IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In *Inter Partes* Reexamination of	:	Examiner: Sharon L. Turner
Mansour SAMADPOUR	:	Group Art Unit: 3991
Patent No.: 7,534,584 B2	:	**Control No.: 95/001,294**
Issued: May 19, 2009	:	

Reexam Request Filed: April 5, 2010

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAM INANTS AND/OR CONSTITUENTS

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THIRD-PARTY REQUESTER'S RESPONDENT BRIEF PURSUANT TO 37 C.F.R. § 41.68

This brief is submitted in response to the Patentee's Appeal Brief filed and served May 7, 2012 and is timely filed because it is submitted on or before June 7, 2012. Entry and consideration thereof is therefore requested. Authorization to charge the requisite fee as required by 37 C.F.R. § 41.20(b)(2) to Deposit Account Number 02-2135 is hereby given. Affirmance of the rejection of claims 1-33 is respectfully requested.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST 1

II. RELATED APPEALS AND INTERFERENCES 1

III. STATUS OF CLAIMS 1

IV. STATUS OF AMENDMENTS 1

V. SUMMARY OF CLAIMED SUBJECT MATTER 1

VI. ISSUES TO BE REVIEWED ON APPEAL 1

VII. ARGUMENT 2

A. Ground 1 of the Rejection: 2

1. The RAN is correct 2

2. Appellant mischaracterizes Jarvis 3

a. Jarvis teaches multiple lots 3

b. Jarvis teaches statistical-based sampling plans 4

c. Jarvis teaches compositing samples in the MPN method 4

3. Appellant fails to consider the references in combination 5

B. Ground 2 of the Rejection: 5

1. Appellant ignores the combined teachings of the references 6

2. Appellant mischaracterizes Price 6

a. Price teaches testing of multiple lots of food 6

b. Price does not teach away from use of more than a single portion in each pre-enrichment culture 7

C. Ground 3 of the Rejection: 8

D. Ground 5 of the Rejection: 8

E. Ground 6 of the Rejection: 9

1. Silliker teaches testing multiple lots 9

2. Appellant argues the references individually 10

F. Ground 7 of the Rejection: 10

G. Ground 8 of the Rejection: 11

H. Ground 9 of the Rejection: 12

I. Ground 14 of the Rejection: 13

J. Ground 15 of the Rejection: 13

K. Ground 21 of the Rejection 13

L. Ground 22 of the Rejection: 13

M. Ground 23 of the Rejection: 14

N. Ground 24 of the Rejection: 14

O. Response to Declarations: 14

P. Conclusion 15

VIII. EVIDENCE APPENDIX I-1

IX. RELATED PROCEEDINGS APPENDIX II-1

X. CERTIFICATE OF SERVICE III-1

I. REAL PARTY IN INTEREST

The real party in interest for the Respondent Third-Party Requester is bioMérieux, Inc.

II. RELATED APPEALS AND INTERFERENCES

Respondent is aware of an opposition to European Patent No. 1786920, which is the European counterpart of U.S. Pat. No. 7,534,584 involved in this reexamination.

III. STATUS OF CLAIMS

Respondent disputes claim 2 is original because, by Appellant's own admission, it has been amended. With that exception, Respondent accepts Appellant's statement.

IV. STATUS OF AMENDMENTS

Respondent disputes the claims shown in the accompanying appendix are an accurate representation of the pending claims. In claim 1, subpart (e), the term "modular" has been added by Appellant during re-examination, and thus should be underlined, or otherwise denoted as a claim amendment. With that exception, Respondent accepts Appellant's statement.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Respondent disputes Appellant's summary of the claimed subject matter because claim 1 is not recited in its entirety. Claim 1, subpart (a) should read "collecting a plurality of portions from each of a plurality of separate test lots..." The underlined portion is not included in the Appellant's recitation of claim 1. With that exception, Respondent accepts Appellant's summary.

VI. ISSUES TO BE REVIEWED ON APPEAL

Respondent disputes Appellant's recitation of the Issues to be Reviewed on Appeal. Appellant has incorrectly identified the claims on appeal with respect to issues 1 and 2. An accurate description of those issues is as follows:

1) Whether claims 1-3, 8, 10-20, 22, 24-27, 31 and 32 are rendered obvious over Jarvis in view of FSIS and Midura. (*See* RAN p. 8).

2) Whether claims 1-4, 6-18, 20, 22, 24-26, and 31 are rendered obvious over FSIS in view of Price and Midura. (*See* RAN p. 22).

Respondent accepts Appellant's recitation of the remaining issues.

VII. ARGUMENT

A. Ground 1 of the Rejection:

Respondent respectfully requests affirmance of the rejections of claims 1-3, 8, 10-20, 22, 24-27, 31 and 32 as obvious over Jarvis, FSIS and Midura. Appellant's arguments for patentability are based on an incorrect and irrational interpretation of the primary reference, Jarvis, and an improper attack on each of the references on which the obviousness rejection is based separately, rather than a consideration of their combined teachings.

1. The RAN is correct

Appellant contends that in the RAN, the Examiner adopted misleading and unsupportable rebuttals to Appellant's arguments concerning Ground 1 of the rejection. (App. Br. at 16-18). However, it is Appellant's arguments that are in fact misleading and unsupportable. A centerpiece of Appellant's argument is the contention that the Jarvis method is limited to a single lot of food, and does not teach the testing of multiple lots. (App. Br. at 16). Appellant's interpretation is irrational and is inconsistent with the stated purpose of the Jarvis method. Specifically, the whole point of Jarvis' Method 2 (Jarvis at 141-42) would be negated if the ten samples inoculated into separate pre-enrichment broths were from the same lot of food product.

Appellant further argues that Jarvis admits that follow-up testing would not permit release into commerce, as follow-up testing only gives "some indication of a proportion of the

contaminated samples." (App. Br. at 17-18). That argument is nonsensical and a person of ordinary skill would not have so understood Jarvis. Microbial testing of food products for microbial contamination is for quality control, and its purpose is to identify contaminated products that are not safe for release to consumers. It would have been clear to a skilled person that Jarvis' interest in the proportion of contaminated samples was to gain an understanding of which of those samples can be released and which must be rejected.

2. Appellant mischaracterizes Jarvis

a. Jarvis teaches multiple lots

As discussed in detail in the RAN, Jarvis teaches, on page 136, the testing of multiple lots of food. (Jarvis, p. 136, Example 8.4; RAN p. 14-15). Appellant attempts to avoid this teaching by arguing that there is not a defined relationship between Jarvis' teachings on pages 135 – 136 and those on pages 141 - 142. (App. Br. at 11). A person of ordinary skill would have recognized the relationship between those passages, which appear in the same section of the reference, five pages apart. Jarvis is a textbook devoted to statistical sampling methods for food validation. A skilled person would have understood from Jarvis' Section 8.4 that the compositing methods taught in sub-section 8.4.2.1 were subject to the statistical sampling procedures disclosed in adjacent passages. Appellant relies heavily on Jarvis' use of the singular term "lot" as used by Jarvis on one occasion in a different context concerning compositing method 4. Appellant ignores the specific usage of the plural term "lots" in Section 8.4 in which Jarvis discusses the method referenced by the Examiner in the RAN. Appellant's strained interpretation of Jarvis is contrary to the very purpose of the methodology that Jarvis describes. Jarvis teaches the retesting of stored pre-enrichment media in the event of a positive indication of contamination. (Jarvis, p. 141-142). If all of the samples were from the same operational lot of

food product, a positive test would require rejection of the contaminated lot. No purpose would be served in retesting stored samples. Indeed, the introduction to sub-section 8.4.2.1 indicates that the purpose of compositing is to reduce work load. In most instances, the composited sample will test negative, in which case one test takes the place of ten. The logical reading of Jarvis is that the samples are from separate lots so that retesting identifies the contaminated lots for destruction while simultaneously identifying the uncontaminated lots for release. The impact of this reference should not be diminished based on semantic, rather than substantive, differences between the reference and the '574 patent.

b. Jarvis teaches statistical-based sampling plans

Appellant's contention that Jarvis does not teach statistical-based sampling plans for release of lots into commerce also ignores the purpose of Jarvis. (App. Br. at 12). The title of the Jarvis reference is "Statistical Aspects of the Microbiological Analysis of Foods," and the reference discloses statistical-based sampling plans in explicit detail. (*see* Jarvis). More important, Appellant's only support for this contention is, again, an argument based on usage of the singular term "lot" on one occasion while ignoring the overall purpose and description of the method.

c. Jarvis teaches compositing samples in the MPN method

Appellant argues there is no instruction in Jarvis as to how to combine the compositing method on pages 141 – 142 with the MPN method disclosed on Jarvis pages 135-136. (App. Br. at 12-13). This argument ignores the first sentence of section 8.4 that states, "[i]n the analysis of foods for low numbers of pathogenic organisms (e.g. salmonella), it is normal to inoculate one or more samples…" (Jarvis, p. 135 (emphasis added)). Similarly, the first sentence of section 8.4.2.1 states, "[w]hen a number of samples is to be tested it is sometimes recommended that the

samples be composited..." (Jarvis, p. 141 (emphasis added)). It is clear pages 141-142 of Jarvis are illustrative of methods for compositing samples to be used in conjunction with the MPN method on pages 135-136 to perform statically significant presence or absence tests. Contrary to Appellant's assertion, it is also clear the composited samples are subject to the product dilutions discussed on pages 135-136. (App. Br. at 12-13).

3. Appellant fails to consider the references in combination

Appellant contends that FSIS and Midura are only secondary references that teach that a statistically-based number of portions must be examined for release of food into commerce. (App. Br. at 18). However, Appellant ignores that a person of ordinary skill would apply the sampling and analytical procedures described in those references to the compositing and re-testing method of Jarvis. Thus, even if Appellant's flawed interpretation of Jarvis were correct, the claims would nevertheless be unpatentable because FSIS and Midura provide the features that Appellant contends are missing from Jarvis.

FSIS and Midura both teach sampling "a plurality of separate test lots." FSIS is a sampling method that a person of ordinary skill would have understood to apply to multiple separate test lots of ground beef to produce a set of separate test lot samples. (Bailey Dec., ¶19). Midura discloses a "Three-Class Attribute Plan" (Midura, p. 18) and a "Multiple Sampling (2-Class) Attribute Plan" that is "designed to inspect lots based on multiple samplings." (Midura, p. 17). Thus, FSIS and Midura teach statistical-based sampling plans to test multiple lots. A skilled person readily would have understood the benefits of the compositing procedure of Jarvis method 2 (p. 141) with the multiple-lot testing procedure of Midura and FSIS

B. <u>Ground 2 of the Rejection:</u>

Appellant's arguments regarding Ground 2 are based on a mischaracterization of one of the principal references upon which the rejection was based (in this case, Price) and fails to take into account the combined teachings of all three references. Respondent respectfully requests that the Board affirm the Examiner's rejection of claims 1-4, 6-18, 20, 22, 24-26, and 31 as obvious over the combination of FSIS, Price, and Midura.

1. Appellant ignores the combined teachings of the references

Appellant addresses the FSIS and Midura references in only a cursory manner and then argues that the Ground 2 rejection based on these references is merely duplicative of the Ground 1 rejection. (App. Br. at 19). Appellant ignores that even if Appellant's flawed interpretation of Price were correct, FSIS and Midura teach the testing of multiple lots, and the combination of multiple portions of a single lot to obtain a statistically representative sample. (Bailey Dec., ¶19; Midura, p. 17-18). Accordingly, the combination of references renders the claimed invention obvious. (RAN, p. 29).

