is "commercially possible to market." *Id.* at 185 (§ 10.2). Based on the foregoing, ICMSF teaches step (e)(2) regarding lots (claim 1) and lot samples (claim 17).

403. Gombas also teaches step (e)(2) because a negative test result is the end of the procedure in Gombas:

> If a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay with the PBS from the second mLCA plate or by the BAX assay with the secondary enrichment broths. Individual samples that tested negative were not tested further.

Ex. 1014 at 564 (highlighting added). Gombas teaches a negative test result for a composite can be used to treat as negative the samples that contributed to that composite. Thus, in light of this teaching from Gombas, a POSA would have modified ICMSF to rely on a negative test result for a composite of lot samples to "validate" the lots that contributed samples to that composite.

404. Gombas also depicts stopping after a negative test, as shown below:



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

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

405. Each step (e)(3) for claim 1 for each of the IEH Patents is listed below.

Step (e)(3) of the First Independent Claims		
Claim 1 of '584 Pat.	Claim 1 of '143 Pat.	Claim 1 of '771 Pat.
wherein when such testing is positive, each of the individual separate		
	composited	

test lots are validated for release into commerce, according to the statistical-based sampling plan, by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result for each test lot,	test	
	lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited	
	test	
	lot samples is positive for the target microbe(s), wherein the	
	test	
	lots corresponding to any negatively testing composited	
	test	
	lot samples are validated.	

406. Each step (e)(3) for each second independent claim is listed below.

Step (e)(3) of the Second Independent Claims		
Claim 17 of ’584 Pat.	Claim 35 of ’143 Pat.	Claim 37 of ’771 Pat.
wherein when such testing is positive, individual separate	wherein when such testing is positive, each of the individual separate	
single-unit production lots are validated for release into commerce, according to the statistical-based sampling plan, by further testing of a portion of the respective enriched separate single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result for each single-unit production lot;	composited	
	single-unit production	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-unit production	single production
	lot samples is positive for the target microbe(s), wherein the	
	single-unit production	single production
	lots corresponding to any negatively testing composited	
	single-unit production	single production
	lot samples are validated.	

407. ICMSF discloses methods for "reliable traceability" (Ex. 1012 at 227 (§ 12.2.1)) by, for example, assigning "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" (*id.* at 119 (§ 6.10)), as established in more detail with respect to step (b). ICMSF and Gombas also describe retaining a portion of enriched lot samples after the lot samples are dry composited and enriched, as established above in more detail with respect to steps (b)–(c).

408. For example, ICMSF states:

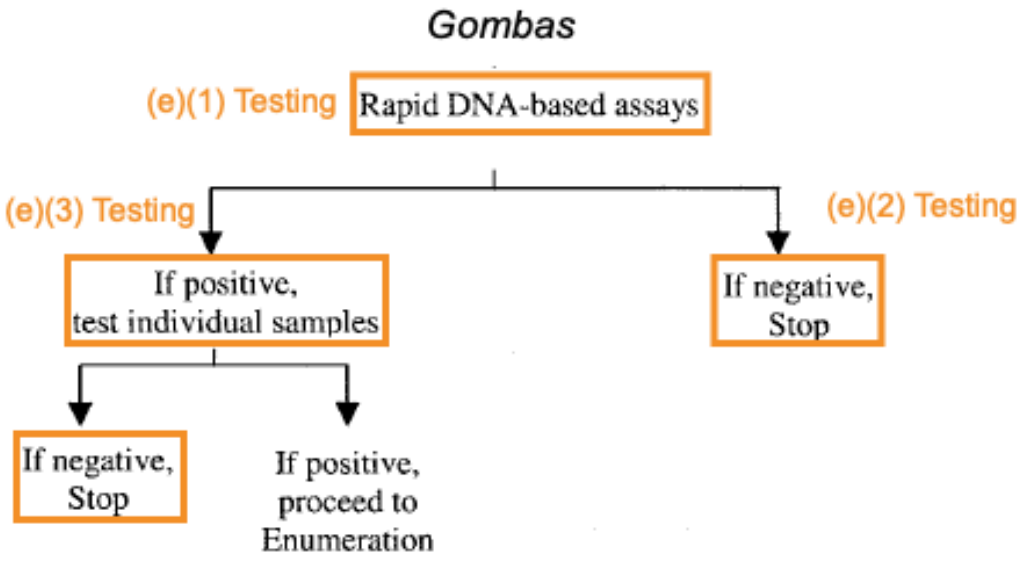
> If a consignment consisting of a mixture of production batches is treated as one lot, a rejection of an acceptable lot (i.e., the situation the producer's risk refers to) can have severe consequences, as the whole lot will be affected by this decision, even though only a few of the production batches 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.

Id. at 119 (§ 6.10) (highlighting added). ICMSF also indicates that "there is often a desire to retest retained samples or resample the lot in question to verify the finding." *Id.* at 191 (§ 10.7). While not explicitly stated in ICMSF, in the context of retesting retained samples in the investigations of pooling portions of enrichment cultures (*id.* at 187 (§ 10.4)), the enrichment cultures are the retained samples that are further tested. This would have been commonly understood by a POSA.

409. Gombas explicitly discloses that portions of the enrichment cultures are retained and are further tested after a positive test of a composite sample by the BAX assay. Ex. 1014 at 564. Indeed, Gombas states:

> If a composite tested negative, all samples in the composite were considered negative (in 25 g) and were not tested further. If a composite tested positive, samples in the composite were tested individually by Gene-Trak assay with the PBS from the second mLCA plate or by the BAX assay with the secondary enrichment broths. Individual samples that tested negative were not tested further.

Id. (highlighting added). The above-quoted section shows that Gombas teaches the use of further testing of a portion of the respective enriched separate lot samples using the protocol used in step (e)(1), the BAX assay. Figure 1 of Gombas, as reproduced below, also depicts testing individual enriched samples if the composited sample tests positive and stopping after a negative result:



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

410. ICMSF discloses validating for release into commerce (Ex. 1012 at 113–15 (§§ 6.2–6.6), 118–19 (§§ 6.9–6.10), 184–85 (§ 10.2), 325–27 (§§ 17.5.3–17.5.3.4); *see also id.* at 186–89 (§ 10.4–10.6)) according to a statistically-based sampling plan

(*id.* at 113 (§ 6.1); *see also id.* at 115–18 (§§ 6.4–6.8), 184 (§ 10.2), 319–21 (§§ 17.2.3.3–17.2.3.4), 326–30 (§§ 17.5.3.1–17.6), as described regarding steps (a) and (e)(2). Reading ICMSF and Gombas, a POSA would understand that after the composited samples test positive, then the individual samples used to form the composited sample are individually tested with the same or a more sensitive protocol to determine which of the separate composited lot samples is positive for the target microbe(s).

411. In a food processing environment, the expected and hoped for outcome is a negative test. This is because foodborne pathogens occur at low incidence in most foods. The modular composite sample, representing several different individual lots, is therefore expected to produce a negative analytical result. However, in the event of a positive analytical result, a POSA would test the individual lots which formed the composite sample to determine which lot was positive. This would result in the release of the negative lots into commerce, while the positive lot would be held for further disposition. Additionally, a POSA would also recognize that any lots corresponding to any negatively testing composited lot samples are then considered to be validated.

i. Step (e)(4) — No Requirement

412. Each step (e)(4) for the independent claims of the ’584 Patent is listed below.

Step (e)(4) of ’584 Patent	
Claim 1	Claim 17
wherein the enrichment in step c), prior to removing portions in step d), is sufficient to enable said validation of individual separate	
test lots	single-unit production lots
with no requirement for further enrichment thereof, and with no requirement for further sampling in a).	

413. The Continuation Patents do not recite an equivalent to step (e)(4) of the ’584 Patent.

414. Step (e)(4) merely recites the well-understood outcome of the enrichment in step (c). Step (c) recites that the lot samples are “enriched for the target microbial agent or organism,” which clearly calls for enrichment. Both ICMSF and Gombas use enrichment as described above regarding step (c), thereby rendering step (e)(4) superfluous. In other words, after the enrichment in step (c), there already “is no requirement for further enrichment thereof” as stated in step (e)(4).

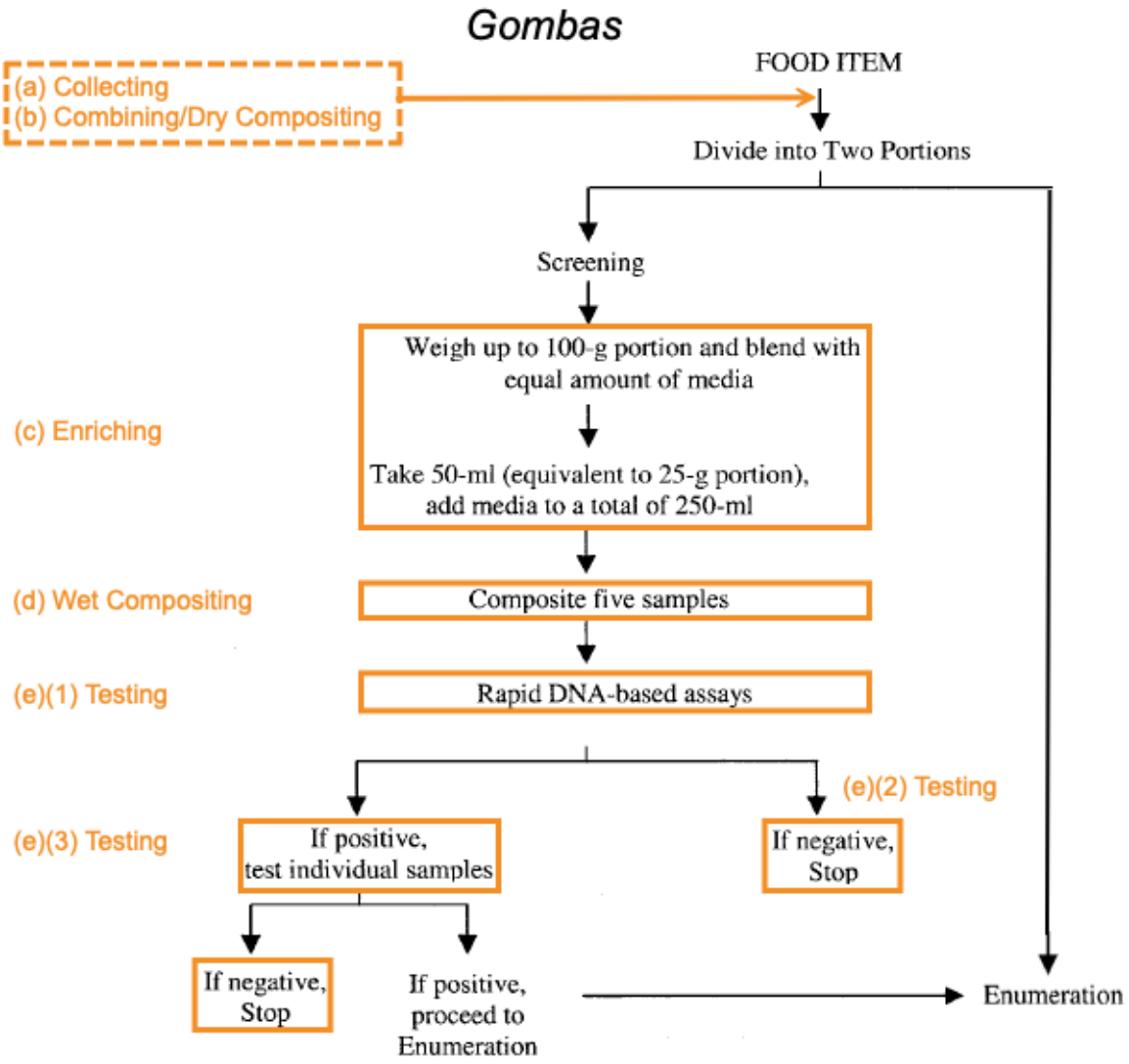
415. The same applies to there being no requirement for further sampling in step (a) under the combination of ICMSF as modified by Gombas. Under the teachings of ICMSF and my experience, the enrichment cultures in ICMSF would only be partially used in an analytical method while the remainder of those cultures would be retained. Plus, as discussed regarding step (e)(3) at § XII-A-1-h *supra*, Gombas explicitly states that portions of the enrichment cultures are retained for further testing, thus there is no need for further sampling in Gombas. Accordingly, the

statement in step (e)(4) that there is no requirement for further sampling in step (a) is clearly superfluous based on the combined teachings of ICMSF and Gombas.

2. Combination Rationales for Ground 1

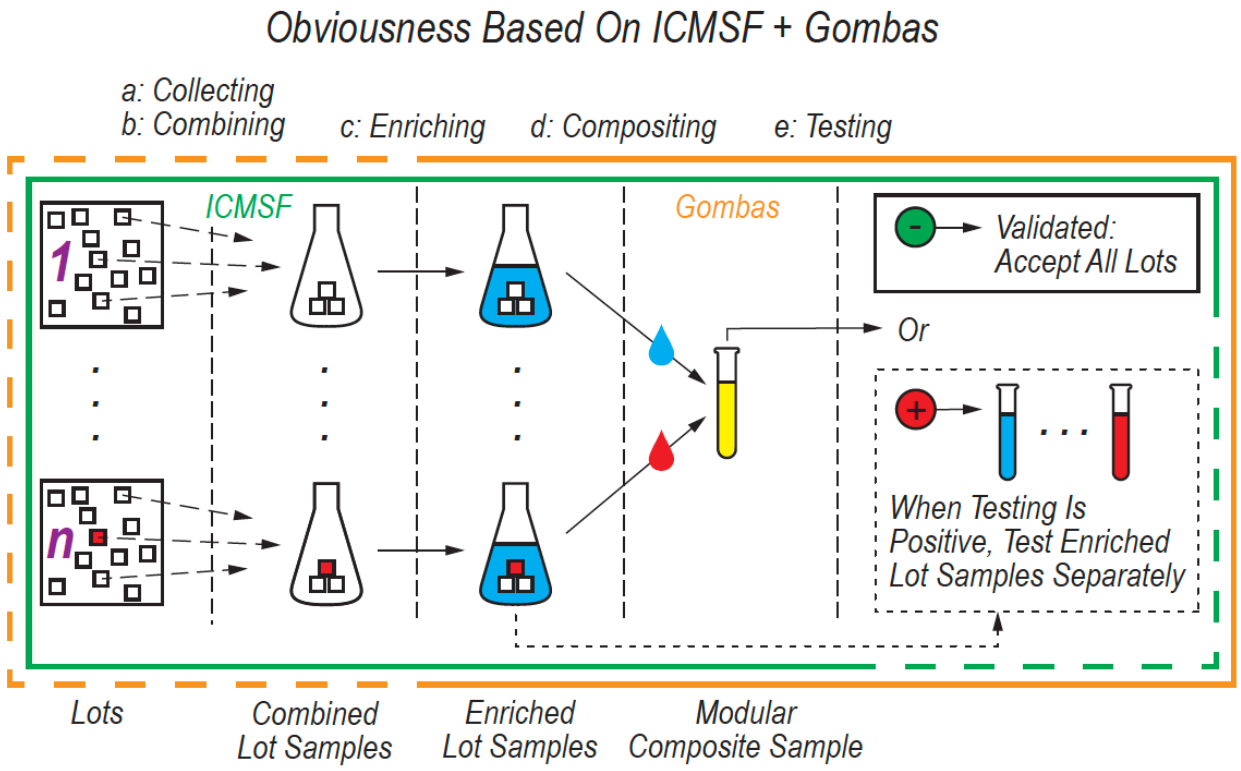
416. ICMSF would have guided a POSA to test production lots of meat, such as beef or poultry, to collect portions from lots (in conformance to a statistical-based sampling plan for release into commerce), to combine the portions, enrich the lot samples, remove portions of each enriched lot sample and combine the portions to provide a composite sample. 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. Inclusion of these teachings in ICMSF verifies they were standard practices before the priority date.