2. Appellant mischaracterizes Price

a. Price teaches testing of multiple lots of food

Appellant criticizes the RAN for its conclusion that the Price reference teaches the testing of multiple lots of food. (App. Br. at 19). There is no basis for Appellant's attorney argument that Price is applicable only to serial tests of a single lot, which is directly contrary to Price's Figure 1 that clearly depicts multiple lot testing. (Price, Fig. 1). The interpretation also renders meaningless Price's teaching that if the composited culture tests positive, then the retained samples should be tested individually. (Price, p. 681, Fig. 1). Testing retained samples from the same lot would be pointless, because the positive result would require the destruction the entire contaminated lot regardless of the results of individual retests. However, if the retained cultures

are representative of separate lots then retesting individual lots makes sense, as the negative lots would then be validated for release. Price clearly teaches multiple lot testing.

b. Price does not teach away from use of more than a single portion in each pre-enrichment culture

Appellant erroneously argues that Price teaches away from compositing multiple portions in each pre-enrichment culture (App. Br. at 19-21). The Examiner found that Price teaches "individual pooled samples and pooled pre-enrichment broths which meet the limitation for the claimed composite testing procedures." (RAN, p. 29). Appellant argues that to meet the requirements of claims 1 and 17, "Price would need to be altered so that the pre-enrichments are loaded not with single portions, but rather with 'a number of portions to be taken sufficient to provide validation and release of the test lot into commerce.'" (App. Br. at 19). This argument reflects a fundamental misunderstanding of the prior art. Price exemplifies his method by analysis of powdered food products, such as dried egg albumin, cocoa and nonfat dry milk. A representative sample of such powdered materials includes numerous separate portions in the form of particles or aggregates of particles. Price's Figure 1 illustrates inoculating a strip of each powdered sample into separate pre-enrichment broths. A person of ordinary skill would know, e.g., from Midura, how to insure that the combined portions of the bulk powdered sample is representative and similarly would know how to obtain representative samples from other types of food products such as liquids or semi-solids (such as meat products). See Midura at 20-21.

The Price reference was directed to "a test procedure that gives a single negative answer for many negative samples [and thus] offers an important saving in analytical effort required for quality control." (Price at 679). The method that Price describes is the same as that claimed in the '574 patent. A skilled person would have understood the benefits of using the multiple-lot

testing procedure as taught by FSIS and Midura, with Price's compositing procedures. It was not necessary for Price to explain how each aliquot of sample subjected to testing was created so as to be representative of the overall sample, because persons skilled in this art already knew (e.g., from Midura) the importance of testing representative samples and how to obtain them.

Appellant's argument that Price teaches away also is wrong. The passage that Appellant quotes (App. Br. at 20) warns against pooling samples from different lots into a single pre-enrichment broth. Price instead teaches inoculating separate samples (i.e., separate lots) into separate broths – which is the same procedure described in claims 1 and 17 of the '574 patent. Rather than teaching away, the cited passage provides an additional rationale for enriching different lots of product in separate pre-enrichment broths.

C. Ground 3 of the Rejection:

As with the previous rejections, Appellant erroneously argues that the rejection is based on "synthetic confusion" between single-lot testing methods applied in serial fashion versus multiple-lot testing methods. (App. Br. at 22). Appellant argues that the Background section of Appellant's patent does not say that simultaneous testing of multiple individual lots was known in the art. (App. Br. at 22). However, Appellant's patent explicitly discloses as background prior art the testing of multiple production lots. ('584 patent, col. 1, ll. 67 – col. 2, ll. 7). Combining the prior art multiple-lot testing with Jarvis' method 2 compositing method would have been obvious to a person of ordinary skill. Appellant's colorful attorney arguments do not detract from the plain teachings of Jarvis and the clear admission in the '574 patent. Accordingly, Respondent respectfully requests the Board to affirm the Examiner's rejection of claims 1 and 17 as obvious over Jarvis, and the Patent Owner's Admissions.

D. Ground 5 of the Rejection:

Respondent disputes Appellant's contention that the combination of Andrews, Price, and Midura does not render claims 1 and 17 obvious. Appellant contends that the only way to arrive at claims 1 and 17 using Andrews is to collect multiple portions of multiple separate food lots, maintain them separately, and introduce them into separate enrichment broths as in Price. (App. Br. at 23-24). However, Appellant contends Price teaches away from enrichment broths containing multiple portions, and cites Appellant's arguments under Ground 2. (App. Br. at 24). But as discussed above, the passage of Price that Appellant argues teaches away actually provides an additional rationale for inoculating samples into separate enrichment broths. Thus, Respondent respectfully requests that the Examiner's rejections of claims 1 and 17 as obvious over Andrews, Price, and Midura be confirmed.

E. Ground 6 of the Rejection:

In disputing Ground 6, Appellant mischaracterizes Silliker, and more important, fails to consider the references in combination. For these reasons, Respondent respectfully requests that the Board to affirm the Examiner's rejection of claims 1 and 17 as obvious over Silliker, Price, and Midura.

1. Silliker teaches testing multiple lots

As with Jarvis and Price, Appellant contends that Silliker teaches only how to test a single lot of food. (App. Br. at 25). Appellant argues that the express disclosure in Table 1 of Silliker is a test of the same lot in serial fashion, and is not a system for validating multiple lots simultaneously. (*Id.*). Appellant offers no evidence to support this point, and, in fact, ignores the explicit disclosure in Table 1 identifying the product as separate lots, *e.g,* Tests 19 – 20, 22 representing fish meal lots 1 - 3. (Silliker, Table 1). Appellant also ignores that when Silliker

tests a single lot multiple times, *e.g.,* Tests 2-4 representing dilutions of the same test lot, he identifies such testing explicitly. (*Id.*)

2. Appellant argues the references individually

Appellant argues that it would be necessary to modify Silliker so that each enrichment is loaded with a stasticially significant number of portions, but seems to suggest Midura does not teach this modification. (App. Br. at 25). However, this argument ignores the explicit teachings of Midura, and is contrary to Appellant's own admission that Midura "[t]eaches particular numbers of portions which must be taken from a lot to achieve statistical significance for a testing plan." (App. Br. at 8). Appellant also argues that Silliker does not teach testing of individual subsamples upon obtaining a positive result from a composite, and that Silliker does not teach preservation of underlying results. (App. Br. at 26). This argument ignores the contributions of Price which provides these limitations. (Price, Figure 1). Accordingly, the claims are obvious over the combination of Silliker, Price, and Midura.

F. <u>Ground 7 of the Rejection:</u>

Appellant argues that the Gabis, Price, and Midura references only teach testing methods where one test lot of food is tested at one time. (App. Br. at 27). In doing so, Appellant relies on the mischaracterizations of Price discussed, and rebutted by Respondent, in Ground 2. Appellant also argues that Gabis is limited to serial use of a method upon one lot of food at time, with materials from separate test lots never coming into contact with each other. (App. Br. at 27). Appellant's argument regarding Gabis is unsupported attorney argument that is not evidence. (MPEP § 2145). Appellant's argument also overlooks the results in Table 1 and Table 2 of Gabis showing differing test results for the different lots of product, *e.g.,* compare the pork spleen products. (Gabis, p. 665-66, Tables 1 and 2). There is no basis to conclude that this

Table only represents serial retests. For example, if the results were merely retests of the same lot, one would expect similar results. Instead the first pork spleen lot had only a single positive result as opposed to eighteen positive results for the second lot. Regardless, as discussed above, Price and Midura both teach the testing of multiple lots of food. (Price, Figure 1; Midura, p. 17-18). Thus, Respondent respectfully requests the Board to affirm the Examiner's rejection of claims 1 and 17 as obvious over Gabis, Price, and Midura.

G. Ground 8 of the Rejection:

Appellant contends that the RAN is misleading in using various terms, and speculates that Respondent has introduced confusion to support Respondent's arguments. (App. Br. at 28-29). It is actually Appellant's argument that introduces confusion. Jarvis refers to taking samples or "portions" (using the '584 patent claim language) from lots or "specimens" (using the '584 patent claim language). (Jarvis, p. 136-137, 141). The '584 patent claims state "test lots" are comprised of one or more "specimens," and so a single "specimen" can form a "test lot." Jarvis then composites these samples or "portions" to form a pre-enrichment series, or what is referred to in the '584 patent as a "test lot sample." (Jarvis, p. 141). Following formation and incubation of the "test lot sample," Jarvis teaches compositing a sample of each incubated pre-enrichment series, or "test lot sample" to form what is referred to in the '584 patent as a "modular composite sample." (Jarvis, p. 141). Thus, despite Appellant's arguments regarding confusion of terms, it is clear that Jarvis teaches the steps of the claimed invention.

Appellant admits that BAM teaches a certain number of food portions must be taken from a lot to provide adequate testing for release into commerce. (App. Br. at 29). However, Appellant argues that neither reference teaches gathering of samples from multiple lots. (*Id.*). This argument ignores the express disclosure in Jarvis of testing multiple lots discussed in the

Ground 1 rejection. (Jarvis, p. 136, Example 8.4). Respondent respectfully requests the Board to affirm the rejections of claims 1 and 17 as obvious over Jarvis and BAM.

H. Ground 9 of the Rejection:

Respondent disputes Appellant's contention that claims 1 and 17 are not rendered obvious by the combination of Price, BAM, and Davies. Appellant initially relies on the mischaracterization of Price as teaching away from pooling multiple portions of a lot into a single pre-enrichment culture that has been fully addressed under the Ground 2 rejection. (App. Br. at 30). Because Price does not teach away from using multiple portions in a pre-enrichment culture, a skilled person would have had a reason to combine the teachings of Price and BAM so that a statistically significant number of samples are obtained from each lot to form the pre-enrichment culture. Thus, Appellant's argument that a person of ordinary skill in the art would have to choose the correct point in the process for applying the BAM derived number, or that the BAM derived number would somehow have to be used twice is nonsensical. (App. Br. at 32).

Appellant also argues Price concerns only the testing of a single lot which is in direct contravention to Price Figure 1 depicting three separate lots. (App. Br. at 31; Price, Fig. 1). Appellant also argues Davies does not teach multiple lots. (App. Br. at 31). Appellant's argument is in direct contravention to Appellant's own statement that "Davies teaches taking multiple samples from herds of pigs, which are directly analogous to lots of food." (*Id.*). Davies used twenty distinct herds, and thus teaches sampling of twenty distinct lots. (Davies, p. 1017). Appellant also argues that Davies does not make a "modular composite sample." (App. Br. at 32). However, Davies teaches compositing serum and meat juice samples from 5, 10, or 20 separate herds or "lots" to form a "modular composite sample" within the meaning of the '584 patent. (Davies, p. 1018). Moreover, Price also teaches the individual pig herds may be

combined into a "modular composite sample" while retaining the saved individual lot cultures for retesting in the event of a positive test of the "modular composite sample." (Price, Figure 1). For at least these reasons, Respondent respectfully requests the Board to affirm the rejections of claims 1 and 17 as obvious over the combination of Price, BAM, and Davies.

I. Ground 14 of the Rejection:

Respondent disputes Appellant's contention that Ground 14 does not render claims 5, 23, 29, and 30 obvious over Jarvis, FSIS, Midura, and Entis. Ground 14 incorporates the Ground 1 rejection by reference but also relies on the Entis reference. Appellant does not address Entis on the merits, and merely relies on arguments presented in Ground 1. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 14 rejection.

J. Ground 15 of the Rejection:

Respondent disputes Appellant's contentions that Ground 15 does not render claims 5, 6, 29, and 30 obvious over FSIS, Price, Midura and Entis. Ground 15 incorporates the Ground 2 rejection by reference but also relies on the Entis reference. Appellant does not address Entis on the merits, and merely relies on arguments presented in Ground 2. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 15 rejection.

K. **Ground 21 of the Rejection:**

Respondent disputes Appellant's contentions that Ground 21 does not render claim 21 obvious over Jarvis, FSIS, Midura, and Cousin Ground 21 incorporates the Ground 1 rejection by reference but also relies on the Cousin reference. Appellant does not address Cousin on the merits, and merely relies on arguments presented in Ground 1. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 21 rejection.

L. Ground 22 of the Rejection:

Respondent disputes Appellant's contentions that Ground 22 does not render claim 21 obvious over FSIS, Price, Midura, and Cousin Ground 22 incorporates the Ground 2 rejection by reference but also relies on the Cousin reference. Appellant does not address Cousin on the merits, and merely relies on arguments presented in Ground 2. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 22 rejection.

M. Ground 23 of the Rejection:

Respondent disputes Appellant's contentions that Ground 23 does not render claim 23 obvious over Jarvis, FSIS, Midura, and Price. Ground 23 incorporates the Ground 1 rejection by reference but also relies on the Price reference. Appellant does not address Price on the merits of this rejection, and merely relies on arguments presented in Ground 1. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 23 rejection.

N. Ground 24 of the Rejection:

Respondent disputes Appellant's contentions that Ground 24 does not render claims 24, 28, 2, and 33 obvious over FSIS, Price, Midura, and Gabis. Ground 24 incorporates the Ground 2 rejection by reference but also relies on the Gabis reference. Appellant does not address Gabis on the merits, and merely relies on arguments presented in Ground 2. Respondent has rebutted those arguments, and thus requests affirmance of the Ground 24 rejection.

O. Response to Declarations:

Respondent disputes Appellant's contentions that the RAN improperly marginalized Appellant's declarations. (App. Br. at 39-40). Clearly, the Examiner carefully considered

Appellant's declarations, but did not find them persuasive. (RAN, p. 65 – 72). It is well within the Examiner's right to weigh declaration evidence and determine whether it is sufficient to overcome a rejection. (MPEP § 716). Moreover, even taken at face value, secondary considerations may not overcome a strong *prima facie* case of obviousness, such as the one presented here. *Asyst Tech., Inc. v. Emtrak, Inc.,* 544 F.3d 1310, 1316 (Fed. Cir. 2008).

P. Conclusion

For the foregoing reasons, Respondent respectfully requests that the Board affirm the rejections of claims 1-33.

Date: 6/7/12

Respectfully submitted,

Rothwell, Figg, Ernst & Manbeck
607 14th Street, N.W., #800
Washington, D.C. 20005
(202) 783-6040

By: _____
E. Anthony Figg
Reg. No. 27,195

VIII. EVIDENCE APPENDIX

Pursuant to 37 C.F.R. § 41.68(b)(1)(viii), Respondents rely upon the following evidence previously submitted and made of record in the present inter partes reexamination, Control Number 95/001294.

1. The Declaration of Stan Bailey ("Bailey Dec"), under 37 C.F.R. § 1.132, submitted with the Request for Reexamination filed on April 5, 2010.
2. The prior art references listed in Exhibits K – L, N – R, T – W of the Appellant's Appeal Brief, submitted with the Request for Reexamination filed on April 5, 2010.
3. Reference Berri, et al. ("Berri"), *The detection of Coxiella burnetii from ovine genital swabs, milk and fecal samples by use of a single touchdown polymerase chain reaction,* Veterinary Microbiology, 72 (2000) 285 – 293, submitted with the Third-Party Requester Comments filed on August 25, 2010.

IX. RELATED PROCEEDINGS APPENDIX

There are no decisions rendered by a court or the Board to be included pursuant to 37 C.F.R. § 41.68(b)(1)(ix).

X. CERTIFICATE OF SERVICE

Timely service to the Appellant, Institute for Environmental Health, Inc., via their attorney Barry L. Davison at Davis Wright Tremaine, LLP, 1201 Third Avenue, Suite 2200, Seattle, Washington 98101, is being affected by first class mail sent on June 7, 2012.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 07/17/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
07/17/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Transmittal of Communication to Third Party Requester *Inter Partes* Reexamination	Control No.	Patent Under Reexamination	
	95/001,294	7534584	
	Examiner	Art Unit	
	SHARON TURNER	3991	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th Street, N.W.
Suite 800
Washington, D.C. 20005

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination prceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	95001294
Filing Date	2010-04-05
First Named Inventor	Mansour Samadpour
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	66090-008US2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	95001294
	Filing Date	2010-04-05
	First Named Inventor	Mansour Samadpour
	Art Unit	N/A
	Examiner Name	N/A
	Attorney Docket Number	66090-008US2

/S.T./	1	JARVIS, "Errors Associated With Quantal Response Methods," STATISTICAL ASPECTS OF THE MICROBIOLOGICAL EXAMINATION OF FOODS, Chapter 8, pp. 143-176, 2008, Academic Press, Amsterdam, London, and San Diego	☐
/S.T./	2	JARVIS, "On the compositing of samples for qualitative microbiological testing," Letters in Applied Microbiology, 2007, pp. 592-598, Volume 45	☐
/S.T./	3	SILLIKER et al., "Laboratory Methods," FOOD-BORNE INFECTIONS AND INTOXICANTS," Chapter XI, pp. 455-474, 1969, Academic Press, New York and London, Edited by Hans Riemann	☐
/S.T./	4	THOMAS et al., "Examination of Stockfeeds for Salmonella," Australian Veterinary Journal, 1981, pp. 69-71, Volume 57	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Sharon Turner/	Date Considered	06/25/2013

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]See Kind Codes of USPTO Patent Documents at www.USPTO.GOVor MPEP 901.04. [2]Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5]Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	95001294
	Filing Date	2010-04-05
	First Named Inventor	Mansour Samadpour
	Art Unit	N/A
	Examiner Name	N/A
	Attorney Docket Number	66090-008US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2010-07-26
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	95001294
Filing Date	2010-04-05
First Named Inventor	Mansour Samadpour
Art Unit	3991
Examiner Name	Brenda G. Brumback
Attorney Docket Number	66090-008US2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/S.T./	1	7919232		2011-04-05	Institute for Environmental Health (Samadpour)	
	2					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/S.T./	1	20040241773		2004-12-02	Institute for Environmental Health (Samadpour)	
/S.T./	2	20090258359		2009-10-15	Institute for Environmental Health (Samadpour)	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	95001294
	Filing Date	2010-04-05
	First Named Inventor	Mansour Samadpour
	Art Unit	3991
	Examiner Name	Brenda G. Brumback
	Attorney Docket Number	66090-008US2

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Sharon Turner/	Date Considered	12/27/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	95001294
Filing Date	2010-04-05
First Named Inventor	Mansour Samadpour
Art Unit	3991
Examiner Name	Brenda G. Brumback
Attorney Docket Number	66090-008US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2011-05-31
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Inter Partes Reexamination Examiner's Answer	Application No.	Applicant(s)	
	95/001,294	7534584	
	Examiner	Art Unit	
	SHARON TURNER	3991	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Incorporation by Reference of the Right of Appeal Notice

The Right of Appeal Notice (RAN) mailed on 8 February 2012, including all of the grounds of rejection, determinations of patentability, and explanations set forth in the RAN is incorporated by reference. Every ground of rejection and every determination not to make a proposed rejection set forth in the RAN are being maintained by the examiner.

This examiner's answer does not contain any new ground of rejection and any new determination not to make a proposed rejection.

Status of Amendment After Action Closing Prosecution

The amendment(s) filed on _____ has/have been entered.
The amendment(s) filed on _____ has/have not been entered.

Period for providing a Rebuttal Brief

Appellant(s) is/are given a period of ONE MONTH from the mailing date of this examiner's answer within which to file a rebuttal brief in response to the examiner's answer. Prosecution otherwise remains closed.

The rebuttal brief of the patent owner may be directed to the examiner's answer and/or any respondent's brief. The rebuttal brief of the third party requester(s) may be directed to the examiner's answer and/or the respondent's brief of the patent owner. The rebuttal brief must (1) clearly identify each issue, and (2) point out *where* the issue was raised in the examiner's answer and/or in the respondent's brief. In addition, the rebuttal brief must be limited to issues raised in the examiner's answer or in the respondent's brief. The time for filing the rebuttal brief may not be extended. No further submission (other than the rebuttal brief(s)) will be considered, and any such submission will be treated in accordance with 37 CFR 1.939 and MPEP 2667.

☒ Attachment(s)
IDS's 7-26-10, 5-31-11, and 3-5-13.

☐ Other:
_____

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at one of the following addresses:

Please mail any communications to:
Attn: Mail Stop "Inter partes Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Please hand-deliver any communication to:
Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria VA 22314

Please FAX any communications to: (571) 273-9900

/Sharon Turner/	/Johnny Railey/	/Deborah Jones/
Patent Reexamination Specialist	Patent Reexamination Specialist	Supervisory Reexamination Specialist
CRU-3991	CRU-3991	CRU-3991

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	95001294
Filing Date	2010-04-05
First Named Inventor	Mansour Samadpour
Art Unit	3991
Examiner Name	Sharon L. Turner
Attorney Docket Number	66090-008US2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/S.T./	1	8389233		2013-03-05	SAMADPOUR, Mansour	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	95001294
	Filing Date	2010-04-05
	First Named Inventor	Mansour Samadpour
	Art Unit	3991
	Examiner Name	Sharon L. Turner
	Attorney Docket Number	66090-008US2

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Sharon Turner/	Date Considered	06/25/2013

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	95001294
Filing Date	2010-04-05
First Named Inventor	Mansour Samadpour
Art Unit	3991
Examiner Name	Sharon L. Turner
Attorney Docket Number	66090-008US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2013-02-01
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Mansour Samadpour
Control No.:	95/001,294
Confirmation No.:	1914
Filed:	05 April 2010

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Examiner:	Sharon Turner
Art Unit:	3991
Docket No.:	66090-008US2
Date:	04 October 2013

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

APPELLANT'S REBUTTAL BRIEF IN RESPONSE TO EXAMINER'S ANSWER AND REQUESTER'S RESPONDENT BRIEF, PURSUANT TO 37 C.F.R. § 41.71

This *substitute* Rebuttal Brief is timely filed on 04 October 2013 in response to an Office Communication dated 06 September 2013, and is in support of the Patent Owner's appeal from the Right of Appeal Notice ("RAN"), finally rejecting claims 1-33. Fees having been submitted for Appellant's Rebuttal Brief of 16 August 2013, no fee is now deemed due under 37 C.F.R. § 41.20(b)(2)(ii). If additional fees are necessary, Commissioner is authorized to charge any deficiency (or credit any overpayments) to Deposit Account No. 04-0258.