417. Gombas also establishes it was a standard practice before the priority date to enrich portions of collected meat, wet composite the enriched portions, and then test a portion of the enriched culture, as shown in its diagram below.



Ex. 1014 at 563 (Figure 1 (annotated)).

418. The diagram below accurately reflects my view of the combined teachings of ICMSF and Gombas.

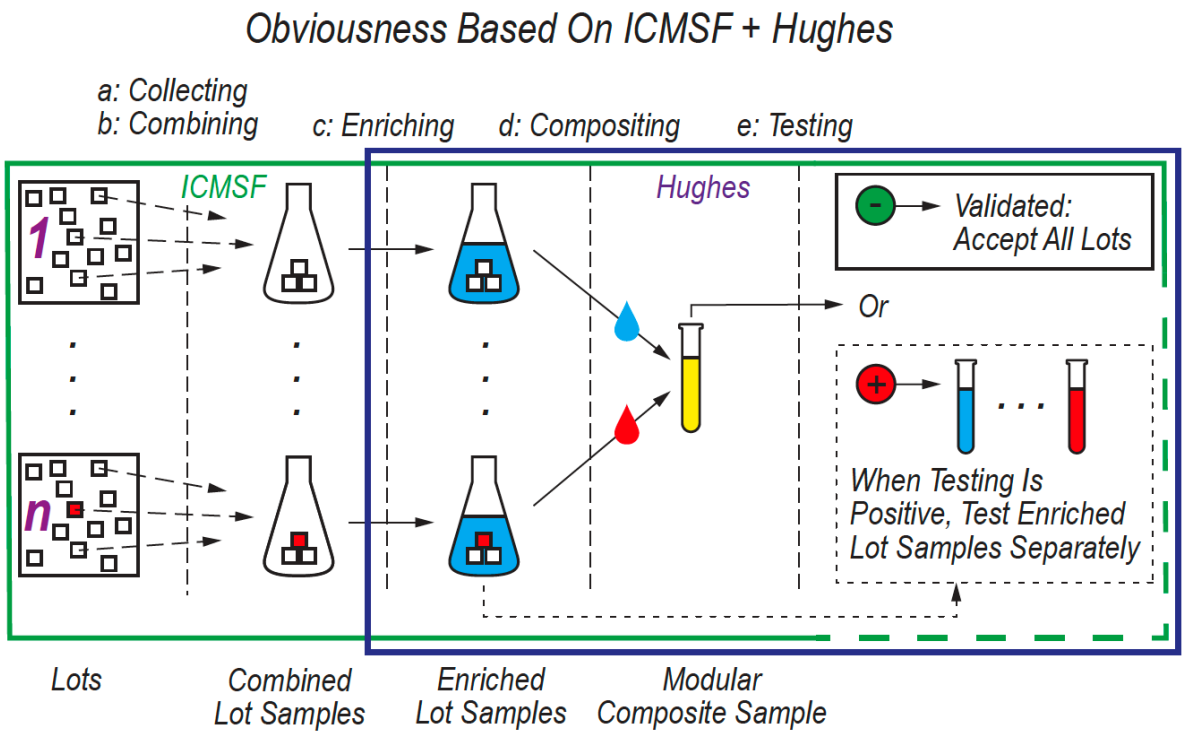


419. A POSA would have been motivated to modify or add to ICMSF based on Gombas. Gombas would have motivated a POSA to retain portions of the enrichment culture for further testing after a positive test of a composite sample by the same protocol for lot validation. Because ICMSF and Gombas disclose selectively enriching prior to removing and retaining portions, a POSA would consider there to be no requirement for further enrichment or sampling. A POSA would be motivated to modify or add to ICMSF to reduce waste and to avoid waiting for a selective enrichment process when retesting after a positive test. Additionally, a POSA would have had a reasonable expectation of successfully achieving these objectives by the combination of ICMSF and Gombas.

420. These benefits would be predictable to a POSA because combining ICMSF and Gombas merely involves known methods for assessing the safety of meat. Given ICMSF's recognition of the benefits of tracing a lot to improve efficiency, using Gombas to improve ICMSF with further testing after a positive test just as further testing is used in Gombas, is a slight change or substitution, and the benefits would be entirely predictable to a POSA. Gombas clearly just considered such further testing to be standard practice, not a new innovation. The foregoing supports my conclusion that the independent claims of the IEH Patents would have been obvious to a POSA based on ICMSF and Gombas.

B. Ground 2 Combination of ICMSF and Hughes

421. ICMSF discloses essentially the same procedure claimed in IEH's independent claims but lacks an explicit teaching for testing retained samples after a positive test. Hughes discloses steps (c)–(e). The combination of ICMSF and Hughes is depicted below.



422. The discussion of ICMSF in Ground 1 is relied upon in Ground 2 but is not repeated so reference is made to the discussion in Ground 1. Additionally, my analysis of Ground 2 below does not include a listing of the independent claims because they have already been listed above, such as in the discussion for each step addressed in Ground 1.

1. Independent Claims

a. Preamble

423. The concepts mentioned in the preambles are taught by the combination of ICMSF and Hughes, as described below. To avoid repetition, these teachings are discussed below with reference to claim steps (a) and steps (e)(1)–(e)(4). *See* §§ XII-B-1-b and XII-B-1-f to XII-B-1-i *infra*.

b. Step (a) — Collecting

424. Step (a) is taught by ICMSF as shown above at § XII-A-1-b. Hughes discloses a testing protocol for food products including for raw turkey. Ex. 1015 at 634.

c. Step (b) — Combining

425. Step (b) is taught by ICMSF as shown at § XII-A-1-c *supra*.

d. Step (c) — Enriching

426. Step (c) is taught by ICMSF as shown at § XII-A-1-d *supra*.

427. Step (c) is also taught by Hughes. Below is a section of Hughes titled "F. Preparation of Sample." The highlighted text includes instructions to enrich portions of "the incubated pre-enrichment mixtures" in two different selective enrichment broths, Rappaport-Vassiliadis (R10) broth and tetrathionate (TT) broth, both of which were widely used when Hughes was published in 1999:

F. Preparation of Sample

(a) *Pre-enrichment.*—Pre-enrich product in noninhibitory broth to initiate growth of *Salmonella* spp. Methods used may vary with product and should be performed as indicated in **967.26A** or BAM, 7th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, chapter 5, section C. Pre-enrichment broths should be incubated at 35°–37°C.

(b) *Selective enrichment.*—Transfer 0.1 mL incubated pre-enrichment mixtures to Rappaport-Vassiliadis R10 broth (9.9 mL) and 1 mL to TT broth (9 mL). For all foods other than raw foods or foods having a high microbial load, incubate 6–8 h at 41°–43°C. Selective enrichments of raw foods or foods having a high microbial load must be incubated 16–20 h at 41°–43°C. An air incubator is suitable for this purpose.

(c) *Post-enrichment.*—Remove selective broths from incubation and mix by hand or by Vortex mixer. Remove 1 mL from TT tube and transfer to separate tube of sterile M broth (10 mL) that has been warmed to 35°–37°C. Also remove 1 mL from Rappaport-Vassiliadis R10 tube and transfer to a separate tube of prewarmed M broth (10 mL). For all foods other than raw foods or foods having a high microbial load, incubate M broth tubes 16–20 h at 35°–37°C and return selective enrichment broth tubes to 41°–43°C incubator and incubate for additional 16–18 h. For raw foods or foods having a high microbial load, incubate M broth tubes 6 h at 35°–37°C and return selective enrichment broth tubes to 41°–43°C and incubate for an additional 6 h.

(d) *Preparation of sample for EIA analysis.*—Remove M broth tubes from incubation and mix tubes by hand or Vortex mixer. Combine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube and heat in boiling H_2O bath or in flowing steam 15 min. Refrigerate (2°–8°C) remaining M broth and TT and Rappaport-Vassiliadis R10 tubes from (c) for culture confirmation of any EIA-positive samples (*see* **967.26B, 967.26C, 967.27** and **967.28**). Cool heated M broths to 25°–37°C prior to analysis.

Ex. 1015 at 636, 638 (highlighting added).

428. The objective of a selective enrichment step is to provide an environment enabling a target microbial agent to reach detectable levels and become uniform. Creating such an environment may be achieved by use of an appropriate enrichment broth, sufficient incubation, appropriate temperatures, and mixing. Hughes discloses each of these factors, thus Hughes discloses that the target microbial agent or organism reaches detectable levels and becomes substantially uniform throughout the separate samples.

e. Step (d) — Wet Compositing

429. Step (d) is taught by ICMSF as shown at § XII-A-1-e *supra*.

430. Step (d) is also taught by Hughes as shown here:

> (**d**) *Preparation of sample for EIA analysis.*—Remove M broth tubes from incubation and mix tubes by hand or Vortex mixer. Combine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube and heat in boiling H_2O bath or in flowing steam 15 min. Refrigerate (2°–8°C) remaining M broth and TT and Rappaport-Vassiliadis R10 tubes from (**c**) for culture confirmation of any EIA-positive samples (*see* **967.26B, 967.26C, 967.27** and **967.28**). Cool heated M broths to 25°–37°C prior to analysis.

Ex. 1015 at 638 (highlighting added). The highlighted text of Hughes shows that Hughes teaches combining portions of enrichments to provide a modular composite sample. More specifically, after incubating the samples in separate R10 and TT broth enrichments, Hughes transferred a portion of the R10 enrichment into one M broth enrichment and a portion of the TT enrichment into another M broth

enrichment. After incubation, portions of the separate M broth enrichments were composited into a single tube for analysis. This combined tube consisted of material from both the R10 and TT enrichments.

f. Step (e)(1) — Testing

431. Step (e)(1) is taught by ICMSF as shown at § XII-A-1-f *supra*.

432. Step (e)(1) is also taught by Hughes because Hughes indicates that testing of the composite sample is "by an enzyme immunoassay (EIA) method." Ex. 1015 at 635, 638.

g. Step (e)(2) — Tested Negative

433. Step (e)(2) is taught by ICMSF as shown at § XII-A-1-g *supra*.

434. Step (e)(2) is also taught by Hughes because a negative test is the desired outcome in food testing, yet Hughes explains the steps to be taken when testing is positive (*see* § XII-B-1-h *infra*). The objective of testing food, such as meat, is to determine that the food is safe for consumption so that the food may be released into commerce.

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

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

436. In the section of Hughes titled "(d) Preparation of sample for EIA analysis," Hughes instructs that the "remaining M broth and TT and Rappaport-Vassiliadis R10 tubes" are refrigerated and retained "for culture confirmation of any EIA-positive samples" as shown in the highlighted text below:

> (**d**) *Preparation of sample for EIA analysis.*—Remove M broth tubes from incubation and mix tubes by hand or Vortex mixer. Combine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube and heat in boiling H_2O bath or in flowing steam 15 min. Refrigerate (2°–8°C) remaining M broth and TT and Rappaport-Vassiliadis R10 tubes from (**c**) for culture confirmation of any EIA-positive samples (*see* **967.26B, 967.26C, 967.27** and **967.28**). Cool heated M broths to 25°–37°C prior to analysis.

Ex. 1015 at 638 (highlighting added). Culture confirmation of an EIA-positive sample equates to further testing after a positive result. Hughes also states "[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must be streaked on selective media." *Id.* at 635. This is an instruction to use "a more sensitive protocol" because culture confirmation, including streaking, is more sensitive than the EIA method. *Id.* This is confirmed by the teachings of D'Haese. Ex. 1018 at 979. Thus, Hughes discloses step (e)(3).

i. Step (e)(4) — No Requirement

437. The teachings of ICMSF as related to step (e)(4) are provided at § XII-A-1-i *supra*. ICMSF and Hughes each disclose use of selective enrichment and not just pre-enrichment, as discussed regarding step (c) at § XII-B-1-d *supra*. After the

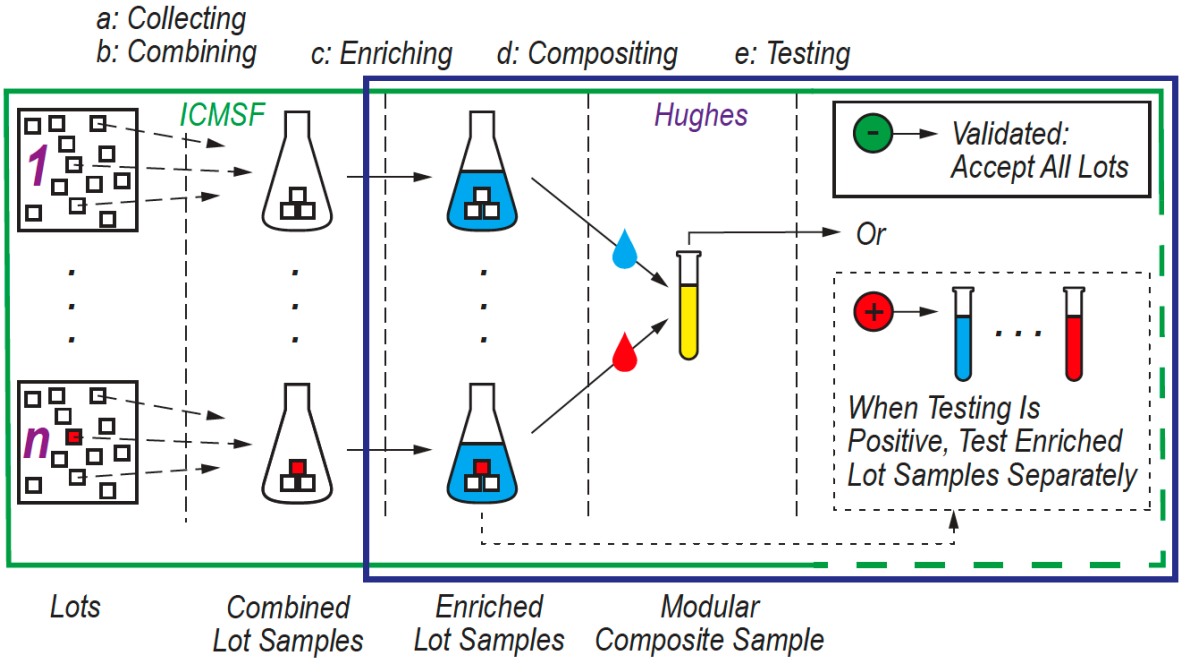
enrichment in step (c), there already "is no requirement for further enrichment thereof" as stated in step (e)(4). The same applies to there being no requirement for further sampling in step (a) under the combination of ICMSF and Hughes, because, as discussed regarding step (e)(3) at § XII-B-1-h *supra*, Hughes specifically instructs that portions of the enrichment cultures are retained for further testing so there is no need for further sampling like that of step (a). It was and remains a common laboratory practice to retain samples at different stages of the analysis, prior to the final test, so that the retained samples of different stages may be examined further, if necessary. In any event, the recitations of step (e)(4) are superfluous based on the combined teachings of ICMSF and Hughes.