TABLE OF CONTENTS

I. STATEMENT OF THE REAL PARTY IN INTEREST 3
II. RELATED APPEALS AND INTERFERENCES....3
III. STATUS OF CLAIMS 3
IV. STATUS OF AMENDMENTS 3
V. SUMMARY OF CLAIMED SUBJECT MATTER 3
VI. ISSUES TO BE REVIEWED ON APPEAL 3
VII. ARGUMENT 4
VIII. CONCLUSION....18
IX. APPENDIX; INDEPENDENT CLAIMS 1 AND 17 19
X. EVIDENCE APPENDIX....22
XI. RELATED PROCEEDINGS APPENDIX....22
XII. CERTIFICATE OF SERVICE 22

I. STATEMENT OF REAL PARTY IN INTEREST

The real party in interest is Appellant assignee (Patent owner), Institute for Environmental Health Inc., a Washington corporation with its principal place of business at: 15300 Bothell Way NE, Lake Forest Park, WA 98155.

II. RELATED APPEALS AND INTERFERENCES

Oral Proceedings will take place in Munich on 15 January 2014 in the pending opposition in European Patent No. 1786920, European sister case to Patent No. 7,534,584 of this *inter partes* reexamination.

III. STATUS OF CLAIMS

Claims 1-33 are pending and are presently appealed under 35 U.S.C. § 134. Claims 1, 2, and 17 are Amended. Claims 3-16 and 18-33 are Original. New claims 34-36 were previously Cancelled. Claims 1-33 stand rejected under 35 U.S.C. §103(a).

IV. STATUS OF AMENDMENTS

Twice amended claims 1 and 17 shown in the accompanying Appendix IX are an accurate representation of those claims. Claims 2-16 and 18-33 are as listed in Appellant's Appeal Brief (App. Br.).

V. SUMMARY OF CLAIMED SUBJECT MATTER

In compliance with the requirements of 37 C.F.R. § 41.67(c)(1)(v), independent claims 1 and 17 are directed to methods of sampling, testing and validating a plurality of individual separate test lots for release into commerce. All other claims on appeal are as presented in App. Br., and incorporated by reference herein.

VI. ISSUES TO BE REVIEWED ON APPEAL

The issues to be reviewed on appeal are the Examiner's rejections due to alleged obviousness – 35 U.S.C. 103

1. Whether claims 1-3, 8, 10-20, 22, 24-27, 31 and 32 are rendered obvious under 35 U.S.C. §103(a) over Jarvis (Exhibit U) in view of FSIS (Exhibit O) and Midura (Exhibit L);
2. Whether claims 1-4, 6-18, 20, 22, 24-26 and 31 are rendered obvious under 35 U.S.C. §103(a) over FSIS (Exhibit O) in view of Price (Exhibit Q) and Midura (Exhibit L);

3.-15. Issues 3 through 15 are as stated in App. Br.

VII. ARGUMENT

All art cited against this invention pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots, but not in the simultaneous fashion of Appellant's claims. The two references concerning "composite" (aggregated) samples contemplate that all samples come from the same food lot, where the sole motive for compositing is a desire to limit the number of samples to minimize testing costs. Nothing in cited art motivates combination of samples from separate lots of food within a single method. No art, alone or in combination discloses or motivates performing the tasks of Appellant's independent claims 1 and 17; to simultaneously operate on a plurality of separate test lots each to be validated for release into commerce, and involving creation of a modular composite sample from aliquots of separate enriched test lots each attributed to a particular corresponding separate test lot, and where each separate test lot is separately sampled from the respective plurality of separate test lots according to a statistical sampling plan, and **not** with a single-portion per pre-enrichment scheme as in Price or Jarvis (2).

Moreover, contrary to the position urged by the RAN/ACP in relation to Ground 3, forming a pool from aliquots of "pre-enrichment" cultures is NOT equivalent to the methods of claims 1 and 17; "removing portions of each *enriched* separate test lot sample, and combining the removed portions to provide a modular composite sample".

A. Ground 1

Appellant traverses the rejection of Claims 1-3, 8, 10-20, 22, 24-27, 31 and 32, under 35 U.S.C. §103(a), over Jarvis in view of FSIS and Midura.

1. **The RAN/ACP/Requester's respondent's brief (Resp. Br.) is incorrect**. The cited references have been misconstrued and overextended by hind-sight. Resp. Br. states (p. 2) that a centerpiece of Appellant's argument is that the Jarvis method is limited to a single lot of food, and that this is "irrational".

No asserted art however, alone or in combination, teaches or motivates simultaneous testing of multiple lots in the course of a single application of a method. Jarvis is devoted solely to reducing the number of samples taken for efficiency, in the context of a single lot (App. Br.,

under "***second***", beginning at the bottom of page 11 through page 18; the only way that lots A, B and C are related is that Jarvis' method was separately applied to each lot serially).

Resp. Br. (p. 2-3) additionally states that Appellant argues that Jarvis admits that follow-up testing would not permit release into commerce, as follow up testing only gives some indication of a proportion of the contaminated samples (citing App. Br., p. 17-18), and calls this argument nonsensical because a person of skill in the art would have understood Jarvis' interests in the proportion of contaminated samples as to gain an understanding of which of those samples can be released and which rejected.

Requester's position in this regard is not supportable. Per App. Br. (p.17-18), whether a test is "tiered" has nothing to do with where the sample comes from, and at no time does Jarvis make reference to simultaneous use of samples from multiple test lots or in ANY manner deals with the concept of simultaneous multiple-lot testing. Even if Jarvis was imputed to teach follow up testing, it would not permit release in commerce, but as explicitly stated by Jarvis–only "…so that some indication of the proportion of contaminated samples can be obtained (Jarvis at page 142, line 1).

Secondary references to FSIS and Midura merely support the proposition that a statistically-based number of portions must be examined to release food into commerce. But there is no teaching, motivation or *nexus* as to how to use this in the context of Jarvis, except what Jarvis himself does; Jarvis starts with N as the number required to validate a lot, and either composites N in one lump in method (1); or uses separate enrichments in method (2), or arbitrarily divides the samples into two groups, and separately enriches these in method (3). Jarvis (last sentence, p. 141) fundamentally ***teaches away*** from patent owner's Patent by stating that "**only**" method (2), which requires that each portion be in an individual pre-enrichment, will allow the advantage of (limited utility) follow-up testing. The present claimed invention does not use either pre-enrichment or enrichments each having only individual samples as in Jarvis method (2), and moreover enables simultaneous validation of multiple separate test lots. At best, Jarvis, alone or in combination, is construable to validate one lot of food for each application of the method.

2. **a. Appellant has not mischaracterized Jarvis**. Resp. Br. at page 3 attempts to blur the distinction between Appellant's claims method and serial application of a method one lot

at a time by urging that Jarvis teaches testing of multiple lots of food (citing Jarvis p. 136, Example 8.4, RAN p. 14-15). But this is based on a vague '*spatial*' argument that the alleged Jarvis teachings at page 135-136 are only 5 pages away from the alleged teachings at Jarvis pages 141-142. In fact, the description of the 7-tube MPN method of Jarvis pp. 135-138 (also shown in Example 8.4 is that of a single series of "product dilutions" prepared from a single, initial 10E-1 dilution. There is no nexus with the separate discussion of compositing at Jarvis pp. 141-142. While Jarvis may be construable to validate one lot of food for each application of the method, such does NOT equate to simultaneous screening of a plurality of separate test lots, involving forming of a modular composited sample from a corresponding plurality of respective separate enriched test lot samples each comprising a statistically significant number of portions from the corresponding separate respective test lots. The fiction that Jarvis teaches simultaneous screening of multiple test lots is not only unsupported, but amounts to hind-sight.

b. Even if Jarvis is construed to teach statistical-based sampling plans, Jarvis alone or in combination does not motivate Appellant's methods.

Resp. Br. (p. 4; citing App. Br. at 12) misleadingly urges that Appellant contends that Jarvis does not teach statistical-based sampling plans for release of lots into commerce. As discussed in the record, while Jarvis, alone or in combination, may teach statistical based sampling plans to validate one lot of food for each serial application of the Jarvis method, each application of Appellant's claimed methods encompass simultaneous screening of a plurality of separate test lots, defining a relationship between samples from different lots of food and how these are to be eventually combined into a single composite result.

c. Jarvis merely lumps samples and does not teach modular compositing as presently claimed.

Rspd. Br. (p. 4) urges that Jarvis teaches a compositing of samples, allegedly based on the Jarvis sentences of section 8.4 stating: "[i]n the analysis of foods for low numbers of pathogenic organisms (e.g., salmonella) it is normal to inoculate one or more samples…"; and "[w]hen a number of samples is to be tested it is sometimes recommended that the samples be composited…" Requester's statements support nothing more than a teaching of merely aggregating/lumping of samples taken from a single lot, is not what is being claimed or accomplished by Appellant's modular composite sample.

3. **Appellant considers the references in combination**.

In considering references in combination, the teachings of each reference as a whole must also be considered under U.S. patent law. The secondary references to FSIS and Midura merely support that a statistically-based number of portions must be examined to release food into commerce. As stated above, there is no teaching, suggestion or *nexus*, as to how to use this in the context of Jarvis, except what Jarvis himself does (i.e., methods (1), (2) and (3)), and Jarvis ***teaches away*** by stating that "**only**" method (2), which requires that each portion be in an individual enrichment, will allow the advantage of (limited utility) follow-up testing. Jarvis is at best construable to validate one lot of food for each application of the Jarvis methods.

B. Ground 2

Appellant traverses the rejection of Claims 1-4, 6-18, 20, 22, 24-26 and 31, under 35 U.S.C. §103(a), over the combination of FSIS, in view of Price and Midura.

1. **Appellant does not ignore the combined teachings**. Rspd. Br. (p. 8, citing App. Br. at 19) urges that Appellant argues that Ground 2 is merely duplicative of Ground 1, and states that even if Appellant's interpretation of Price is correct, FSIS and Midura teach the testing of multiple lots, and the combination of multiple portions of a single lot to obtain a statistically representative sample, and that accordingly the combined references render Appellant's claims obvious.

Appellant agrees that Price merely teaches Jarvis method (2) (**single-portion** per **pre-enrichment** scheme), and FSIS and Midura merely supports the number of samples sufficient to achieve statistical significance in a sampling scheme for a single sampled lot. Appellant's rebuttal of Ground 1 thus applies directly to Ground 2. Per App. Br. (p. 19), Price shows his method being applied to various, disparate lots of food at different times; namely serial application of a single-lot testing method, and additionally, alone or in combination, *teaches away* from the use of anything more than a single portion in each pre-enrichment.

2. **Price *teaches away* from compositing multiple sample portions of a test lot in each pre-enrichment**.