2. Combination Rationales for Ground 2

438. ICMSF would have guided a POSA to test production lots of meat, such as beef or poultry, to collect portions from lots (in conformance to a statistical-based sampling plan for release into commerce), to combine the portions, enrich the lot samples, remove portions of each enriched lot sample and combine the portions to provide a composite sample. 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. Inclusion of these teachings in ICMSF verifies they were standard practices before the priority date.

439. Hughes, like ICMSF, merely involves known methods for assessing the safety of meat and other food products. Hughes also establishes it was a standard practice before the priority date to enrich portions of collected meat, wet composite the enriched portions, and then test a portion of the enriched culture. The diagram below accurately reflects my view of the combined teachings of ICMSF and Hughes.

Obviousness Based On ICMSF + Hughes



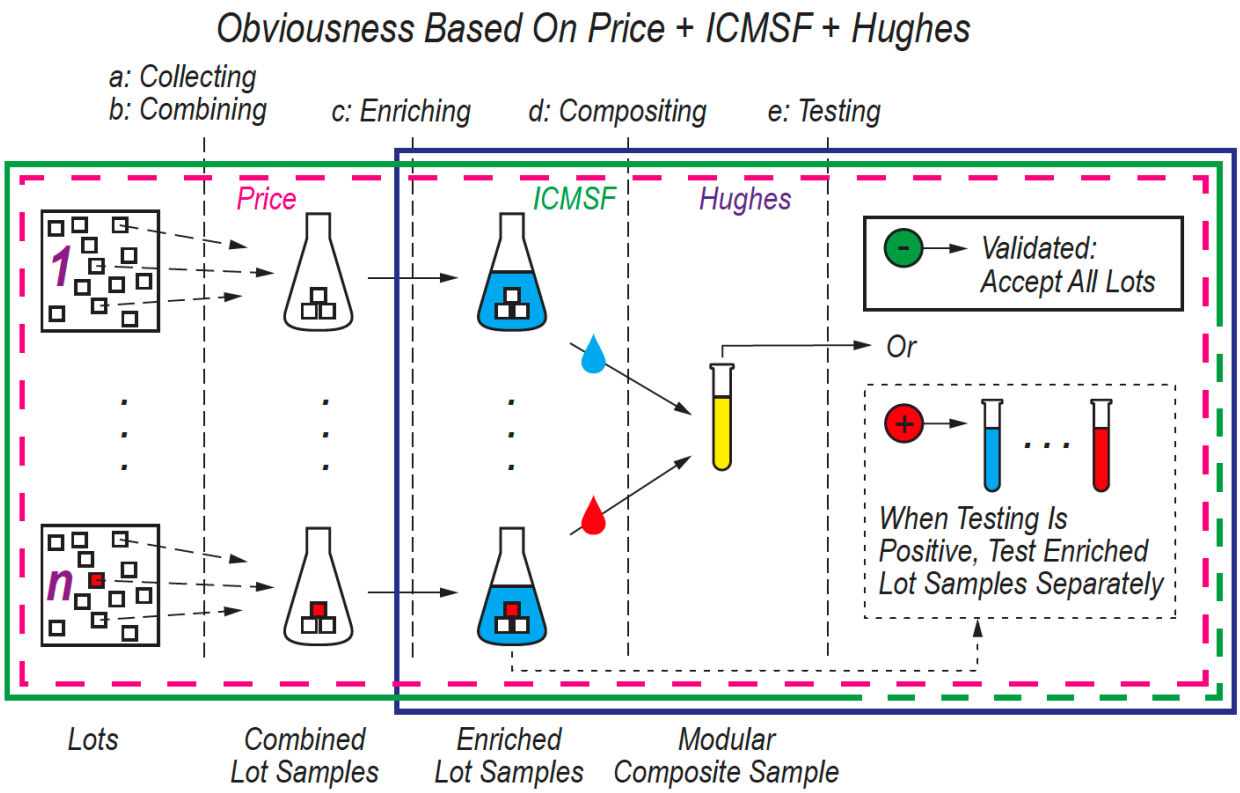
440. A POSA would have been motivated to modify or add to ICMSF based on Hughes. Hughes would have motivated a POSA to retain portions of the enrichment culture for further testing after a positive test of a composite sample by a more sensitive protocol for lot validation. Because ICMSF and Hughes disclose selectively enriching prior to removing and retaining portions, a POSA would consider there to be no requirement for further enrichment or sampling. A POSA

would be motivated to modify or add to ICMSF to reduce waste and to avoid waiting for a selective enrichment process when retesting after a positive test. Additionally, a POSA would have had a reasonable expectation of successfully achieving these objectives by the combination of ICMSF and Hughes.

441. In my view, using Hughes to improve ICMSF with further testing after a positive test just as further testing is used in Hughes, is a slight change or substitution, and the benefits would be entirely predictable to a POSA. Hughes, like Gombas, simply considered such further testing to be standard practice, not a new innovation. The foregoing supports my conclusion that the independent claims of the IEH Patents would have been obvious based on ICMSF and Hughes.

C. Ground 3 Combination of Price, ICMSF, and Hughes

442. Price discloses most of steps (a)–(e) but it relates to dry food materials and pools of pre-enrichments, rather than meat and pools of enrichments. ICMSF and Hughes focus on assessing the safety of meat and involve pooling enrichments. ICMSF lacks an explicit teaching for testing retained samples after a positive test, but such a teaching is described by Hughes. The combination of Price, ICMSF, and Hughes is depicted below:



443. The discussion of ICMSF in Ground 1 and the discussion of Hughes in Ground 2 are not repeated so reference is made to the discussion in Grounds 1 and 2. Additionally, my analysis of this ground below does not include a listing of the independent claims because they have already been listed above such as in the discussion for each step addressed in Ground 1.

1. Independent Claims

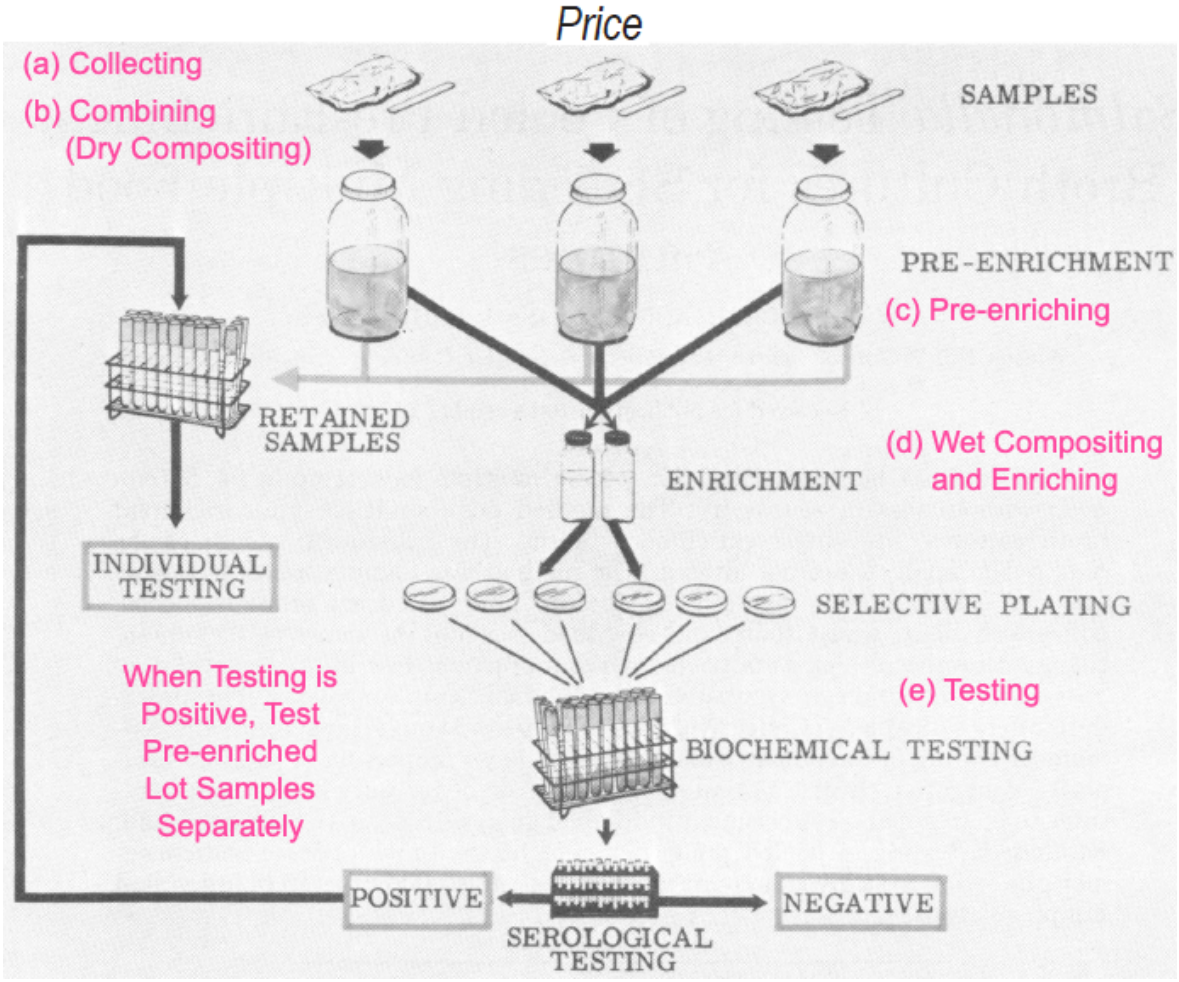
a. Preamble

444. The concepts mentioned in the preambles are taught by the combination of Price, ICMSF, and Hughes, as described below. To avoid repetition, these teachings

are discussed below with reference to claim steps (a) and steps (e)(1)–(e)(4). *See* §§ XII-C-1-b and XII-C-1-f to XII-C-1-i *infra*.

b. Step (a) — Collecting

445. Price depicts, in Figure 1 shown below, three sources of dry food materials from which a plurality of portions are necessarily collected for pre-enrichment:



Ex. 1017 at 680 (Figure 1 (annotated)).

446. In IEH's Figure 3 (reproduced at VIII-C-3 *supra*) the three sources equate to lots because they are an assemblage of specimens. The text of Price indicates larger

numbers of lots may be pre-enriched including 5, 9, 14, and 25. *Id.* at 679–81. For example, Price states that "samples were analyzed both individually and after pooling with 5, 9, and 14 pre-enrichments of uninoculated samples." *Id.* at 679–80. Price also states in its abstract, as shown below in the highlighted text, that "as many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis":

> **A method has been described for testing multiple food samples for *Salmonella* without loss in sensitivity. The method pools multiple pre-enrichment broth cultures into single enrichment broths. The subsequent stages of the *Salmonella* analysis are not altered. The method was found applicable to several dry food materials including nonfat dry milk, dried egg albumin, cocoa, cottonseed flour, wheat flour, and shredded coconut. As many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis. The procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found. *Salmonella* testing of pooled pre-enrichment broths provides increased consumer protection for a given amount of analytical effort as compared to individual sample analysis.**

Id. at 679 (highlighting added).

447. Other studies built on Price's procedure with dry food materials as discussed above regarding Silliker (Ex. 1025) and Gabis (Ex. 1026), which tested meat. *See* § X-D-1 *supra*. These studies are discussed by ICMSF. Ex. 1012 at 187 (§ 10.4). A POSA would have naturally turned to ICMSF when modifying Price for meat testing because ICMSF built on the studies that built on Price. In addition to ICMSF (*see* X-A-1 *supra*), MLG (*see* X-D-3 *supra*) also indicates that wet compositing or

pooling became commonly used for a variety of food products, including beef and poultry.

448. ICMSF teaches collecting a plurality of portions of meat including beef or poultry (Ex. 1012 at 114 (§ 6.3), 184–91 (§§ 10.2–10.6), 225–26 (§ 12.1), 285 (§ 16.1), 313–30 (Chapter 17)) from lots (*id.* at 118–20 (§§ 6.10–6.11), 225 (§ 12.1)) including consignments of lots such as separate operationally-linked test lots and operationally-linked single-unit production lots (*id.* at 114 (§ 6.3), 118–20 (§§ 6.10–6.11), 225–26 (§ 12.1), 326–27 (§ 17.5.3.2)). ICMSF also teaches following the standard practice of using of a "statistically based sampling plan" (*id.* at 113 (§ 6.1); s*ee also id.* at 115–21 (§§ 6.4–6.12), 184 (§ 10.2), 276 (§ 15.3.3), 282 (§ 15.6.3), 308–09 (§§ 16.6.3), 317–21 (§§ 17.2.3.1–17.2.3.4), 326 (§ 17.5.3.1)) to provide for validation and release of the lot into commerce (*id.* at 184–89 (§§ 10.2–10.6)) as discussed throughout ICMSF.

449. Before the priority date, a POSA would understand from ICMSF that the sources or bins of dry food materials in Price could be replaced by meat such as beef or poultry. Ex. 1012 at 114 (§ 6.3), 184–91 (§§ 10.2–10.6), 225–26 (§ 12.1), 285 (§ 16.1), 313–30 (Chapter 17). A POSA also would have understood the well-known step of collecting a plurality of sample units (samples/portions) from the lots. *Id.* at 118–20 (§§ 6.10–6.11), 225 (§ 12.1), 326–27 (§ 17.5.3.2). Additionally, a POSA would have recognized that the meat could have included consignments of lots

including separate operationally-linked test lots and operationally-linked single-unit production lots (*id.* at 114 (§ 6.3), 118–20 (§§ 6.10–6.11), 225–26 (§ 12.1), 326–27 (§ 17.5.3.2)). Because it was the standard practice long before the priority date to utilize a "statistically based sampling plan" (*id.* at 113 (§ 6.1); s*ee also id.* at 115–21 (§§ 6.4–6.12), 184 (§ 10.2), 276 (§ 15.3.3), 282 (§ 15.6.3), 308–9 (§§ 16.6.3), 317–21 (§§ 17.2.3.1–17.2.3.4), 326 (§ 17.5.3.1)) to provide for validation and release of the lot into commerce (*id.* at 184–89 (§§ 10.2–10.6)), ICMSF thoroughly discusses such plans.

450. Collecting sample units is not prominently discussed in Price because Price is a paper focused on laboratory methods and the paper's audience was presumed to be familiar with standard practices for collecting sample units. Thus, Price simply indicates "*Salmonella* analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths." Ex. 1017 at 679. The version of BAM identified in Price's endnotes is BAM 1969. *Id.* at 682. BAM 1969 includes section 10.04 identified as the "reference method" for detection and identification of *Salmonella* in dried food products. Ex. 1032 at 1 (§ 10.04). Section 10.04 cites to "Detection and Identification of Salmonella in Egg Products," JAOAC 50 (1) at 231–39 (1967). The relevant section from the JAOAC is provided below:

Detection

37.X18 Preparation of Sample Cultures

Open sample container aseptically and weigh aseptically 25 g sample into sterile, empty, wide-mouth, screw-cap pint jar. Add ca 15 ml sterile lactose broth, **37.X16(a)**. Stir with sterile glass rod, sterile spoon, or sterile tongue depressor to smooth suspension. Add 3 addnl portions of lactose broth, 10, 10, and 190 ml for total of 225 ml. Stir after each addn until sample is suspended without lumps. Cap jar securely and let stand at room temp. 60 min. Mix well by shaking, and det. pH with test paper, **37.X17(1)**. Adjust pH, if necessary, to 6.8 ± 0.2 with sterile 1*N* NaOH or HCl, **37.X17(c)** or **(d)**, capping jar securely and mixing well before detg final pH. Loosen jar cap ca ¼ turn and incubate 24 ± 2 hr at 35°.

Ex. 1033 at 234. A POSA would understand these were standard practices for collecting sample units. Thus, IEH's diagram of Price instructs, with reference to step 1, which corresponds to IEH's step (a), to "[t]ake individual portions . . . from each Sample." Ex. 1007 at 298; *see also* § VIII-C-3, VIII-D-11, X-A-4 *supra*.

451. The Board previously recognized in the appeal from the reexamination, regarding Price, that "[i]t would have been commonsense to combine samples from the same bin and subject them to enrichment, since each bin represents a discrete unit of the production run and results obtained from the enriched sample could be attributed to the bin from which the sample was obtained," as shown in the highlighted text of the First Board Decision shown below:

> The purpose of Jarvis and Price was to determine whether pooling samples reduced the ability to detect contaminated food lots. It would have been commonsense to combine samples from the same bin and subject them to enrichment, since each bin represents a discrete unit of the production run and results obtained from the enriched sample could be attributed to the bin from which the sample was obtained.

Ex. 1007 at 1575 (First Board Decision of January 20, 2015 at 16).

452. Price's audience would have understood that dry food materials are typically already mixed and the product merely needs to be scooped from each bin in a manner that allows the product to be traced back to the bin. An example of Price teaching tracing is provided by the statement that "small portions of pre-enrichment broth cultures [are] to be retained for subsequent individual analysis if positive tests are found" as shown in the highlighted text of the abstract of Price shown below:

> A method has been described for testing multiple food samples for *Salmonella* without loss in sensitivity. The method pools multiple pre-enrichment broth cultures into single enrichment broths. The subsequent stages of the *Salmonella* analysis are not altered. The method was found applicable to several dry food materials including nonfat dry milk, dried egg albumin, cocoa, cottonseed flour, wheat flour, and shredded coconut. As many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis. The procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found. *Salmonella* testing of pooled pre-enrichment broths provides increased consumer protection for a given amount of analytical effort as compared to individual sample analysis.

Ex. 1017 at 679 (highlighting added).

453. In another example, Price states that "a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4°C for later reference to the

individual samples" and that "individual tests on the retained sample can be made to determine which sample or samples contributed to *Salmonella* in the pool," as shown in the highlighted text of the excerpt of Price shown below:

MATERIALS AND METHODS

Salmonella analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths described in the following paragraph.

The procedure for *Salmonella* testing of pooled pre-enrichment broths is illustrated in Fig. 1. Samples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage. During pooling, a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4 C for later reference to the individual samples. If the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.

Id. A POSA would recognize from these teachings of Price that sample units are combined while ensuring that the resulting test lot sample is attributable to a particular lot.

c. Step (b) — Combining

454. A POSA would be encouraged to modify Price based on ICMSF because ICMSF teaches all aspects of step (b), as described at § XII-A-1-c *supra*. ICMSF teaches combining portions from lots. Ex. 1012 at 119–20 (§ 6.11), 187–91 (§§ 10.4–10.6), 225–29 (§§ 12.1–12.2.4). ICMSF also teaches that lot samples are

attributable to a particular lot by tracing via codes. *Id.* at 119 (§ 6.10), 226–29 (§§ 12.2–12.2.5).

455. Testing meat instead of dry food materials means that one could not rely on the inherent mixing involved with dry food materials in Price that yields a homogenized product such that one may simply scoop some of the dry food materials from a bin and be assured the scoop is likely representative of the bin from which the scoop is taken. Instead, one would need to randomly collect sample units of meat to obtain a sample that is representative of the lot being sampled as taught by ICMSF. *Id.* at 225–26 (§§ 12.1–12.2).

456. Like ICMSF, the test lot samples in Price are attributable to a particular lot. For example, Price's abstract states that the procedure "permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found," as shown below:

> **A method has been described for testing multiple food samples for *Salmonella* without loss in sensitivity. The method pools multiple pre-enrichment broth cultures into single enrichment broths. The subsequent stages of the *Salmonella* analysis are not altered. The method was found applicable to several dry food materials including nonfat dry milk, dried egg albumin, cocoa, cottonseed flour, wheat flour, and shredded coconut. As many as 25 pre-enrichment broth cultures were pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis. The procedure offers a simple, yet effective, way to increase sample capacity in the *Salmonella* testing of foods, particularly where a large proportion of samples ordinarily is negative. It also permits small portions of pre-enrichment broth cultures to be retained for subsequent individual analysis if positive tests are found. *Salmonella* testing of pooled pre-enrichment broths provides increased consumer protection for a given amount of analytical effort as compared to individual sample analysis.**

Ex. 1017 at 679 (highlighting added). Price further describes this retention step as enabling "individual tests on the retained sample" to "be made to determine which sample or samples contributed *Salmonella* to the pool" as shown below:

MATERIALS AND METHODS

Salmonella analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths described in the following paragraph.

The procedure for *Salmonella* testing of pooled pre-enrichment broths is illustrated in Fig. 1. Samples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage. During pooling, a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4 C for later reference to the individual samples. If the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.

Id. (highlighting added). Based on the foregoing, a POSA would have considered that collecting sample units of meat instead of dry food products would have been a simple substitution and both references, ICMSF and Price, disclose tracking the source of the sample units to its source so that a positive test can be traced to a particular lot.

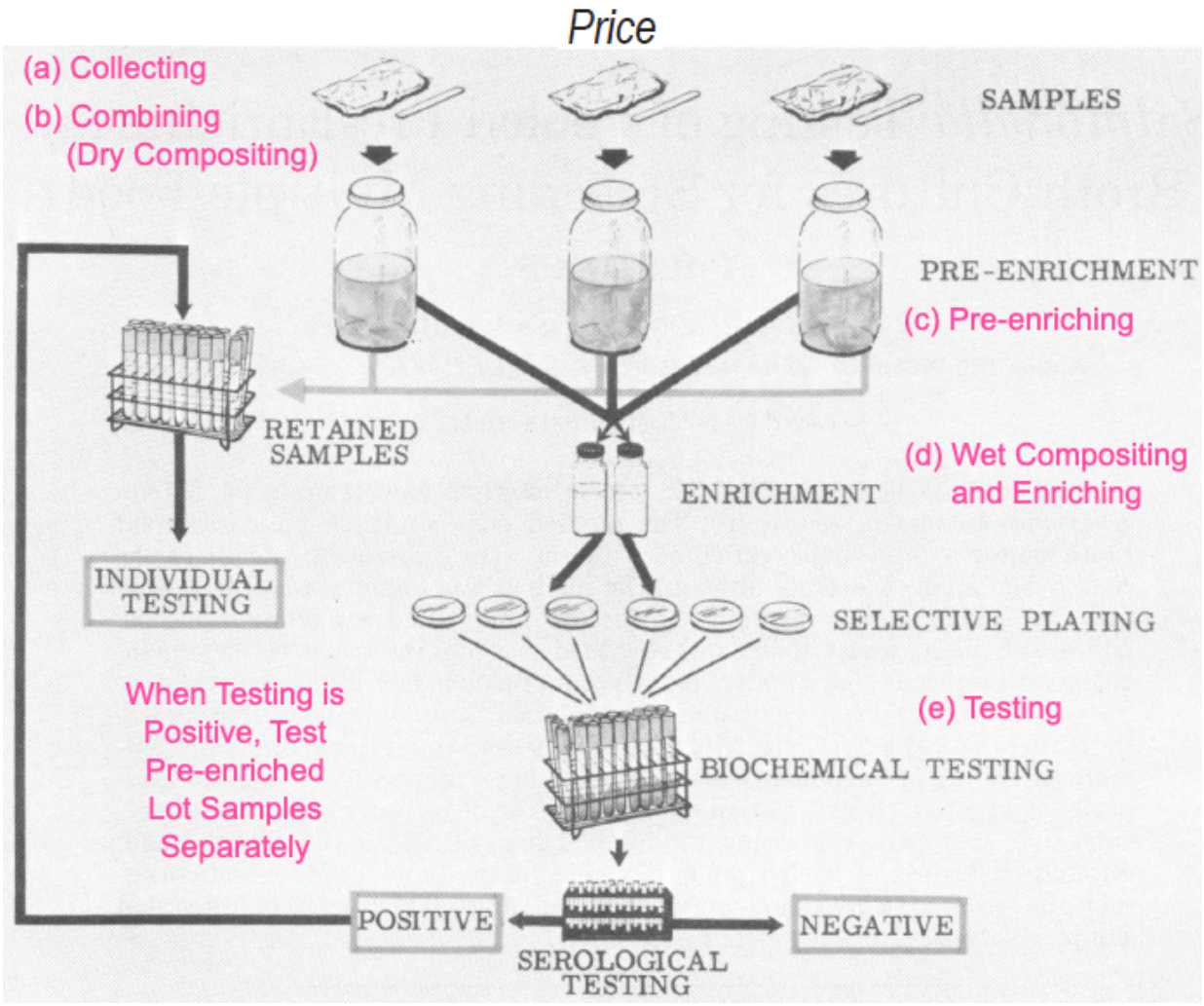
d. Step (c) — Enriching

457. As shown below by the highlighted text, 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" as shown here:

Effect of volume of pre-enrichment broth transferred. The BAM method (2) for *Salmonella* detection in egg products calls for the transfer of 1 ml of pre-enrichment broth culture to 10 ml of enrichment broth. In the multiple pooling of pre-enrichment broth cultures that has been described, 1-ml quantities of cultures were transferred, generally, to a volume of enrichment broth determined by the number of samples to be pooled to maintain a fixed pre-enrichment-to-enrichment ratio. Thus, 150 ml of enrichment broth was used to receive 15 1-ml poolings, 100 ml for 10 1-ml poolings, etc. However, for routine laboratory operations, it is more desirable to dispense enrichment broth at a constant volume. Since the number of samples to be pooled may vary considerably from time to time, it is important to know whether variations in enrichment ratio would significantly affect the detection of *Salmonella*.

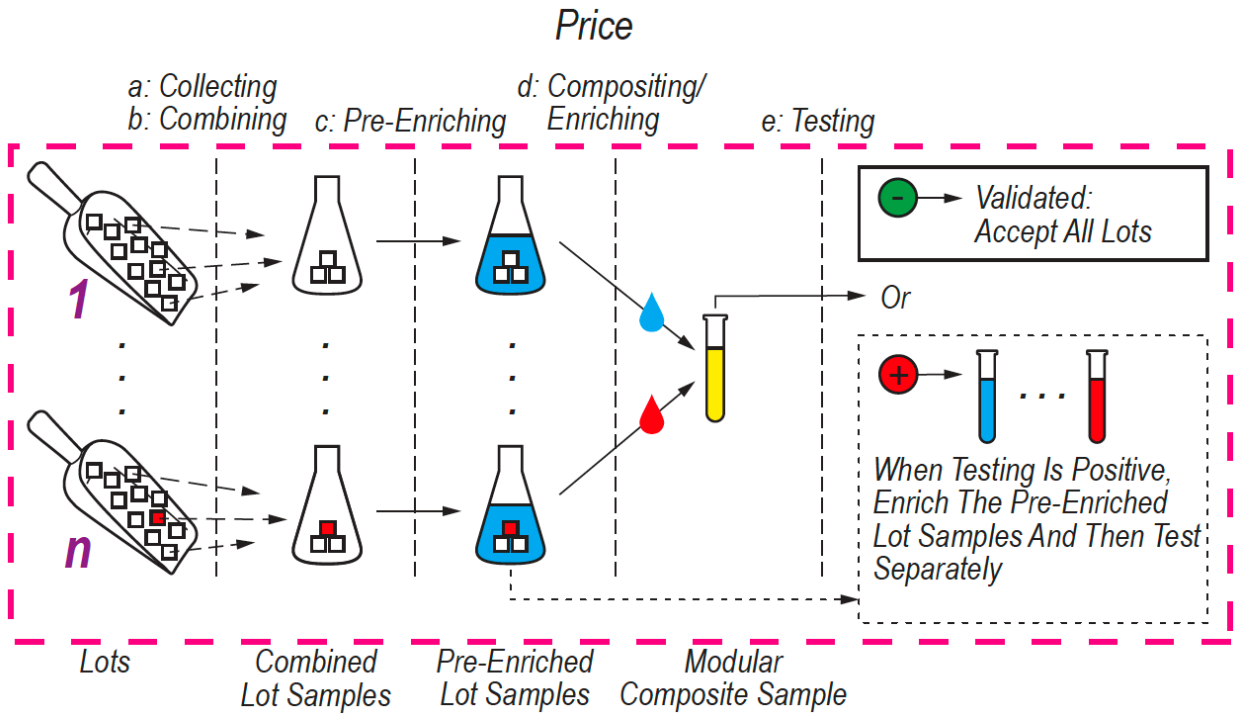
Ex. 1017 at 682 (highlighting added).