Price Figure 1 does not depict multiple separate lot testing, does not indicate that the samples are other than separate individuation portions from a single test lot. Rspd. Br. (p. 7)

actually acknowledges this. The method of Price is serially applied (per Fig. 1), not simultaneously applied to various disparate lots of inoculated albumen, cocoa and nonfat dry milk. Price uses method (2) of Jarvis to do this with a single-portion per pre-enrichment scheme. With respect to retained samples, the aim of Price (e.g., Abstract) was to establish that there was no loss in sensitivity in pooling as many as 25 pre-enrichment broth cultures compared to individual pre-enrichments, and thus individual pre-enrichments were retained merely to compare the test results of the pool with what could be detected by assaying the individual pre-enrichments. Price individual pre-enrichments are from a single test lot, and the Requestor's urged fiction that retaining individual pre-enrichments in Price provides for negative retesting of retained single-portion pre-enrichments to validate lots for release is **impossible**, as Price (like Jarvis method (2)) is a single-portion per pre-enrichment scheme, not a statistical sampling scheme where testing any one single-portion pre-enrichment would not validate lots for release. Statistical sampling of FSIs and Midura fails to cure this deficiency because Price (second full paragraph at page 681) explicitly *teaches away* from pooling samples from a lot because of loss in sensitivity. The statistical basis of the Price pre-enrichment broths as informed by FSIs and Midura is taking a statistically sufficient number of single portion samples from a single test lot (Fig. 1). Price teaches away by stating that use of cultures containing only a single sample of a food product "permits small portions to be retained for subsequent analysis" whereas "direct pooling of food ***samples*** (*emphasis supplied)* into pre-enrichment results in the loss of individual sample identity". Contrary to Price, claims 1 and 17 require the use of "a plurality of portions ... sufficient to provide for validation and release" go into test lot sample.

Additionally, Appellants method requires over-sampling as compared to the prior art, and thus further contraindicated on that basis (see Exhibit F (p. 4-5, paragraph 10) and beginning at page 15, under paragraph "30." through page 16, paragraph 31, and paragraphs 34 and 35, beginning at page 18; stating that "I was faced with high degree of skepticism by experts in the field, and regulatory agencies (FSIS). **It took years to overcome the skepticism of the experts in the field.**").

C. Ground 3

Appellant traverses the rejection of claims 1 and 17, under 35 U.S.C. §103(a) over Jarvis

(Exhibit U) in view of "Patent owner's admissions".

The RAN states that Jarvis characterizes the incubation medium for the individual test lot samples as "pre-enrichment" medium, while the instant claims do not specify the incubation medium. This is **incorrect**. As claimed, the medium is suitable to enrich the target microbial agent or organism to detectable levels and become uniform. "Pre-enrichment medium" is a term of art, and no one of ordinary skill in that art would have attempted to assay a "pre-enrichment" stage culture, but rather convert/transition the pre-enrichment culture to enrichment medium for further incubation under enrichment conditions prior to assay (e.g., Exhibit F (p. 4, paragraph 8); **None of the asserted art alone or in combination teaches assay at the pre-enrichment stage**. Any pooling in the asserted prior art, including that of Jarvis, occurred only at the pre-enrichment stage, rather than at an enriched stage that would be acceptable as providing an assayable culture. Contrary to the RAN/ACP, forming a pool from aliquots of "pre-enrichment" cultures is **NOT** equivalent to "removing portions of each *enriched* separate test lot sample, and combining the removed portions to provide a modular composite sample" (Exhibit F (p. 13, under paragraph 27 through p. 15 to paragraph 30)).

RAN (p. 31) states that Patent owner admits that obtaining a plurality of portions from test lots and combining portions for subsequent testing was known in the art. Appellant's statement in the background section of the Patent, is merely a statement that aggregation (lumping) of a plurality of portions into a combined sample was known in the art (e.g., in the meat fabrication business for the last 40 years). The remainder of Ground #3 is an unsupportable rehash of the Jarvis discussions under Ground #1.

D. Ground 5

Appellant traverses the rejection of claims 1 and 17, under 35 U.S.C. §103(a) over Andrews in view of Price and Midura.

The claims are not obvious over the combined references

The RAN at page 34 urges that Andrews teaches testing foods for Salmonella by collecting a plurality of portions from the analyzed food and aggregating the portions to comprise a large sample unit used to determine the acceptability of the entire lot of food. RAN at pages 34-35 then reiterates the mischaracterizations of Price and Midura, and states that it

would have been obvious to have incubated the pre-enrichment cultures of Andrews separately, as suggested by Price, to specifically identify the contaminated food lots, and that one of skill in the art would have found it obvious to collect a plurality of samples according to a statistically-based sampling plan and/or to have performed multiple sampling runs, as recommended by Midura to detect highly pathogenic organisms.

Andrews (like FSIS and Midura), however, merely teaches how many samples should be taken from a particular lot of food under a sampling plan, and fails to teach statistical sampling by simultaneously taking portions from a plurality of separate lots to form a plurality of respective separate enrichment broths, and in no event alone or in combination teaches formation of Appellant's modular composite sample. Ground #5 relies upon Price for the concept of separate enrichment broths, but Price ***teaches away*** from pre-enrichment broths containing more than a single portion.

Combining Andrews and Price is contraindicated because such would defeat the purpose and operability of Price. Midura merely supports the number of samples sufficient to achieve statistical significance, but adds nothing since Price would have this number spread out among many pre-enrichment broths (not individually provided in each enrichment). <u>These references, alone or in combination, merely teach testing of a single lots of food per application of the method</u>.

E. Ground 6

Appellant traverses the rejection of Claims 1 and 17, under 35 U.S.C. §103(a), over Silliker in view of Price and Midura.

<u>The claims are not obvious over the combined references</u>.

The RAN (p. 36) states that Silliker teaches sampling foods for *Salmonella* contamination comprising collecting a plurality of subsamples, incubating these in individual cultures of pre-enrichment broth, and wet compositing the pre-enrichment cultures in groups of five or three. RAN states that Silliker differs from the claimed method in that Silliker defines the incubation step of individual cultures as "pre-enrichment." RAN (p. 36-37) reiterates the mischaracterizations of Price and Midura. RAN states that it would have been obvious to

combine the composite testing of Silliker with the individual tests of subsample pre-enrichments upon obtaining a positive result for the composite sample, as suggested by Price.

Silliker, however, teaches only how to test a single lot of food with each application of the methof, taking a 1500 g sample from the lot, dividing this into various numbers of subsamples, lumping these subsamples into groups of various sizes, and optionally grouping arbitrary numbers of subsamples into pre-enrichments prior to testing. On the other hand, Price explicitly taught that lumping subsamples into groups or putting more than one subsample into a pre-enrichment is **undesirable** (see above). While Silliker may teach testing of separate lots (including the tests cited by Requester in Table 1 of Silliker (see Rspd. Br., bottom p. 9), these lots are **tested with separate, serial applications of Silliker's method**, and not as part of a system for validating multiple lots simultaneously. The fact that dilutions are explicitly identified (see Requester's statement at top p. 10 of Rspd. Br.) does not alter this conclusion. Midura merely supports the number of samples sufficient to achieve statistical significance and validation in Salmonellae testing.

To arrive at the Claims 1 and 17 from these references, it would be necessary to (a) ignore Price's objections to putting multiple portions into an enrichment; (b) collect multiple sets of portions from different lots instead of a single lot, with each such set having a statistically significant number of portions; and (c) modify Silliker so that each enrichment is loaded with one of these statistically significant sets rather than the arbitrary numbers of portions from a single lot as actually used by Silliker. A need to collect a statistical number of samples (Midura) fails to motivate placement of more samples into the pre-enrichments, particularly given Price's explicit contraindication of such. One of ordinary skill in the art would only be motivated to use more individual pre-enrichments, consistent with Price, and serially screen lots.

RAN (p. 36, line 2) admits that "Silliker does not teach testing of individual subsamples separately upon obtaining a positive result from the composite sample". This is not surprising—since Silliker takes all samples from a single food lot, a positive result indicates that the lot is contaminated and must be destroyed in any event; no motive to investigate particular subsamples.

RAN (p. 38, line 8) states that Silliker "...specifically refers to preservation of the underlying lots with the use of the term subsamples". The term "subsamples", however, merely

means a subdivision of a sample, containing absolutely no implication about "preservation". There is no teaching that efforts toward later testing of the "preserved" materials were made, or that these materials were maintained in environmental conditions suitable for later testing.

The argument under "2." of Rspd. Br. (p. 10) is meritless, because merely teaching that a statistically significant number of samples must be taken (Midura) does not provide for combination urged by the Requester. Such would be contrary to Price's explicit contraindication of putting multiple portions into a pre-enrichment. Respondent's argument parses limitations guided by hindsight while ignoring the teachings of each reference as a whole.

F. Ground 7

Appellant traverses the rejection of claims 1 and 17, under 35 U.S.C. §103(a), over Gabis in view of Price and Midura.

The claims are not obvious over the combined references

RAN (p. 40) states that Gabis discloses methods for sampling and testing high moisture foods by collecting 13 specimens, inoculating each individual specimen individually into pre-enrichment broth cultures, incubation of each pre-enrichment culture, pooling portions of each individual pre-enrichment culture into a composite, incubating the composite enrichment culture, and subsequently recovering and identifying the *Salmonellae*. RAN (p. 40-41) reiterates the mischaracterizations of Price and Midura, stating that it would have been obvious to follow the composite testing of Gabis with the individual tests of subsample pre-enrichments upon obtaining a positive result for the composite sample, as suggested by Price.

Requester urges that Appellant's argument that Gabis is limited to a serial use of a method on one food lot at a time is only attorney argument, because Gabis shows differing test results for different lots of products (citing Gabis 665-66, Tables 1 and 2).

Gabis, however, merely teaches taking samples from a **single lot** of food and either putting all samples as one lump, comparable to Jarvis method (1) or putting each sample into a separate single pre-enrichment, comparable to Jarvis method (2). Midura merely teaches what quantity of portions might comprise a statistically significant sample for a single lot of food. These references, alone or in combination, don't even teach or motivate taking multiple portions of multiple lots of food and placing these into separate enrichments, much less for subsequent

formation of a modular composite sample. Price teaches placing single samples into pre-enrichments, and teaches against placing more than single samples therein. Since each of the references individually teach only testing methods which test one lot of food at a time, a combination of these references teaches only as much. There is no motivation for the methods of Claims 1 and 17.

RAN (p.41, line 22) states that "Gabis is not limited to single lots as it studies multiple meat and egg product samples." Requestor's reliance on Gabis 665-66, Tables 1 and 2 is unsupportable because Gabis shows only **serial use of a method upon one lot of food at a time**, with materials from separate lots never coming into contact with each other.

G. Ground 8

Appellant traverses the rejection of claims 1 and 17, under 35 U.S.C., over Jarvis in view of BAM.

The claims are not obvious over the combined references

Ground #8 is a minor variation of previous grounds based upon Jarvis, with the reference BAM standing in for Midura or FSIS as a simple teaching concerning the number of samples sufficient for statistical significance purposes.

It should be noted that the RAN's description of Jarvis in this instance (RAN (p.42, line 23) is misleading in the use of the word "specimen", in place of "samples", as written by Jarvis, and in place of "portions", as used in Claims 1 and 17 for this purpose. "Specimens" in Appellant's Patent refer to pieces of food product that make up the underlying lot of food to be sampled; "portions" are taken from the specimen or specimens of which the lot consists. Confusion between "specimen" and "portion" appears to have been introduced by the Resp. Br. (p. 11) in an attempt to support various lines of refuted arguments.

RAN (p. 43, line 5) further misuses the term "test lot samples", where it is stated that "Jarvis defines the medium used for incubation of the individual test lot samples as a ...". This is fundamentally misleading since Jarvis never uses the term "test lot samples" in the sense of Appellant's Claim 1, step b), defining a "test lot sample" as a collection of a plurality of "portions" taken from the specimens which comprise a test lot. In contrast to the individual particles of food that go separately into a Jarvis method (2) enrichment, each of the enrichments

of Claims 1 and 17 is loaded with an entire "test lot sample", which comprises a statistically significant number of portions. Moreover, Jarvis method (2) enrichments all contain food taken from the same lot. RAN (p. 43, line 20) in fact admits that:

> *Jarvis does not specify collecting plural portions from each of a plurality of test lots, each test lot comprising one or more specimens, and combining the portions to provide a corresponding set of separate test lot samples for testing.*

BAM adds nothing more than that a certain number of food portions need to be taken from a single lot to provide adequate testing for release into commerce. Jarvis teaches a one-lot at a time testing method, and BAM merely teaches how many samples should be taken in order to test this one lot. Again, RAN (p. 44, line 4) confirms that Jarvis and BAM pertain only "a" single lot, where it is stated:

> *It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have collected a (emphasis supplied) plurality of food samples in a statistically-based sampling plan.*

Claims 1 and 17, step a) require the simultaneous collection of **multiple, separate pluralities** of portions from each of a plurality of lots of food (to eventually provide for a modular composite sample), which are elements not taught by Jarvis and BAM, alone or in combination.

Respondent (Rspd. Br., p. 11) again perpetuates the prior mischaracterization of Jarvis.

H. Ground 9

Appellant traverses the rejection of claims 1 and 17, under 35 U.S.C. §103(a), over Price in view of BAM and Davies.

The claims are not obvious over the combined references

RAN (p. 45-46) combines BAM for teachings of collecting a plurality of samples according to a sampling plan for *Salmonella*. RAN (p. 36) states that Davies teaches sampling and testing pooled samples taken from different pig herds, incubating composite pooled samples into enrichment medium and subsequently testing from *Salmonella*.

Ground 9 is, therefore, essentially duplicative of earlier Grounds #1, #5, and #6 which also involve Price. BAM merely teaches how many samples should be taken from a lot when testing for *Salmonella*; and Davies merely teaches the taking of various samples from various pig

herds. The combination proposed by Ground 9 would have the single portion pre-enrichments of Price loaded, instead, with a number of portions determined by the BAM, but is directly against the teachings of Price, who emphasizes the disadvantages of multiple portions being placed into a pre-enrichment, and there is no support to combine Price and BAM in the manner urged by RAN or Requestor. Moreover, Price, BAM, and Davies all concern the **serial** testing of single lots (application of the method on one lot at a time).

Davies, limited to the use of pooled samples to provide a cheaper *Salmonella* monitoring program to identify infected finishing pig herds, involves taking of multiple samples from herds of pigs, which are directly analogous to lots of food. Per the RAN (p. 47, line 6), the samples are maintained with "separate herd designations" throughout, **and at no point are enriched samples from one herd/lot combined with samples from any other herd/lot as is required by Claim 1 d)** where is "...combining the removed portions to form a modular composite sample."

The conclusion of Davies is that while there is a poor correlation between serological and bacteriological results, pooled serum or meat juice samples can be used as a cheaper substitute for serological screening for Salmonella than individual samples. Davies, alone or in combination with Price and/or BAM teaches pooling of samples to provide cheaper monitoring; nothing more.

Davies teaches only simple sample pooling to make a classical composite (lumped) sample for enrichment and assaying the enriched sample directly. As explained on page 1017 and 1018 (under "Laboratory tests"), pooled pen faeces samples are added to media and incubated (enriched) before assay. Specifically, Davies teaches only classical sample pooling to make a composite sample for enrichment and testing. **But none of the pooled samples of Davies et al. were used after enrichment to prepare a "modular composite sample" as in Claims 1 and 17**.

To arrive at the method of Claims 1 and 17 based upon these references, one would:

first need to ignore Price's teachings against putting more than one portion into a pre-enrichment broth;

change the teaching of BAM which teaches that a given number N samples should be used in a testing method, and rather use N samples for each pre-enrichment broth, rather than using N as a total number of samples for all enrichment broths, as in Price; and

additionally ignore the teaching of Davies that samples from each herd/lot should be kept separate until the point of detection, rather than being combined at some point before the detection step.

To arrive at Appellant's method from these references one must:

change both the objective of the work; change the task of testing individual lots of food on a one-by-one basis into the different goal of testing multiple lots in a simultaneous mode;

then implement physical changes in what is done; contrary to Price, pre-enrichments must be loaded with many portions, rather than just single portions;

choose the correct point in the process for applying the requirements of the BAM; whereas normally BAM sets the overall number of samples that must be gathered to implement testing of a single lot, one must now use the BAM number to drive separate collections of samples from each of a plurality of lots, then maintain these collections separately, and then load each into separate enrichment, wherein the BAM number is used multiple times in working the method (once for each separate lot of food to be tested), whereas BAM in previous methods was used only once, for the purpose of setting the total number of portions used in the overall method); and

a modular composite sample must be created and assayed, where neither the creation or the assay of a modular composite sample is motivated by the combined asserted art.

The only reference which motivates Appellant's use is Appellant's Patent.

I. Ground 14

Appellant traverses the rejection of claims 5, 23, 29, and 30, under 35 U.S.C. §103(a), over Jarvis in view of FSIS, Midura, and Entis.

"Entis teaches rapid procedures for the detection, identification, and enumeration of microorganisms in foods (page 89, third paragraph).

Ground 14 incorporates Ground 1 by reference (RAN, p. 51). Rejection of the dependent claims of Ground 14 should be reversed with the reversal of Ground 1. Entis, alone or in combination, does not cure the deficiencies of the other references.

J. Ground 15

Appellant traverses the rejection of claims 5, 6, 23, 29, and 30, under 35 U.S.C. §103(a), over FSIS in view of Price, Midura, and Entis.

The RAN incorporates Ground 2 by reference (RAN, p52). Rejection of the dependent claims 5, 23, 29, and 30 based on Ground 15 should be reversed with the reversal of Ground 2.

Entis, alone or in combination, does not cure the deficiencies of the other references.

K. Ground 21

Appellant traverses the rejection of claim 21, under 35 U.S.C. §103(a), over Jarvis in combination with FSIS, Midura, and Cousin.

The RAN incorporates Ground 1 by reference (RAN, p. 58). Rejection of the dependent claim of Ground 21 should be reversed with the reversal of Ground 1.

Cousin, alone or in combination, even as construed in the RAN/ACP does not cure the deficiencies of the other references.

L. Ground 22

Appellant traverses the rejection of claim 21, under 35 U.S.C. §103(a), over FSIS in combination with Price, Midura, and Cousin.

The RAN incorporates Ground 2 by reference (RAN, p. 60). Rejection of the dependent claim of Ground 22 should be reversed with the reversal of Ground 2.

Cousin, alone or in combination, does not cure the deficiencies of the other references.

M. Ground 23

Appellant traverses the rejection of claim 23, under 35 U.S.C. §103(a), over Jarvis in combination with FSIS, Midura, and Price.

The RAN incorporates Ground 1 by reference (RAN, p. 61). Rejection of the dependent claim of Ground 23 should be reversed with the reversal of Ground 1.

Price, alone or in combination, does not cure the deficiencies of the other references.

N. Ground 24

Appellant traverses the rejection of claims 24, 28, 32 and 33, under 35 U.S.C. §103(a), over FSIS in combination with Price, Midura, and Gabis.

The RAN incorporates Ground 2 by reference (RAN, p. 63). Rejection of the dependent claims of Ground 24 should be reversed with the reversal of Ground 2.

Gabis, alone or in combination, does not cure the deficiencies of the other references.

Declarations

Appellant's (6) Declarations (Exhibits E-J), and comments regarding same in the App. Br., are incorporated herein by reference, and should be carefully considered by the Board in support of the current Appeal brief and Rebuttal brief.

Response to Declarations

Appellant incorporates by reference herein Appellant's comments in the App. Br. relating to various incorrect statements made in the RAN/ACP Section entitled "Response to Declarations." Moreover, the RAN/ACP has failed the legal requirement to properly consider Appellant's *indicia* of objective non-obviousness of record in this *inter partes* reexamination and appeal.

VIII. CONCLUSION

For the reasons provided herein, Appellant submits the RAN/ACP has improperly rejected the claims that are the subject of the present appeal.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Patentee
Registration No. 47,309

IX. APPENDIX; INDEPENDENT CLAIMS 1 AND 17

1. (Twice amended) A method of sampling, testing and validating a plurality of test lots for release into commerce[[microbial contamination]], comprising:

a) collecting a plurality of portions from each of a plurality of separate test 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 is separately sampled[[, according to a statistical sampling plan]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 lots [[samples]] are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots [[may nonetheless yet be]]are validated[[, according to the statistical sampling plan,]] 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. (Twice amended) A method of sampling, testing and validating a plurality of test lots for release into commerce[[microbial contamination]], comprising:

a) collecting a plurality of portions from each of a plurality of single-unit 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 is separately sampled[[, according to a statistical sampling plan for a particular microbial agent or organism,]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 [[may nonetheless yet be]] 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).

X. EVIDENCE APPENDIX

Evidence required under 37 CFR § 41.67(c)(1)(ix). Appellants rely upon evidence, such as listed in the table below, submitted and of record in the *inter partes* reexamination case, Control No. 95/001,294.

Evidence (Exhibits A-Y) used in the Appeal Brief, filed 07 May 2012, is incorporated by reference herein.

XI. RELATED PROCEEDINGS APPENDIX

There are no decisions by a court or the BPAI pursuant the 37 C.F.R. § 41.67(c)(1)(x) that are submitted herein.

XII. CERTIFICATE OF SERVICE

Timely service to the third party requester, bioMerieux, via their attorney E. Anthony Figg, at Rothwell, Figg, Ernst & Manbeck, P.C., 607 14th Street N.W., Suite 800, Washington, D.C. 20005 is being affected by first class mail sent on 04 October 2013.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 01/20/2015

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
01/20/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMÉRIEUX, INC.
Requester and Respondent

v.

Patent of
INSTITUTE FOR ENVIRONMENTAL HEALTH INC.
Patent Owner and Appellant

Appeal 2014-007983
Reexamination Control 95/001,294
Patent 7,534,584 B2
Technology Center 3900

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal by the Patent Owner from the Patent Examiner's decision to reject claims 1–33 in the above-identified *inter partes* reexamination of United Stated Patent (US) 7,534,584 B2. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315 (pre-AIA).

We affirm, but designate our affirmance as a new ground of rejection pursuant to 37 C.F.R. § 41.77(b).

I. BACKGROUND

The patent in dispute in this appeal is US 7,534,584 B2 ("the '584 patent") which issued May 19, 2009. The real party in interest and assignee is Institute for Environmental Health Inc. ("Patent Owner" or "IEH"). Appeal Br. 2 (May 7, 2012). The sole named inventor is Mansour Samadpour who is the CEO of IEH. Samadpour 2000 Decl. ¶ 2 (July 26, 2010).

A request for *inter partes* reexamination of the '584 patent was filed April 5, 2010 by bioMérieux, Inc. ("Requester") under 35 U.S.C. §§ 311–318 and 37 C.F.R. §§ 1.902–1.997. An oral hearing was held December 17, 2014. An oral transcript has been entered into the record ("Oral Transcript").