458. Price's Figure 1, shown below, also shows the pre-enrichments being pooled and enriched:



Id. at 680 (Figure 1 (annotated)).

459. The same is shown in the diagram below, which I consider to be an accurate reflection of the teachings of Price.



460. As shown below by the highlighted text, Price states "[a]lternatively, problems with interfering organisms may warrant the use of direct selective enrichments":

> **Whether pooled pre-enrichments are less sensitive than individual tests in the presence of interfering organisms probably is not known. For the present, we would recommend that, if numerous non-*Salmonella* colonies that resemble *Salmonella* on selective agar media are encountered in the pooled test, the retained pre-enrichment cultures should be tested individually. Alternatively, problems with interfering organisms may warrant the use of direct selective enrichments, two selective enrichments, or possibly even a reduction in the incubation time of the pre-enrichment cultures.**

Id. at 682 (highlighting added). Based on the above quote, Price would have been considered as encouraging a POSA to utilize selective enrichment prior to pooling.

461. Even without any encouragement from Price to enrich the lot samples prior to pooling, a POSA would have been motivated to do so based only on ICMSF (Ex. 1012 at 187 (§ 10.4), 231–32 (§ 12.5.2)). *See* § XII-A-1-d *supra*. To the extent that Price and ICMSF are considered not to disclose some aspect of step (c), it would have also been obvious to combine Price, ICMSF, and Hughes (*see* § XII-B-1-d *supra*). Hughes shows that it was well known prior to the priority date to follow non-selective enrichment with selective enrichment and then wet composite the enrichments. For example, Hughes states that portions of the "incubated pre-enrichment mixtures" should be transferred to two different selective enrichment broths, "Rappaport-Vassiliadis R10 broth" and "TT broth." Ex. 1015 at 636.

e. Step (d) — Wet Compositing

462. As shown below by the highlighted text, Price states "[s]amples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage":

MATERIALS AND METHODS

Salmonella analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths described in the following paragraph.

The procedure for *Salmonella* testing of pooled pre-enrichment broths is illustrated in Fig. 1. Samples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage. During pooling, a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4 C for later reference to the individual samples. If the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.

Ex. 1017 at 679 (highlighting added).

463. As discussed regarding step (d) in Ground 1 at § XII-A-1-e *supra*, a POSA would have been motivated to selectively enrich and then wet composite the enrichments based only on ICMSF. For example, ICMSF states "it would be helpful to **combine** either groups of analytical units or the **enrichment cultures** therefrom." Ex. 1012 at 187 (§ 10.4) (emphasis added). A POSA would have thus been motivated to modify Price based on ICSMF such that pre-enrichment is followed by enrichment and then wet compositing.

464. To the extent that Price and ICMSF are considered not to disclose some aspect of step (d), it would have also been obvious to combine Price, ICMSF, and Hughes as discussed regarding step (d) in Ground 2 at § XII-B-1-e *supra*. Hughes shows that it was well known prior to the priority date to follow non-selective enrichment

with selective enrichment and then wet composite the enrichments. For example, Hughes instructs to "[r]emove M broth tubes from incubation and mix tubes by hand or Vortex mixer" then "[c]ombine equal volumes (0.5–1 mL) from each M broth tube in a clean screw-cap tube." Ex. 1015 at 638.

f. Step (e)(1) — Testing

465. Price is titled "*Salmonella* Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples." The test necessarily uses a suitable detection assay for *Salmonella*. Ex. 1017 at 680. Price's Figure 1 indicates that selective plating, biochemical testing, and serological testing are used. *Id.* (Figure 1).

466. ICMSF describes testing composite samples of enrichment cultures (Ex. 1012 at 187 (§ 10.4)) with suitable detection assays and "presence/absence tests" (*id.* at 233 (§ 12.7)). *See* § XII-A-1-f *supra* regarding ICMSF in step (e)(1) in Ground 1. While testing methodologies are not the focus of ICMSF, Hughes explicitly refers to testing "by an enzyme immunoassay (EIA) method." Ex. 1015 at 635; *see* § XII-B-1-f *supra* regarding Hughes in step (e)(1) in Ground 2.

g. Step (e)(2) — Negative Test

467. As shown below by the highlighted text, 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":

> **Positive test results are relatively rare among the many samples of food ingredients and products which are analyzed for *Salmonella*. Therefore, 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. These studies support the conclusion that *Salmonella* pre-enrichment broths can be pooled for analysis without loss in sensitivity to *Salmonella* in the individual samples.**

Ex. 1017 at 679 (highlighting added). Price indicates that "positive test results are relatively rare." *Id.* ICMSF similarly indicates that a negative test result is expected when testing food. Ex. 1012 at 113–15 (§§ 6.1–6.6), 120 (§ 6.8), 183–91 (§§ 10.1–10.6), 308–09 (§ 16.6.3), 325–26 (§§ 17.5.3–17.5.3.1). It is well-understood and supported by ICMSF that the objective of any commercial operation involved in testing meat is to validate, for release into commerce and ultimately consumption by the public, the source of the meat (i.e., the lot). *Id.* at 118–19 (§§ 6.9–6.10), 184–91 (§§ 10.2–10.6). Additionally, ICMSF teaches correlating lots in a consignment with lot samples such that a negative or positive test result enables a lot to be validated or rejected. *Id.* at 118–19 (§§ 6.9–6.10).

468. Step (e)(2) is also taught by Hughes, which indicates enriched test lot samples should be retained for further testing after a positive result. Ex. 1015 at 635, 638. A negative test is not specifically mentioned in Hughes because it is understood that is the desired outcome. *Id.*

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

469. As shown below by the highlighted text, Price states "[i]f the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool":

MATERIALS AND METHODS

Salmonella analyses were carried out as described in the *Bacteriological Analytical Manual* (BAM) (2) except for the pooling of pre-enrichment broths described in the following paragraph.

The procedure for *Salmonella* testing of pooled pre-enrichment broths is illustrated in Fig. 1. Samples are individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage. During pooling, a portion of each pre-enrichment is transferred to a sterile culture tube and retained at 4 C for later reference to the individual samples. If the *Salmonella* test of the pooled pre-enrichment broths is positive, individual tests on the retained samples can be made to determine which sample or samples contributed *Salmonella* to the pool.

Ex. 1017 at 679 (highlighting added). While the composited lot samples in Price that are retained are only pre-enriched, a POSA would have considered retention of samples that had been selectively enriched as an option.

470. As discussed more above regarding steps (b)–(d), ICMSF discloses methods for "reliable traceability" (Ex. 1012 at 227 (§ 12.2.1)) by correlating lots in a consignment with lot samples by assigning "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" (*id.* at 119 (§ 6.10)), such that a negative or positive test result enables a lot to be validated or rejected (*id.* at 118–19 (§ 6.9–6.10)). Similarly, Hughes indicates enriched test lot samples should be retained for further testing after a positive result. Ex. 1015 at 635, 638.

471. ICMSF discloses validating for release into commerce (Ex. 1012 at 184–89 (§§ 10.2–10.6)) according to a statistically-based sampling plan (*id.* at 113 (§ 6.1); s*ee also id.* at 115–21 (§§ 6.4–6.12), 184 (§ 10.2), 276 (§ 15.3.3), 282 (§ 15.6.3), 308–09 (§§ 16.6.3), 317–21 (§§ 17.2.3.1–17.2.3.4), 326 (§ 17.5.3.1)), as described above regarding steps (a) and (e)(2) in Ground 1.

472. Hughes includes a step for refrigerating the "remaining M broth and TT and Rappaport-Vassiliadis R10 tubes [that were enriched] for culture confirmation of any EIA-positive samples." Ex. 1015 at 638. Thus, Hughes shows that before the priority date a POSA would have considered the option of retention of samples that had been selectively enriched. Hughes also indicates that "[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must be streaked on selective media." *Id.* at 635. Culture confirmation using streaking is more sensitive than the EIA method, as confirmed by the teachings of D'Haese. Ex. 1018 at 979.

i. Step (e)(4) — No Requirement

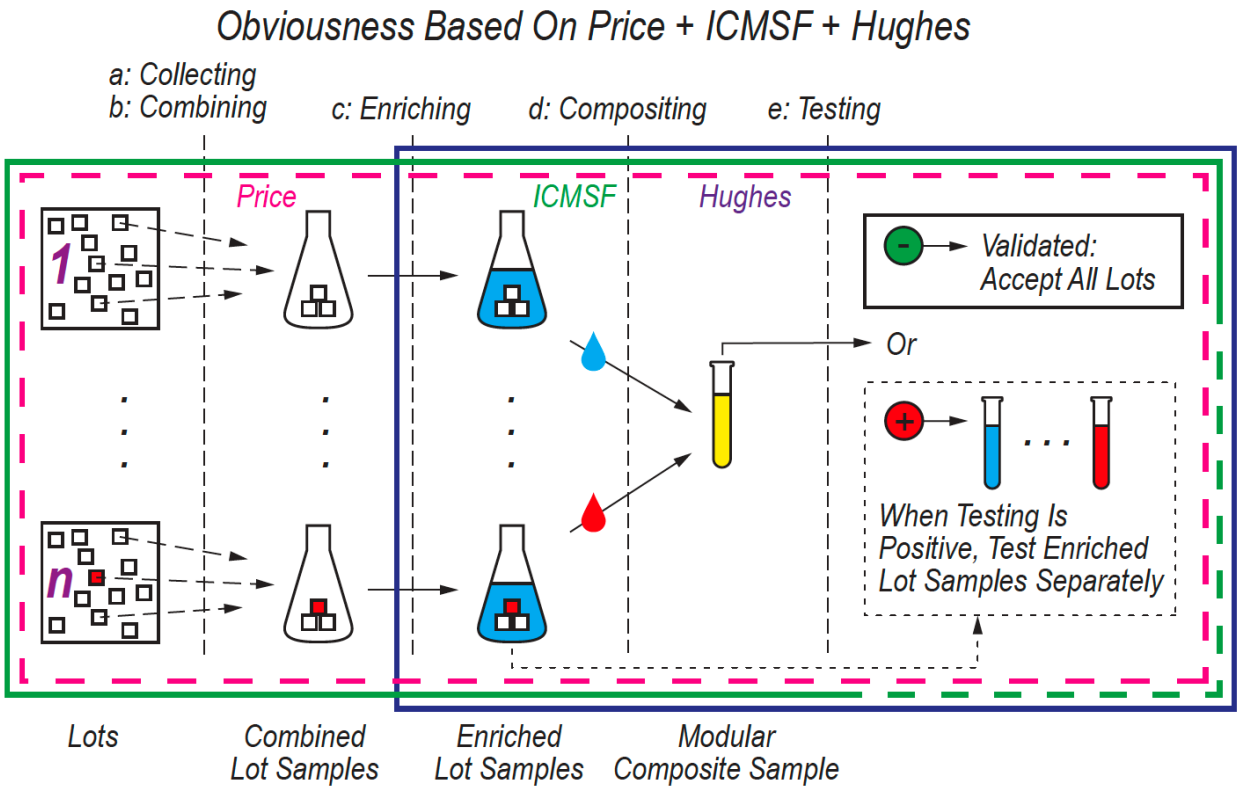
473. A POSA would understand that the non-selective enrichment of Price may be followed or replaced by selective enrichment, as discussed above regarding steps (c) and (d) in Ground 1 regarding ICMSF and Ground 2 regarding Hughes. For example, ICMSF discloses use of enrichment. Ex. 1012 at 187 (§ 10.4), 231–32 (§ 12.5.2). Also, Hughes discloses use of non-selective enrichment followed by selective enrichment. Ex. 1015 at 636. After being enriched, the composited samples in ICMSF and Hughes have no need for further enrichment.

474. As discussed above regarding step (e)(3) in Ground 2 regarding Hughes (§ XII-B-1-h), Hughes instructs that enriched test lot samples should be retained for further testing after a positive result, by stating that the "remaining M broth and TT and Rappaport-Vassiliadis R10 tubes" are refrigerated and retained "for culture confirmation of any EIA-positive samples." *Id.* at 638. Because Hughes explicitly states that portions of the enrichment cultures are retained for further testing, there is no need for further sampling in Hughes.

2. Combination Rationales for Ground 3

475. The diagram below accurately reflects my view of the combined teachings of Price, ICMSF, and Hughes. Price provides a POSA with a framework for two-stage compositing and discloses at least the essence of each of the five steps of the independent claims but with pre-enrichment instead of selective enrichment.

ICMSF teaches steps (a)–(d) and most of step (e). Hughes teaches steps (c)–(e). A POSA would have been motivated to modify Price's framework based on ICMSF and to make further modifications based on Hughes.



476. To the extent that sufficient details are not provided in Price corresponding to steps (a) and (b) that is because Price's audience was a POSA who would have understood from industry-accepted guidelines like ICMSF all aspects of the subject matter recited in steps (a) and (b) were standard practices. Additionally, a POSA seeking to test lots of meat, such as beef or poultry, would be motivated to replace the sources of dry food materials in Price with lots of meat as taught by ICMSF and

Hughes and do so according to a statistical-based sampling plan for validation and release of lots into commerce as taught by ICMSF.

477. With regard to steps (c) and (d), a POSA would understand that the non-selective enrichment of Price may be replaced by selective enrichment as taught by ICMSF or followed by selective enrichment as taught by Hughes. The selective enrichments would then be wet composited/pooled as taught by ICMSF and Hughes to yield one composite sample for testing. Price's disclosure is clear that such wet compositing reduces workload and increases sample testing capacity. Ex. 1017 at 679. Thus, the combination teaches steps (c) and (d).

478. Price, ICMSF, and Hughes would have each guided a POSA to test a modular composite sample and to consider the process complete after a negative result. Additionally, Price as modified by ICMSF teaches that the sources of the modular composite sample, the lots, could be released into commerce after a negative test. Inclusion of these teachings in ICMSF verifies they were standard practices before the priority date.

479. Price discloses the concept of retaining pre-enrichments, as it was a common practice to retain portions at each step of a testing method until the method was completed. ICMSF and Hughes would have motivated a POSA to retain portions of the enrichment cultures for further testing after a positive test of a composite sample by the same or a more sensitive protocol for lot validation without any additional

enrichment or sampling. A POSA would be motivated to modify or add to Price based on ICMSF and Hughes to reduce waste and to avoid waiting for a selective enrichment process when retesting after a positive test. Additionally, a POSA would have had a reasonable expectation of successfully achieving these objectives by the combination of Price, ICMSF, and Hughes. The foregoing supports my conclusion that the independent claims of the IEH Patents would have been obvious based on Price, ICMSF, and Hughes.

480. In my view, improving on Price with the changes summarized above based on ICMSF and Hughes are slight changes, and the benefits would be entirely predictable to a POSA. For example, a POSA would simply substitute the steps in Price's framework with those of ICMSF and Hughes, as explained above. The benefits of efficient validation would be predictable to a POSA because combining Price, ICMSF, and Hughes merely involves known methods for assessing the safety of meat. The foregoing further supports my conclusion that the independent claims of the IEH Patents would have been obvious based on Price, ICMSF, and Hughes.

D. Dependent Claims

481. In this section, § XII-D, for the sake of efficiency the dependent claims of the three IEH Patents are listed in groups according to the grounds that are germane to the claims across the three IEH patents. Similarly, the claims are clustered based on their subject matter and analyzed on the same basis. Claims 2–6, 10, 11, 13–16, 18–

20, 22, 23, 26–33 of the ’584 Patent; claims 2–7, 11, 12, 14–20, 22–24, 26, 29–34, and 36 of the ’143 Patent; and claims 2–11, 15, 16, 18–24, 26–31, 33, 38, and 41–49 of the ’771 Patent are challenged.

1. Grounds 1–3 — Claims 2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, and 29–33 of the ’584 Patent; Claims 2, 3, 5–7, 11, 12, 14–20, 22–24, 26, 29, 31–34, and 36 of the ’143 Patent; and Claims 2–4, 6, 8–11, 15, 16, 18–24, 26–31, 33, 38, 41–44, 46, 48, and 49 of the ’771 Patent

482. Below is my analysis of claims 2, 4–6, 10, 11, 13–16, 18–20, 22, 23, 26, 27, and 29–33 of the ’584 Patent; claims 2, 3, 5–7, 11, 12, 14–20, 22–24, 26, 29, 31–34, and 36 of the ’143 Patent; and claims 2–4, 6, 8–11, 15, 16, 18–24, 26–31, 33, 38, 41–44, 46, 48, and 49 of the ’771 Patent. These claims would have been obvious based on the teachings of the references of at least ground 1. Additionally, with the exception of claim 30 of the ’584 Patent, claim 32 of the ’143 Patent, and claim 11 of the ’771 Patent, these claims would have also been obvious based on the teachings of the references of each of grounds 2 and 3.

a. Lots — Claims 2, 10, 11, 26, and 27 of the ’584 Patent; Claims 2, 3, 11, 12, 26, and 29 of the ’143 Patent; and Claims 2–4, 15, 16, 33, and 46 of the ’771 Patent

483. Claims 2, 10, 11, 26, and 27 of the ’584 Patent are listed below.

Claims Depending from Claim 1 of the ’584 Patent	
2	The method of claim 1, wherein each of the test lots is a single-unit production lot, comprised of operationally-linked product specimens.
10	The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
11	The method of claim 1, wherein the number of separate test lots is from 3 to 10.
26	The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.
27	The method of claim 2, wherein product specimens are synonymous with product portions.

484. Claims 2, 3, 11, 12, 26, and 29 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
2	The method of claim 1, wherein each of the multiple separate test 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-unit product lot comprising multiple operationally-linked product specimens, and combinations thereof.
3	The method of claim 1, wherein each of the multiple separate test lots is a single-unit production lot, comprised of operationally-linked product specimens.
11	The method of claim 1, wherein each [of] the test lots is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.
12	The method of claim 1, wherein the number of separate test lots is from 3 to 10.
26	The method of claim 1, wherein each of the multiple separate test lots are separate production lots of a ready-to-eat product.

29	The method of claim 3, wherein product specimens are synonymous with product portions.

485. Claims 2–4, 15, 16, 33, and 46 of the ’771 Patent are listed below.

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.
15	The method of claim 1, wherein each 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.
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, wherein each of the multiple separate single production lots are separate single production lots of a ready-to-eat product.

486. ICMSF teaches that a lot is “produced with as little variation as possible for a given process or commodity” and is a “collection of units of a product.” Ex. 1012 at 119 (§ 6.10). ICMSF also teaches that “batches (lots) of food [are] produced over short time periods (e.g., a day or part of a day) for particular processes.” *Id.* Additionally, ICMSF discloses that “a continuous process may produce a relatively homogeneous product, in which case a lot could include units produced continuously

over a relatively long time." *Id.* ICMSF teaches "[t]reating the individual production batches as lots." *Id.* ICMSF states "a lot is considered as a collection of units." *Id.* at 327 (§ 17.5.3.2). Based on the foregoing, claims 2 and 10 of the '584 Patent; claims 2, 3, and 11 of the '143 Patent; and claims 2, 3, and 15 of the '771 Patent would have been obvious based on grounds 1–3.

487. ICMSF states that a consignment may be "composed of several lots." *Id.* at 119–20 (§ 6.11). Gombas necessarily tests five lots. *See* § XII-A-1-b *supra*. Price tests at least three lots. *See* § XII-C-1-b *supra*. Because "several" lots includes at least three lots, claim 11 of the '584 Patent; claim 12 of the '143 Patent; and claim 16 of the '771 Patent would have been obvious based on grounds 1–3.

488. ICMSF discloses testing production lots of a ready-to-eat product. Ex. 1012 at 288–89 (§ 16.2.2). On this basis, claim 26 of the '584 Patent; claim 26 of the '143 Patent; and claims 33 and 46 of the '771 Patent are obvious based on grounds 1–3.

489. Steps (a) of the independent claims recite collecting portions or samples. In the context of step (a), portions and samples are synonyms. *See* § XII-A-1-b *supra*. The same is true for "product specimens" and "product portions." Synonymous use of product specimen and product portion was typical as exemplified by, for example, ICMSF and BAM. ICMSF interchangeably refers to "samples" and "sample units" and states that "[a] sample unit is a small portion of the lot." Ex. 1012 at 225 (§ 12.1). Thus, ICMSF shows portions and samples are synonyms. BAM refers to "the

sample or specimen received for examination" that "are representative of the sampled lot." Ex. 1022 at 10 (Chapter 1 at 1). Additionally, MLG uses "sub-sample" and "portion" as synonyms. Ex. 1028 at 15, 16, 31, 32, 46, 47. These references reflect the common interchangeable usage of "product specimens" and "product portions." Thus, claim 27 of the '584 Patent; claim 29 of the '143 Patent; and claim 4 of the '771 Patent are obvious based on grounds 1–3.

b. Enrichment — Claim 4 of the '584 Patent; Claim 5 of the '143 Patent; and Claim 6 of the '771 Patent

490. Claim 4 of the '584 Patent is listed below.

Claims Depending from Claim 1 of the '584 Patent	
4	The method of claim 1, wherein incubating each separate test lot sample in c) comprises incubating each separate test lot sample with enrichment medium suitable to enrich for the target microbial agent or organism, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate test lot sample and combining the removed portions to provide a modular composite sample.

491. Claim 5 of the '143 Patent is listed below.

Claims Depending from Claim 1 of the '143 Patent	
5	The method of claim 1, wherein enriching each separate composited test lot sample in c) comprises incubating each separate composited test 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 test lot sample and combining the removed portions to provide a pooled modular composite sample.

492. Claim 6 of the '771 Patent is listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.

493. Claim 4 of the ’584 Patent, claim 5 of the ’143 Patent, and claim 6 of the ’771 Patent differ from the independent claim from which each depends by reciting enrichment medium. ICMSF discloses combining enrichment cultures to form enriched test lot samples. Ex. 1012 at 187 (§ 10.4); *see* § XII-A-1-d *supra*. Gombas discloses incubating the enriched, test lot samples. Ex. 1014 at 563; *see* § XII-A-1-d *supra*. Hughes also discloses incubating the enriched, test lot samples. Ex. 1015 at 636, 638; *see* § XII-B-1-d *supra*. On at least this basis, claim 4 of the ’584 Patent; claim 5 of the ’143 Patent; and claim 6 of the ’771 Patent would have been obvious based on grounds 1–3.

c. Concentration — Claims 5 and 29 of the ’584 Patent; Claims 6 and 31 of the ’143 Patent; and Claims 8 and 9 of the ’771 Patent

494. Claims 5 and 29 of the ’584 Patent are listed below.

Claims Depending from Claim 1 of the ’584 Patent	
5	The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay further comprises a concentration step to concentrate the target microbial agent or organism.

29	The method of claim 5 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

495. Claims 6 and 31 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
6	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).
31	The method of claim 6 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

496. Claims 8 and 9 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.

497. These claims recite the well-known use of “immunomagnetic beads to concentrate cells,” which use is mentioned in ICMSF. Ex. 1012 at 318 (§ 17.2.3.1 at Table 17–2). Thus, claims 5 and 29 of the ’584 Patent; claims 6 and 31 of the ’143 Patent; and claims 8 and 9 of the ’771 Patent would have been obvious based on grounds 1–3. Another related ground is discussed at § XII-D-3 *infra*.

d. More Sensitive Protocol — Claims 6 and 30 of the ’584 Patent; Claims 7 and 32 of the ’143 Patent; and Claims 10 and 11 of the ’771 Patent

498. Claims 6 and 30 of the ’584 Patent are listed below.

Claims Depending from Claim 1 of the ’584 Patent	
6	The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples are further tested, such further testing comprises the more sensitive protocol.
30	The method of claim 6, wherein the more sensitive protocol further comprises a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol that is used to test the modular composite sample.

499. Claims 7 and 32 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
7	The method of claim 1, wherein where testing in e) of the pooled modular composite sample is positive, and wherein the separate individual composited test lot samples are further tested using a more sensitive protocol.
32	The method of claim 7, 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.

500. Claims 10 and 11 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.
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.

501. These claims recite use of a more sensitive protocol for further testing and that a concentration step may be used for the more sensitive protocol. Such a concentration step was well known before the priority date. For example, ICMSF discloses use of a concentration step. Ex. 1012 at 318 (§ 17.2.3.1 at Table 17–2).

502. When further testing after a positive test, it would have been and remains counterintuitive to use a less sensitive test. Rather, conventional wisdom indicated and continues to require that the same test or a more sensitive test should be used.

503. Gombas discloses further testing using the same protocol. Ex. 1014 at 563. A POSA would have been motivated to combine ICMSF and Gombas as provided in ground 1 and to use the concentration step of ICMSF when using the same protocol as taught by Gombas to increase the likelihood of an accurate result when further testing the individual lot samples. Based on the foregoing, claims 6 and 30 of the '584 Patent; claims 7 and 32 of the '143 Patent; and claims 10 and 11 of the '771 Patent would have been obvious based on ground 1.

504. Hughes indicates that "[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must be streaked on selective media." Ex. 1015 at 635; *see* § XII-B-1-h *supra*. It is well-known that streaking is a more sensitive protocol than the EIA method. A POSA would have been motivated to modify ICMSF with the more sensitive protocol of Hughes for further testing. On this basis, claim 6 of the '584 Patent; claim 7 of the '143 Patent; and claim 10 of the '771 Patent would have been obvious based on grounds 2 and 3.

505. In summary, claims 6 and 30 of the '584 Patent; claims 7 and 32 of the '143 Patent; and claims 10 and 11 of the '771 Patent would have been obvious based on grounds 1–3. Another related ground is discussed at § XII-D-4 *infra*.

e. Number of Portions — Claims 13–16 of the ’584 Patent; Claims 14–17 of the ’143 Patent; and Claims 18–21 of the ’771 Patent

506. Claims 13–16 of the ’584 Patent are listed below.

Claims Depending from Claim 1 of the ’584 Patent		
13	The method of claim 1, wherein, in a), separately collecting said plurality of portions from each of said plurality of separate test lots comprises separately collecting	from each separate test lot a number of portions from 5 to 100.
14		from each separate test lot 30 to 60 portions.
15		30 portions from each separate test lot.
16		from each separate test lot about 60 portions.

507. Claims 14–17 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent		
14	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting	from each separate test lot a number of samples from 5 to 100.
15		30 to 60 samples from each separate test lot.
16		at least 30 samples from each separate test lot.
17		at least 60 samples from each separate test lot.

508. Claims 18–21 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent		
18	The method of claim 1, wherein, in a), separately collecting said multiple independent samples from each of the multiple separate test lots comprises separately collecting	from each separate test lot a number of samples from 5 to 100.
19		30 to 60 samples from each separate test lot.
20		at least 30 samples from each separate test lot.
21		at least 60 samples from each separate test lot.

509. ICMSF teaches collecting 5, 30, 60, 95, and 100 portions. *Id.* at 184–185 (§ 10.2), 189 (§ 10.6), 276 (§ 15.3.3), 282 (§ 15.6.3)), 309 (§ 16.6.3)), 318–21 (§§ 17.2.3.2–17.2.3.4), 326–330 (§§ 17.5.3.1–17.6)). Thus, claims 13–16 of the '584 Patent; claims 14–17 of the '143 Patent; and claims 18–21 of the '771 Patent would have been obvious based on grounds 1–3.

f. Equal Portions — Claims 18, 22, and 31 of the '584 Patent; Claims 18, 22, and 36 of the '143 Patent; and Claims 22, 26, and 38 of the '771 Patent

510. Claims 18, 22, and 31 of the '584 Patent are listed below.

Claims Depending from Claim 1 of the '584 Patent	
18	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 test lot samples.
22	The method of claim 1, wherein removing portions of each enriched separate test lot sample comprises removing equal volume portions of each enriched separate test lot sample.

Claim Depending from Claim 17 of the '584 Patent	
31	The method of claim 17, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate single-unit production lot samples.