The claimed subject matter of the '584 patent relates to methods of sampling, testing and validating a plurality of "test lots" for release into commerce. The claims specify testing for the presence or absence of a microbial agent or organism in test lots. A test lot can be a food, environmental sample, pharmaceutical, or other lots which are analyzed for the present of a microbial agent or organism. '584 patent, col. 1, ll. 18–32. The purpose of the method is to improve the safety and quality of the food and other products by efficiently testing for microbial contamination. *Id.*

II. REJECTIONS AND CLAIMS

Patent Owner appeals 14 grounds of rejections made by the Examiner. Appeal Br. 5–6; Right of Appeal Notice ("RAN") (the numbering of rejections in

National Beef Ex. 1007
Page 1561

the Appeal Brief and the RAN are different). Because Rejections 1, 2, 10, 11, 13, and 14 (as numbered in the Appeal Brief) include all the appealed claims, we discuss only those rejections herein.

As explained in more detail below, our interpretation of the claims differs from the Examiner's. Consequently, the cited prior art of record has been applied to the claims differently in this decision than applied by the Examiner in the RAN, which set forth the basis of each rejection. Rejections 1, 2, 10, 11, 13, and 14 are affirmed, but have therefore been designated new grounds of rejection under 37 C.F.R. § 41.77(b).

Two of the cited publications, Jarvis[1] and Price,[2] have similar teachings. In some of the rejections, only Jarvis was cited, and in other rejections, only Price. To avoid repetitive arguments and responses, the rejections have been modified by citing to both Jarvis and Price. For this reason, as well, we have designated the rejections as new grounds of rejection. Rejections 1, 2, and 13 are similar and have been combined. The new grounds of rejection have been renumbered and are as follows:

1. Claims 1–4, 6-20, 22, 24–27, 31, and 32 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS,[3] and Midura.[4] RAN 8, 22, 56.

---

[1] B. Jarvis, *Statistical Aspects of Microbiological Analysis of Foods Progress in Industrial Microbiology: Errors Associated with Dilution Count and Presence/Absence Methods,* Vol. 21, Elsevier (1989) Chapter 8, pp. 117–142.
[2] W. R. Price, R. A. Olsen and J. E. Hunter, *Salmonella Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples* , Applied Microbiology, Vol. 23, No. 4 (1972), pp. 679–682.
[3] US Dep't of Agriculture, FSIS Directive, *Microbiological Testing Program and Other Verification Activities for Escherichia coli 0157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components,* 10.010.1, Revision 1, (2004) pp. 1–28.

National Beef Ex. 1007
Page 1562

2. Claims 5, 6, 23, 29, and 30 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Entis.[5] RAN 50, 51, 53.

3. Claim 21 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Cousin.[6] RAN 58, 60.

4. Claims 24, 28, 32, and 33 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Gabis.[7] RAN 62.

Obviousness is determined in the context of the scope and content of the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). In addition to the publications above, Andrews,[8] Bam,[9] and Silliker[10] of record in this proceeding are

---

[4] Thaddeus F. Midura and Raymond G. Bryant, *Compendium of Methods for Microbiological Examination of Foods: Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis,* 4th Ed., American Public Health Association (2001), Chapter 2.

[5] Phyllis Entis, Daniel Y.C. Fung, Mansel W. Griffiths, Lynn Mclntyre, Scott Russell, Anthony N. Sharpe, and Mary Lou Tortorello, *Compendium of Methods for Microbiological Examination of Foods: Rapid Methods ffor Detection, Identification, and Enumeration,* 4th Ed., American Public Health Association (2001), Chapter 10.

[6] M. A, Cousin, J. M. Jayy, and P.C. Vasavada, *Compendium of Methods for Microbiological Examination of Foods: Psychrotrophic Microorganisms,* 4th Ed., American Public Health Association (2001), Chapter 13.

[7] D. A. Gabis and J. H. Silliker, *ICMSF Methods Studies. II. Comparison of Analytical Schemes for Detection of Salmonella in High-Moisture Foods,* Can J. Microbiol, Vol. 20, (1974), pp. 663–669.

[8] Wallace H. Andrews, Russell S. Flowers, John Silliker, and J. Stan Bailey, *Compendium of Methods for Microbiological Examination of Foods: Salmonella,* 4th Ed., American Public Health Association (2001), Chapter 37.

[9] BAM: *Food Sampling/Preparation of Sample Homogenate,* US FDA (2003), (Bacteriological Analytical Manuel), Chapter 1, pp. 1–11.

[10] J. H. Silliker and D. A. Gabis, *ICMSF Methods Studies. I. Comparison of Analytical Schemes for Detection of Salmonella in Dried Foods,* Can J. Microbiol, Vol. 19, (1973), pp. 475–479.

considered to further define the scope and content of the prior art and have been cited as additional evidence of the obviousness of the appealed claims.

Claim 1 is representative and reads as follows (underlining and brackets indicate changes to the claim, relative to the original claim, made by Patent Owner during the reexamination proceeding):

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

a) collecting a plurality of portions from each of a plurality of separate test 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 is separately sampled[[, according to a statistical sampling plan]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 lots [[samples]] are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots [[may nonetheless yet be]]are validated[[, according to the

statistical sampling plan,]] for release into commerce, according to 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).

III. CLAIM INTERPRETATION

Step c)

Step c) of claim 1 recites "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" (emphasis added). The "incubating" step is further recited "to provide a set of separate test lot samples enriched for the target microbial agent or organism" (emphasis added). The interpretation of this step is disputed. Claim 17 has similar language.

The Examiner contends that step c) corresponds to the prior art "pre-enrichment" step. *See, e.g.*, RAN 11, 23. Patent Owner contends that step c) corresponds to the prior art "enrichment" step. Substitute Patent Owner Rebuttal Br. 9 & 13. The issue is whether the incubation conditions and resulting "test lot samples enriched for the target microbial agent or organism" corresponds to the prior art "pre-enrichment" and/or "enrichment" step.

During reexamination of an unexpired patent, claims are given their broadest reasonable interpretation consistent with the patent specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1259 (Fed. Cir. 2010); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1148 (Fed. Cir. 2012). The "PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary

usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Accordingly, we begin with the specification of the '584 patent to see if the terms in the disputed phrase are defined or given a special meaning.

The '584 patent repeatedly refers to enriching samples for a target bacteria to be detected. In the Background section of the patent, the inventor describes prior art steps in which individual samples are combined ("composited") to form a single sample for testing. '584 patent, col. 1, l. 67–col. 2, l. 21. The patent teaches that once samples are composited, they have to be "enrich[ed] . . . to achieve the desired sensitivity." *Id.* at col. 2, ll. 21–25.

The patent describes prior art in which a sample is "enriched" to provide sufficient bacteria for the detection steps:

> 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 . . .."

Id. at col. 2, ll. 46–55 (emphasis added).

In describing its own invention, the '584 patent does not appear to give "enrich" a meaning that is any different from how it is used in the prior art. For example, in the "Summary of the Invention," it is stated:

> With respect to testing each reportable lot (e.g., each single unit of production), a plurality of pieces/portions of sample are separately

> collected from each single reportable lot (e.g., from each single production unit; individual test unit) and composited to form, for example, one 'single-unit production lot sample' (corresponding, in each case, to a particular single unit of production), which is enriched using appropriate enrichment protocols to allow for the levels of the target organism to reach detection levels and uniformity of presence in the enriched sample.

Id. at col. 4, ll. 2–12 (emphasis added).

The patent also defines "enrichment," consistent with how the term is used in the prior art and in the claim, to mean "incubating a test lot sample (e.g., single-unit production lot sample) under conditions suitable to allow levels of a target agent/ organism that is present to reach detectable levels and become uniform or substantially uniform throughout the enriched test." *Id.* at col. 6, ll. 7–12 (emphasis added). The patent explains that "[p]referably" enrichment is carried out in an enrichment medium that includes "selective agents" that inhibit undesired organisms or select for desired ones. *Id.* at col. 6, ll. 25–27.

The prior art defines "pre-enrichment" and "enrichment" steps. Pre-enrichment in explained in the Andrews publication:

> The introduction of large amounts of food directly into selective media tends to reduce the selectivity of the media for *Salmonella* organisms. Further, the *Salmonella* organisms in foods are often in poor physiological condition as a result of food processing and storage. These two problems are simultaneously circumvented by pre-enrichment of the sample in a non-selective medium which permits resuscitation of debilitated organisms. Inoculation of selective media from the pre-enrichment medium obviates introduction of food into the selective medium.

Andrews 357, Section 37.121.

> Andrews also describes enrichment as follows:
>
> Enrichment media, which are inoculated with portions of pre-enrichment cultures, favor the growth of *Salmonella* organisms. In

> the past, direct enrichment of highly contaminated raw products, such as meats and sewage, was advocated. However, it has been concluded that such samples should be pre-enriched for greater recovery of the target organism.

Id. at 360, Section 37.124. Andrews describes the use of enrichment media to "favor" or select for the target bacteria, which in Andrews' case is Salmonella. *Id.*

In other words, "pre-enrichment" is performed to resuscitate the bacteria and "enrichment" is for growing and favoring the growth of the target bacteria over other bacteria and organisms in the sample.

As indicated above, "enrichment" as described in the '584 patent is for growing and multiplying bacteria ('584 patent, col. 2, ll. 46–55), which is the same as the enrichment step described in Andrews. Thus, the '584 patent and Andrews use the term "enrich" in the same way. Step c) of claim 1 does, as well. Step c) provides for "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." This step, like the prior art enrichment step described in the '584 patent and Andrew, is for growing the "target" organism under "suitable conditions" to recover it in sufficient amounts to enable detection. Accordingly, we interpret step c) of claim 1 to correspond to the prior art enrichment step aimed at growing the target organism in contrast to "pre-enrichment" which only resuscitates the target organism for subsequent growth in an enrichment media.

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

National Beef Ex. 1007
Page 1568

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).

IV. REJECTION 1

This is a new ground of rejection. As indicated above, our interpretation of claim 1 differed from the Examiner's. We interpret step c) to be an enrichment step, not a pre-enrichment step as construed by the Examiner. This difference in claim interpretation changed the way the prior art has been applied to the claims, necessitating new grounds of rejection.

Claim limitations

For further reference, we have numbered the various limitations in claim 1 below. Such list is intended to make it easier to refer to the claim limitations when addressing the prior art rejections. While the limitations may have been abbreviated from how they appear in the claim, we have fully considered the claim in its entirely and have not ignored any words in the claim.

Claim 1

Step a)

a1. "collecting a plurality of portions from each of a plurality of separate test lots"

a2. "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"

Step b)

b1. "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"

Step c)

c1. "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" or "enrichment" step

Step d)

d1. "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample"

Step e)

e1. "testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism"

e2. when testing is "negative," "all of said separate test lots are validated for release into commerce"

e3. when 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" of step c)

e4. "obtaining a negative test result for each test lot"

Discussion

Each of Jarvis and Price were relied upon by the Examiner for the basic steps of the claimed method. RAN 8-10, 13, and 22-25. Midura was further cited for the "statistical-based sampling plan" and FSIS for obtaining samples from a plurality of test lots as recited in the claims. *Id.* In reaching this determination, the Examiner incorrectly construed step c1 of a claim 1 to be a "pre-enrichment" step. While we do not agree that this is the broadest reasonable interpretation of step c1 consistent with the written description of the '584 patent, nevertheless, we agree with the Examiner that the claimed subject matter would have been *prima facie* obvious to one of ordinary skill in the art in view of the prior art of record.