511. Claims 18 and 22 of the '143 Patent are listed below.

Claims Depending from Claim 1 of the '143 Patent	
18	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 test lot samples.

22	The method of claim 1, wherein removing portions of each separate enriched composited test lot sample comprises removing equal volume portions of each separate enriched composited test lot sample.

512. Claim 36 of the ’143 Patent is listed below.

Claim Depending from Claim 35 of the ’143 Patent	
36	The method of claim 35, wherein removing portions in step d) is removing equal portions, so as to preclude contamination of the enriched separate composited test lot samples.

513. Claims 22 and 26 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.
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.

514. Claim 38 of the ’771 Patent is listed below.

Claim Depending from Claim 37 of the ’771 Patent	
38	The method of claim 37, wherein removing portions in step d) is removing equal portions, so as to preclude contamination of the enriched separate composited single production lot samples.

515. Claims 18 and 31 of the ’584 Patent; claims 18 and 36 of the ’143 Patent; and claims 22 and 38 of the ’771 Patent recite removing “equal portions.” The same claims also require “aseptically” removing the equal portions. The equal portions are further limited in claim 22 of the ’584 Patent; claim 22 of the ’143 Patent; and claim 26 of the ’771 Patent to removing “equal volume portions.” These limitations

are not recited in their respective independent claims. However, these limitations merely recite subject matter that is considered standard practice in the art because a lack of contamination and equal portions are necessary for reliable results.

516. ICMSF states that "[p]aramount in the process of withdrawing sample units is to use aseptic technique to prevent contamination of the analytical unit" (Ex. 1012 at 231 (§ 12.5.1)) and that "[w]eighing the analytical unit into the appropriate diluent (first dilution) must be performed aseptically" (*id.* (§ 12.5.2)). Such aseptic techniques are simply standard practices.

517. Gombas also emphasized the standard practice of aseptic transfers: (1) "laboratories were instructed to transfer samples aseptically into individual sterile plastic bags and discard the original retail packages"; (2) "a sample was aseptically transferred to a sterile stomacher bag and blended with an equal amount of enrichment broth." Ex. 1014 at 563. A POSA would follow such standard aseptic practices as mentioned in ICMSF and Gombas. Thus, a POSA would continue to conduct each transfer aseptically including removing portions of each enriched lot sample.

518. Gombas also states:

> five 1-ml samples of secondary enrichment broths were composited, and the 5-ml composite was tested by the BAX assay according to the manufacturer's procedures.

Ex. 1014 at 564. Gombas thus mentions the standard practice of removing equal volume portions of each enriched separate test lot sample for the wet compositing step (d). *See* § XII-A-1-e *supra*. Based on the foregoing, claims 18, 22, and 31 of the '584 Patent; claims 18, 22, and 36 of the '143 Patent; and claims 22, 26, and 38 of the '771 Patent would have been obvious based on ICMSF and Gombas in ground 1.

519. Hughes describes the wet compositing step as removing equal volume portions of each enriched separate test lot sample. *See* § XII-B-1-e *supra*. 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 at 638. Based on the foregoing, claims 18, 22, and 31 of the '584 Patent; claims 18, 22, and 36 of the '143 Patent; and claims 22, 26, and 38 of the '771 Patent would have been obvious based on ICMSF and Hughes in grounds 2 and 3.

g. Microorganisms — Claims 19 and 20 of the '584 Patent; Claims 19 and 20 of the '143 Patent; and Claims 23, 24, 48, and 49 of the '771 Patent

520. Claims 19 and 20 of the '584 Patent are listed below.

Claims Depending from Claim 1 of the '584 Patent		
19	The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of	*Listeria, Salmonella,* and *Escherichia coli.*
20		*Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

521. Claims 19 and 20 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent		
19	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of	*Listeria, Salmonella,* and *Escherichia coli.*
20		*Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

522. Claims 23 and 24 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent		
23	The method of claim 1, wherein the target microbe(s) comprises at least one selected from the group consisting of	*Listeria, Salmonella,* and *Escherichia coli.*
24		*Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

523. Claim 48 and 49 of the ’771 Patent are listed below.

Claims Depending from Claim 37 of the ’771 Patent	
48	The method of claim 37, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria, Salmonella,* and *Escherichia coli.*
49	The method of claim 48, wherein the target microbe(s) comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

524. ICMSF includes separate chapters for testing for the recited microbial agent or organism including *Listeria* (Ex. 1012 at 285–312 (Chapter 16)), *Salmonella* (*id.* at 273–284 (Chapter 15)), and *Escherichia coli* (*id.* at 313–332 (Chapter 17)). Gombas surveys for *Listeria*. Ex. 1014 at 559. Hughes and Price study procedures

for testing for *Salmonella*. Ex. 1015 at 634; Ex. 1017 at 679. Based on the foregoing, claims 19 and 20 of the ’584 Patent; claims 19 and 20 of the ’143 Patent; and claims 23, 24, 48, and 49 of the ’771 Patent would have been obvious based on grounds 1–3.

h. Assay Types — Claim 23 of the ’584 Patent; Claim 23 of the ’143 Patent; and Claim 27 of the ’771 Patent

525. Claim 23 of the ’584 Patent is listed below.

Claims Depending from Claim 1 of the ’584 Patent	
23	The method of claim 1, wherein testing of the 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.

526. Claim 23 of the ’143 Patent is listed below.

Claims Depending from Claim 1 of the ’143 Patent	
23	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.

527. Claim 27 of the ’771 Patent is listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.

528. The assay types listed in these claims are merely those that were available before the priority date. AAPA #7; Ex. 1001 at 2:54–58; Ex. 1002 at 2:66–3:3; Ex. 1003 at 3:8–12. Gombas discloses use of "DNA-based assays." Ex. 1014 at 559 (abstract). Hughes discloses use of "an enzyme immunoassay (EIA) method," which is an immunochemistry-based method. Ex. 1015 at 635. Based on the foregoing, claim 23 of the '584 Patent; claim 23 of the '143 Patent; and claim 27 of the '771 Patent would have been obvious based on grounds 1–3.

i. Meat Types — Claims 32 and 33 of the '584 Patent; Claims 24, 33, and 34 of the '143 Patent; and Claims 28–31 and 41–44 of the '771 Patent

529. Claims 32 and 33 of the '584 Patent are listed below.

Claim Depending from Claim 1 of the '584 Patent	
32	The method of claim 1, wherein the beef specimens are meat trim pieces.
Claim Depending from Claim 17 of the '584 Patent	
33	The method of claim 17, wherein the meat is that of beef, pork, sheep or bison.

530. Claims 24, 33, and 34 of the '143 Patent are listed below.

Claims Depending from Claim 1 of the '143 Patent	
24	The method of claim 1, wherein each of the multiple separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.
33	The method of claim 24, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.
34	The method of claim 24, wherein the meat is that of beef, pork, sheep or bison.

531. Claims 28–31 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.

532. Claims 41–44 of the ’771 Patent are listed below.

Claims Depending from Claim 37 of the ’771 Patent	
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.

533. These claims merely recite the types of meat that have been conventionally tested long before the priority date. *See* § XII-A-1-b *supra*. ICMSF also discloses that meat is collected from multiple separate lots or test lots such as single production lots. *Id.* at 118–20 (§§ 6.10–6.11), 225 (§ 12.1). ICMSF discloses that the meat may be beef. *Id.* at 114, 189–90 (§ 10.6), 230 (§ 12.3 at Table 12–1), 285 (§ 16.1), 292 (§16.2.3), 296–97 (§ 16.3.4, Table 16–2), 304–07 (§ 16.4), 313–30 (Chapter 17). ICMSF also discloses that the meat may be poultry such as chicken. Ex. 1012 at

185–91 (§ 10.2–10.6), 230 (§ 12.3 at Table 12–1), 285 (§ 16.1), 288 (§ 16.2.2), 292–94 (§§ 16.2.4–16.3.2), 296–98 (§ 16.3.4), 300 (§ 16.3.4.3), and 304–07 (§ 16.4).

534. ICMSF additionally discloses that the meat may be meat trim pieces. For example, ICMSF states that "[t]rimmings to be used for ground beef could be pretested for *E. coli* O157:H7 by various sampling plans." *Id.* at 323 (§ 17.4.2.2). Additionally, ICMSF states that "[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.* at 327 (§ 17.5.3.3); *see also id.* at 226 (§ 12.1), 320 (§ 17.2.3.4), and 323–324 (§ 17.4.2.2).

535. ICMSF also states that "[t]he trimmings commonly are used in the manufacture of raw ground beef and a wide variety of ready-to-eat products (e.g., sausages)." *Id.* at 314 (§ 17.1). Chapter 16 of ICMSF, which discusses *Listeria* in ready-to-eat meats, indicates an example of the raw material used to form ready-to-eat meats is a sausage emulsion that is stuffed into casings. *Id.* at 286 (§ 16.1.) ICMSF discloses obtaining data from raw emulsion for ready-to-eat meats collected at the facility prior to cooking at § 16.3.4 and methods for testing samples at § 16.3.4.1. *Id.* at 296–298; *see also id.* at 183 (§ 10.1), 230 (§ 12.3), and 285–312 (Chapter 16).

536. Based on the foregoing, claims 32 and 33 of the ’584 Patent; claims 24, 33, and 34 of the ’143 Patent; and claims 28–31 and 41–44 of the ’771 Patent would have been obvious based grounds 1–3.

2. Grounds 4 and 5 — Claim 3 of the ’584 Patent; Claim 4 of the ’143 Patent; and Claim 5 of the ’771 Patent — Incubating

537. Claim 3 of the ’584 Patent is listed below.

Claim Depending from Claim 1 of the ’584 Patent		
3	The method of claim 1,	further comprising incubating the modular composite sample of d), prior to testing in e).

538. Claim 4 of the ’143 Patent is listed below.

Claim Depending from Claim 1 of the ’143 Patent	
4	The method of claim 1, further comprising incubating the pooled modular composite sample of d), prior to testing in e).

539. Claim 5 of the ’771 Patent is listed below.

Claims Depending from Claim 1 of the ’771 Patent	
5	The method of claim 1, further comprising incubating the pooled modular composite sample of d), prior to testing in e).

540. These claims recite the well-known practice of incubating a modular composite sample after enrichment and prior to testing. Stewart, which is titled “Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water,” discloses an assay protocol including

pre-enrichment followed by "selective enrichment by transfer of 0.1 ml BPW + n pre-enrichment to 10 mL Rappaport-Vassiliadis (RV) broth and 1.0 mL pre-enrichment to 10 mL tetrathionate (TT) broth, with incubation at 42°C for 5–8 h." Ex. 1019 at 398. The post-enrichment step includes transferring and combining "0.5 mL RV and 1 mL TT into a single tube containing 10 mL prewarmed trypticase soy broth supplemented with novobiocin (TSB + n) at 10 µg/mL with incubation for 16–20 h at 42°C." *Id.* "The post-enrichments were extracted and the assay was performed according to package instructions." *Id.*

541. Based on the teaching in Stewart to incubate after selective enrichment and prior to testing, a POSA would be motivated to incubate the pooled modular composite sample in Gombas or Hughes. On at least this basis, claim 3 of the '584 Patent; claim 4 of the '143 Patent; and claim 5 of the '771 Patent would have been obvious based on grounds 5 and 6.

3. Grounds 6 and 7 — Claims 5 and 29 of the '584 Patent; Claims 6 and 31 of the '143 Patent; and Claims 8 and 9 of the '771 Patent — Concentration

542. Claims 5 and 29 of the '584 Patent are listed below.

Claims Depending from Claim 1 of the '584 Patent	
5	The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay further comprises a concentration step to concentrate the target microbial agent or organism.
29	The method of claim 5 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

543. Claims 6 and 31 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
6	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).
31	The method of claim 6 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

544. Claims 8 and 9 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.

545. These claims recite the well-known practice of concentration of a target microbe via immunomagnetic beads.

546. ICMSF states that a test was conducted using an “improved isolation method (i.e., immunomagnetic beads to concentrate cells).” Ex. 1012 at 318 (§ 17.2.3.1 at Table 17–2). A POSA would have known from this teaching in ICMSF that immunomagnetic beads may be used to concentrate microbes. Additionally, a POSA would have recognized that such a concentration step would have been beneficially used when testing a pooled modular composite sample. *See* § XII-D-1-c *supra*.

547. However, because use of immunomagnetic beads was so well known, ICMSF does not provide more details about their use. However, further details are disclosed by Fratamico, which is titled "Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method." Ex. 1020 at 105. Fratamico discloses that use of immunomagnetic beads resulted in "an increase in the level of *E. coli* B1409 in the sample," as well as "an increase in the number of organisms recovered." *Id.* at 107. Additionally, Fratamico provides detailed instructions for preparing and using immunomagnetic bead separation to concentrate a target microbial agent or organism.

548. These teachings of Fratamico would have motivated a POSA to modify the combination of ICMSF and Gombas in ground 6 and ICMSF and Hughes in ground 7 to use immunomagnetic beads to concentrate microbes in a modular composite sample to benefit from accurate tests. On at least this basis, claims 5 and 29 of the '584 Patent; claims 6 and 31 of the '143 Patent; and claims 8 and 9 of the '771 Patent would have been obvious based on grounds 6 and 7.

4. Grounds 6 and 8 — Claims 6 and 30 of the '584 Patent; Claims 7 and 32 of the '143 Patent; and Claims 10 and 11 of the '771 Patent — More Sensitive Protocol

549. Claims 6 and 30 of the '584 Patent is listed below.

Claim Depending from Claim 1 of the ’584 Patent	
6	The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples are further tested, such further testing comprises the more sensitive protocol.
30	The method of claim 6, wherein the more sensitive protocol further comprises a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol that is used to test the modular composite sample.

550. Claims 7 and 32 of the ’143 Patent are listed below.

Claims Depending from Claim 1 of the ’143 Patent	
7	The method of claim 1, wherein where testing in e) of the pooled modular composite sample is positive, and wherein the separate individual composited test lot samples are further tested using a more sensitive protocol.
32	The method of claim 7, 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.

551. Claims 10 and 11 of the ’771 Patent are listed below.

Claims Depending from Claim 1 of the ’771 Patent	
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.
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.

552. Claim 6 of the ’584 Patent, claim 7 of the ’143 Patent, and claim 10 of the ’771 Patent are listed above and recite further testing with a more sensitive protocol. Claim 30 of the ’584 Patent, claim 32 of the ’143 Patent, and claim 11 of the ’771

Patent are also listed above and recite that the more sensitive protocol comprises use of a concentration step.

553. As described in the preceding section (§ XII-D-3), ICMSF describes the well-known use of "immunomagnetic beads to concentrate cells." Ex. 1012 at 318 (§ 17.2.3.1 at Table 17–2). As also described in the preceding section, such use is more fully explained and encouraged by Fratamico. Ex. 1020 at 105–107. A POSA would be motivated to modify the combination of ICMSF and Gombas based on Fratamico to use immunomagnetic beads to concentrate microbes in a modular composite sample to benefit from accurate tests. On at least this basis, claims 5 and 29 of the '584 Patent; claims 6 and 31 of the '143 Patent; and claims 8 and 9 of the '771 Patent would have been obvious based on ground 6.

554. Hughes discloses that "[e]nrichment broths and M broths from samples positive by an enzyme immunoassay (EIA) method must be streaked on selective media." Ex. 1015 at 635; *see* § XII-B-1-h *supra*. D'Haese explicitly discloses that streaking is the most sensitive method for testing by stating that "conventional culturing still remains the gold standard, as the demonstration . . . on solid agar media is unmistakable proof of their viability, defined as their ability to multiply." Ex. 1018 at 979. A POSA would recognize that the combination of ICMSF and Hughes as further modified by D'Haese ensures that streaking is used to confirm the testing by the EIA method of Hughes. Additionally, a POSA would be motivated to use a

more sensitive test as taught by D'Haese to ensure the further testing is accurate. On this additional basis, claim 6 of the '584 Patent; claim 7 of the '143 Patent; and claim 10 of the '771 Patent would have been obvious based on ground 8.

5. Grounds 9 and 10 — Claim 28 of the '584 Patent; Claim 30 of the '143 Patent; and Claim 7 of the '771 Patent

555. Claim 28 of the '584 Patent is listed below.

Claims Depending from Claim 1 of the '584 Patent	
28	The method of claim 4, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.

556. Claim 30 of the '143 Patent is listed below.

Claims Depending from Claim 1 of the '143 Patent	
30	The method of claim 5, wherein the enrichment medium comprises a selective agent that will inhibit a competing non-target microbe.

557. Claim 7 of the '771 Patent is listed below.

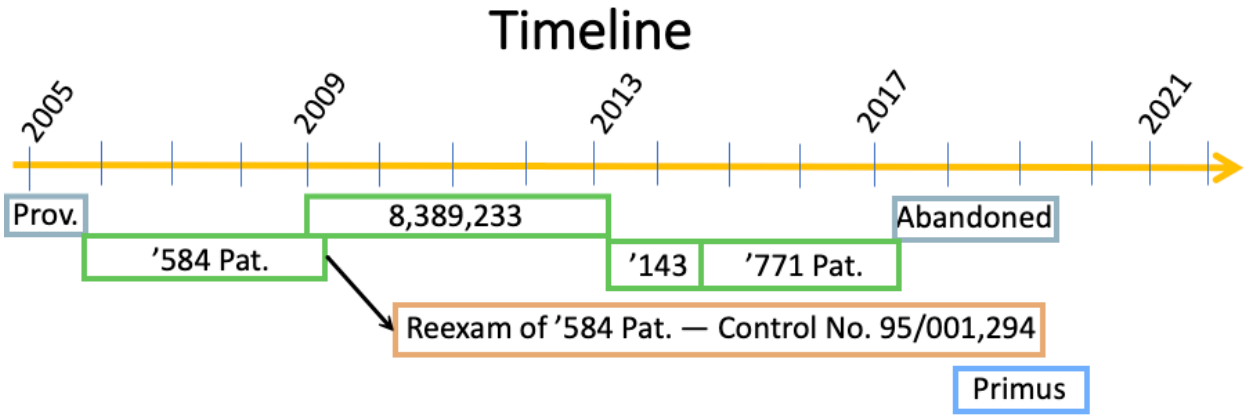
Claims Depending from Claim 1 of the '771 Patent	
7	The method of claim 6, wherein the enrichment medium comprises a selective agent that will inhibit a competing non-target microbe.

558. These claims recite that the enrichment medium comprises a selective agent that inhibits a competing non-target microorganism, a well-known property of selective enrichment mediums. D'Aoust describes "selective enrichment [that] inhibits growth of non-salmonellae and facilitates isolation of *Salmonella* on differential plating media." Ex. 1021 at 369. ICMSF discloses combining

enrichment cultures to form enriched test lot samples. Ex. 1012 at 187 (§ 10.4); *see* § XII-A-1-d *supra*. A POSA would have considered it obvious to use an enrichment medium for the test lot samples as described by ICMSF, Gombas, and Hughes that inhibits competing non-target microbes as described by D'Aoust. This modification would ensure an accurate test. On this basis, claim 28 of the '584 Patent; claim 30 of the '143 Patent; and claim 7 of the '771 Patent would have been obvious based on the references of grounds 1 and 2 as further modified by D'Aoust in grounds 9 and 10.

XIII. IEH'S DUPLICATIVE PATENTS

559. During reexamination of the '584 Patent, IEH prosecuted three continuation applications as depicted below in the timeline provided to me by Petitioner's counsel.



560. During reexamination of the '584 Patent, IEH obtained two patents that claimed the same subject matter as originally claimed in the '584 Patent. As presented below, IEH camouflaged its duplication of the original scope of the claims

of ’584 Patent by relying on minor semantical differences between claim elements. The scope of the claims of the ’143 Patent and the’771 Patent are the same or broader than the scope of the original claims of the ’584 Patent.

A. IEH Duplicated Scope of Original Claim 1 of the ’584 Patent in Claim 1 of the ’143 Patent and Claim 1 of the ’771 Patent

1. Preambles

561. The claim 1 preambles for each of the IEH Patents are listed below.

Comparison of Preamble of Original Claim 1 of ’584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of ’584 Pat.	Claim 1 of ’143 Pat.	Claim 1 of ’771 Pat.
A method of sampling, testing and validating test lots for microbial contamination, comprising:	A method of sampling and testing for microbes in multiple separate test lots, comprising:	A method of sampling and testing for microbes in multiple separate lots, comprising:

562. While the verb “validating,” is not included in the preamble of claim 1 of the ’143 Patent or claim 1 of the ’771 Patent, all of the independent claims of the IEH Patents cover validating in the body of the claims. *See* §§ V-B-1, V-B-3, V-C-1, V-C-3, V-D-1, V-D-3, and XI-B-5 *supra*. There is no difference in meaning between “microbial contamination” and “microbes” in the context of the preambles. Also, there is no difference in meaning between “test lots,” and “lots.” *See* § XI-B-1 *supra*. Thus, there is no difference between the preambles of claim 1 of the ’143 Patent and claim 1 of the ’771 Patent. If the preceding analysis is incorrect, then the scope of

the preamble of the Continuation Patents is broader than the original preamble of the '584 Patent.

2. Step (a) — Collecting

563. Step (a) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (a) of Original Claim 1 of '584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of '584 Pat.	Claim 1 of '143 Pat.	Claim 1 of '771 Pat.
collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately sampled by taking said plurality of portions thereof;	separately collecting multiple independent samples from each of multiple separate test lots, wherein each separate test lot is separately sampled by taking said multiple independent samples thereof;	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;

564. Each step (a) recites the same subject matter. First, each recites collecting "portions" or "samples," which are synonyms. *See* § XI-B-2 *supra*. Second, each recites collecting the portions/samples from test lots/lots, which are terms that lack a difference in meaning. *See* § XI-B-1 *supra*. If the preceding sentence is incorrect, then the scope of step (a) of the '771 Patent is broader than '584 Patent's original step (a) because the '771 Patent recites lots instead of test lots. Third, each lot is "separately sampled," which means that portions are collected from each lot in a way

such that the resulting lot sample is representative of the lot being sampled. *See* § XI-B-2 *supra*.

3. Step (b) — Combining/Compositing

565. Step (b) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (b) of Original Claim 1 of '584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of '584 Pat.	Claim 1 of '143 Patent	Claim 1 of '771 Patent
combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;	separately compositing the collected multiple independent samples from each of the separate test lots to provide a corresponding set of separate composited test lot samples, wherein each of the separate composited test lot samples is attributed to a particular corresponding separate test lot;	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;

566. First, the words "combining" and "compositing" are synonyms. *See* § XI-B-3 *supra*. Second, each step (b) combines/composites portions/samples to provide a corresponding set of lot samples. Third, each step (b) also recites that each lot sample "is attributed to a particular corresponding separate" test lot/lot. Thus, step (b) in each claim 1 recites the same subject matter.

4. Step (c) — Enriched/Enriching

567. Step (c) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (c) of Original Claim 1 of the ’584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of ’584 Patent	Claim 1 of ’143 Pat.	Claim 1 of ’771 Pat.
incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;	enriching each of the separate composited test lot samples to provide a set of separate composited test lot samples enriched for the target microbe(s);	enriching each of the separate composited lot samples to provide a set of separate composited lot samples enriched for the target microbe(s);

568. The only difference between step (c) of claim 1 of the ’143 Patent and claim 1 of the ’771 Patent is the recitation of test lot/lot. *See* § XI-B-1 *supra*. While claim 1 of the ’584 Patent uses more words than its analogs in the Continuation Patents, the ’584 Patent merely recites the inherent result of enrichment, enabling “levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples.” *See* § XI-B-4 *supra*. Because reciting the inherent result flowing from enrichment does not alter the claim scope, step (c) is the same in each patent. *Id.* If the preceding analysis

is incorrect, then the scope of step (c) of the Continuation Patents is broader than the original step (c) of the ’584 Patent.

5. Step (d) — Wet Compositing/Pooling

569. Step (d) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (d) of Original Claim 1 of ’584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of ’584 Pat.	Claim 1 of ’143 Patent	Claim 1 of ’771 Patent
removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and	removing portions of each separate enriched composited test lot sample, and combining the removed portions to provide a pooled modular composite sample; and	removing portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample; and

570. There is no difference between step (d) of claim 1 of any of the IEH Patents. IEH uses synonyms such that in each patent, step (d) describes pooling enriched composited lot samples to provide a pooled composite sample.

6. Step (e)(1) — Testing

571. Step (e)(1) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (e)(1) of Original Claim 1 of ’584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of ’584 Pat.	Claim 1 of ’143 Pat.	Claim 1 of ’771 Pat.

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

572. Reciting "microbe(s)" instead of "microbial agent or organism" merely employs synonyms such that in each patent, step (e)(1) describes testing the composite sample using a detection assay without a difference in scope. Thus, there is no difference in scope between step (e)(1) of claim 1 of any of the IEH Patents.

7. Step (e)(2) — Tested Negative

573. Step (e)(2) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (e)(2) of Original Claim 1 of '584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of '584 Pat.	Claim 1 of '143 Pat.	Claim 1 of '771 Pat.
wherein when such testing is negative all of said separate test lot samples are validated, and	wherein when such testing is negative all of said samples that were composited to form the separate composited test lot samples are deemed negative for the target microbe(s) and each of the multiple separate test lots is validated, and	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

574. There is no difference in scope between step (e)(2) of claim 1 of any of the IEH Patents. Step (e)(2) of the '143 Patent and the '771 Patent differ only based on

the use of synonyms. More words are used for the ’143 Patent and the ’771 Patent relative to the ’584 Patent, but the additional language does not alter the scope.

8. Step (e)(3) — Further Testing after Positive Test

575. Step (e)(3) is listed below for each claim 1 of each IEH Patent.

Comparison of Step (e)(3) of Original Claim 1 of ’584 Patent with those of Claim 1 of Continuation Patents		
Orig. Claim 1 of the ’584 Pat.	Claim 1 of ’143 Pat.	Claim 1 of ’771 Patent
wherein when such testing is positive, individual separate test lots are validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining test result for each test lot.	wherein when such testing is positive, each of the individual separate composited test lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited test lot samples is positive for the target microbe(s), wherein the test lots corresponding to any negatively testing composited test lot samples are validated.	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.

576. There is no difference in scope between step (e)(3) of claim 1 of any of the IEH Patents. Step (e)(3) of the ’143 Patent and the ’771 Patent differ only based on the use of synonyms. More words are used for the ’143 Patent and the ’771 Patent relative to the ’584 Patent, but the additional language does not alter the scope.

B. IEH Duplicated Scope of Original Claim 17 of the ’584 Patent in Claim 35 of the ’143 Patent and Claim 37 of the ’771 Patent

577. Claim 17 of the ’584 Patent originally recited single-unit production lots before reexamination. Claim 35 of the ’143 Patent also recites single-unit production lots. Claim 37 of the ’771 Patent recites single production lots. Single-unit production lots and single production lots are synonyms.

578. The other semantical differences between claim 17 of the ’584 Patent and the other two independent claims, claim 35 of the ’143 Patent and claim 37 of the ’771 Patent, are the same as those discussed above regarding claim 1 of each IEH Patent.

C. IEH’s Duplicative Patents and Disclosure Failures

579. As summarized above, the scope of the claims of the ’143 Patent and the ’771 Patent are the same or broader than the scope of the original claims of the ’584 Patent.

580. As noted above in my detailed analysis regarding the prosecution history of the reexamination and each continuation application of the ’584 Patent, IEH failed to inform the Patent Office in the reexamination about its three co-pending continuation applications. *See* § VIII *supra*. IEH notified the Office during prosecution of the application that yielded the ’233 Patent that a reexamination was pending for the ’584 Patent. *See* § IX-A. However, IEH failed to do the same during prosecution of the applications that yielded the ’143 Patent and the ’771 Patent (i.e.,

the Continuation Patents). *See* §§ IX-B and IX-C. Also, IEH failed to submit any documents filed by IEH or by bioMérieux or issued by the Patent Office in the reexamination during prosecution of any of the related continuation applications. *See* §§ IX-A to IX-C *supra*.

XIV. CERTIFICATION

581. In signing this declaration, I recognize that this declaration will be filed in support of the Petitioner in case numbers IPR2024-00183, IPR2024-00185, and IPR2024-00186 at the U.S. Patent and Trademark Office.

582. I reserve the right to supplement my opinions in the future to respond to any arguments that Institute for Environmental Health, Inc. raises and to consider new information as it becomes available to me.

583. I acknowledge that, as part of these IPRs, if an IPR trial is instituted, I may be subject to cross-examination in the United States regarding the content of this declaration. If cross-examination is required of me, I will make myself reasonably available for cross-examination within the United States during the time allotted for cross-examination.

584. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false

statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: July 10, 2024

Respectfully submitted,

James S. Dickson, Ph.D.

National Beef Ex. 1041