Step a1

Step a1 involves collecting separate samples ("a plurality of portions") from a plurality of separate test lots. Jarvis teaches collecting a plurality of samples in method 2) on page 141 where separate pre-enrichment samples are prepared

("Prepare 10 pre-enrichment series . . . and after incubation"). Jarvis also describes a pre-enrichment step, which is not recited in claim 1. However, the claimed method uses the term "comprising" which means the method is open-ended and does not exclude Jarvis's pre-enrichment step. Price also describes collecting a plurality of samples. Price 680 (Fig. 1).

Neither Jarvis nor Price describes collecting samples from more than one test lot as recited in the claims. The Examiner identified Example 8.4 on page 136 of Jarvis as teaching step a1 of "collecting a plurality of portions from each of a plurality of separate test lots" because three products A, B, and C are listed in it. RAN 8. The Examiner did not provide sufficient evidence that A, B, and C were used in the same method. However, as explained below, "collecting a plurality of portions from each of a plurality of separate test lots" would have been obvious based on FSIS and Midura.

Plurality of test lots

The patent defines a "test lot" as "an assemblage of one or more specimens of a medium or process . . . where the one or more specimens of the assemblage are operationally linked in a manner (e.g., proximity, time, process step, etc.)." '584 patent, col. 5, ll. 21–28. The test lot can be a single production unit, such as a combo or bin. *Id.* at col. 5, ll. 32–36.

FSIS teaches that during processing of meat in a production lot, combo bins are filled with meat. FSIS 27. FSIS teaches taking representative samples from more than one of the combo bins:

> 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. FSIS thus teaches the claimed step a1 of "collecting a plurality of portions from each of a plurality of separate test lots," which each bin is a test lot as defined in the '584 patent.

Midura also describes collecting samples from a plurality of test lots. Specifically, Midura teaches sampling "parts or strata" of a production lot:

> 32. **Stratified random sampling**—A procedure for sampling where the lot is divided into parts or strata that differ with respect to the characteristics under study. In some cases, this is a way of improving the estimate of lot quality.

Midura 16. A combo bin would be an obvious part or strata of a production lot since the combo bins are filled sequentially during the meat processing to form a production lot.

Step a2

Step a2 involves statistical sampling from a "test lot." Jarvis does not state where the samples originate. Price is also deficient in the same way. However, Jarvis discloses sampling of multiple tubes or from "test lots" (Jarvis 136, 137) and statistical-based sampling from a lot is disclosed in Midura. (Midura 14 Section 2.51, "Sampling Plans".) Furthermore, the '584 patent teaches sampling plans, including under guidelines and directives from the United States Department of Agriculture, Food Safety and Inspection Service (FSIS) to ensure food safety. '584 patent, col. 1, ll. 37–43; col. 1, l. 62 to col. 2, l. 25. Appellant appeared to concede that statistical-based sampling from a test lot was known in the prior art. Appeal Br. 14 ("The number of portions that must be gathered from each lot for testing is determined by statistical significance requirements in government

regulations and industry standards, which are cited extensively in prior art i.e. FSIS, Midura, etc."). Accordingly, even if Jarvis and Price are silent on the origin of their samples and whether their sampling was statistically-based, it would have been obvious to have performed statistical sampling on a test lot since the prior art taught that such step is conventional in order to ensure the safety of the food lot for human consumption.

To the extent Appellant challenged the obviousness of using statistical sampling in a method for testing food lots for contamination (Appeal Br. 14–15 and 18), we find such an argument to be baseless in view of the overwhelming evidence of record that sampling was necessarily statistically based to reduce the risk of releasing contaminated food lots for human consumption. Andrews 358–359; BAM; Midura 14 ("Sampling Plans").

Step b1 and c1

Step b1 combines the collected portions to form a separate test lot sample. This step is performed for all of the portions collected from each of the separate test lots, i.e., a plurality of test lot samples are formed, each individual one corresponding to samples ("portions") taken from a separate test lot. Step c1 subjects the separate test lots samples to enrichment.

Jarvis's method 2) describes "composit[ing] equal volumes of each pre-enrichment medium (e.g. 10 x 1ml) to inoculate the 100 ml enrichment broth." Jarvis 141. Price also teaches compositing samples in an enrichment step. Price 680 (Fig. 1). These steps involve combining samples ("portions") and subjecting them to enrichment. However, neither publication describes combining portions from a plurality of test lots to "provide a corresponding set of separate test lot

samples" (b1) which are then enriched (c1). As explained below, we conclude that this step would have been obvious to one of ordinary skill in the art.

Jarvis describes compositing samples in order to reduce the number of samples tested. Jarvis 481. Price also teaches this concept. Price 679. In fact, 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.

Patent Owner argued against the nonobviousness of steps b) and c). The inventor, Dr. Samadpour, 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." Samadpour 2010 Decl. ¶ 8. Dr. Samadpour also criticized the teachings in Jarvis as being theoretical. Samadpour 2011 Decl. ¶ 25 (Declaration of Mansour Samadpour under 37 C.F.R. § 1.132

dated Jan. 31, 2001). We have considered both declarations, but do not find them persuasive.

With regard to enrichment only, the claim does not exclude a pre-enrichment step. Moreover, there is a suggestion in Price (at 682) and Gabis (at 684) of direct enrichment. Even if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use "would render the result inoperable." *In re ICON Health and Fitness Inc.*, 496 F.3d 1374, 1381 (Fed. Cir. 2007).

With respect to Jarvis, even if Jarvis is theoretical as stated by Dr. Samadpour, it still teaches that compositing can be used in multiple steps, providing a reason to have applied this method in food testing to reduce the labor required in sample testing.

Step d1

In step d), portions of the enrichment from each separate test lot sample are combined to form a modular sample which is tested in step e). Neither Jarvis nor Price teaches *combining* samples after enrichment and testing them. However, as indicated by the Examiner, Jarvis does teach compositing both pre-enrichment and enrichment samples, while still attaining the "same degree of statistical confidence." Jarvis 141, method (3). Jarvis expressly teaches that "When a number of samples is to be tested it sometimes recommended that the samples be composited in order to reduce the work load on the laboratory." *Id.* Price's disclosure is also concerned with pooling samples to reduce workload and increase sample testing capacity. Price 679. Based on these teachings, one of ordinary in

the art would have had reason to composite samples for testing in order to reduce the number of tests necessary to perform. RAN 13.

Appellant argues that "Nothing in any cited art teaches the concept of simultaneous testing of multiple lots in course of a single application of a method, as is done in the patented claims." Appeal Br. 7; see also 17 and 19. Appellant also argues that prior art does not motivate combining enriched samples to form modular composite samples and testing them as recited in steps d1 and e. Reply Br. 4.

It is correct that the cited prior art, particularly Jarvis and Price, do not describe compositing samples from different enrichment samples, which themselves have been composited. However, as indicated above, it would have been obvious to pool enriched samples together to reduce the number of tests that need be performed.

"An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009). In this case, as found by the Examiner, pooled enrichment samples were tested in both Jarvis (141) and Price (679, Fig. 1). Jarvis describes compositing both pre-enrichment samples and enrichment samples (141, method 3). Jarvis states that method (3) has "the same degree of statistical confidence as would be attained by testing the 10 samples separately." *Id.* Thus, it would have been reasonably expected that pooling samples at two different steps (enrichment and post-enrichment as recited in claim 1, or, pre-enrichment and enrichment as in Jarvis) would have the requisite sensitivity in detecting positives for contamination. Moreover, compositing in two stages as described in Jarvis

National Beef Ex. 1007
Page 1577

provides the motivation to have carried out the second compositing step recited in step d1.

Step e

Step e1 involves testing which is taught by Jarvis and Price. See, e.g., Price 680 (Fig. 1). Steps e2 involves obtaining a negative and then "all of said separate test lots are validated for release into commerce." The latter limitation is essentially a "mental step" and does not limit the scope of the claim. See Claim interpretation section. As negatives would be obtained by Jarvis and Price, we find that steps e1 and e2 are met by both publications.

Step e3 recites when the 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." Jarvis teaches that "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." Jarvis, 141-142. In other words, if the enriched sample tests positive, Jarvis teaches going back to the pre-enrichment samples, just as the claim recites "further testing of a portion of the respective enriched separate test lot sample." While it is true that Jarvis differs because Jarvis teaches going back to the samples before enrichment, Jarvis still teaches the concept of testing composited samples as in step e1 and going back to the sample before composting as in step e3. Thus, based on this teaching, it would have been obvious to one of ordinary skill in the art to have saved the samples prior to compositing and then to return to them, if the composited sample tests positive in order to determine which samples were positive.

National Beef Ex. 1007
Page 1578

As noted by the Examiner, Price also teaches this step. Fig. 1 shows that when the biochemical testing is positive, the skilled worker is directed to perform individual testing on the samples prior to pooling them in the enrichment step.

V. SECONDARY CONSIDERATIONS

Factual considerations that underlie the obviousness inquiry include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations. *Graham*, 383 U.S. at 17-18. Secondary considerations are "not just a cumulative or confirmatory part of the obviousness calculus but constitute independent evidence of nonobviousness . . . [and] enable[] the court to avert the trap of hindsight." *Leo Pharm. Prods., Ltd. v. Rea,* 726 F.3d 1346, 1358 (Fed. Cir. 2013) (internal quotation marks and citations omitted). "This objective evidence must be 'considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.'" *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) (internal citations omitted).

Commercial success

Dr. Mohammad Koohmaraie, who is the CEO of the Meat Division of Institutes of Environmental Health, testified that surprisingly, while "post-enrichment inter-lot pooling [steps d1 and e2], as disclosed and claimed in the current patent, requires increased sampling/testing expense (about 30% more than with the prior industry standard) it has been rapidly and widely adopted and solves a long standing problem in the art by providing for a more robust testing method

with enhanced safety" for consumers. Koohmaraie Decl. ¶ 13. Further, Dr. Koohmaraie testified that "largely because of IEH's implementation of its modular inter-lot pooling methods, IEH provides laboratory testing for about 30% of the cattle processed in the United States and about 40% of the cattle processed in Canada." *Id.* at ¶ 14.

Dr. Koohmaraie provided data "from an IEH conducted *E. coli* 0157:H7 testing program in beef trim" using "inter-lot composite pooling method, as disclosed and claimed in the current patent." *Id.* at ¶ 15. This data was said by Dr. Koohmaraie to have saved "a representative client of the company . . . 477 combo bins-each containing about 2000 lbs of beef trim," avoiding unnecessarily discarding uncontaminated bins." *Id.* at ¶¶ 15–16. Dr. Samadpour also testified about wide-spread acceptance of the claimed method and the cost-savings of using the method. Samadpour 2010 Decl. ¶ 7.

Dr. Koohmaraie concluded that "Wet composite inter-lot pooling, as disclosed and claimed in the current patent, is the technology that surprisingly makes single combo testing a viable option." Koohmaraie Decl. ¶ 18. Dr. Samadpour also stated that it was surprising that the claimed method was widely adopted because of the costs and large number of samples utilized. Samadpour 2010 Decl. ¶¶ 4, 10.

Dr. Samadpour further testified that "IEH company sales figures for the last four years have increased at an average rate of 30% per year, based on client adoption of the methods claims in the present patent application comprising inter-lot pooling of enriched samples, and the ability to yet validate and release individual lots after obtaining a positive result for an inter-lot pool sample. Samadpour 2010 Decl. ¶ 11.

Dr. Samadpour testified that "the increase in sales for the new inventive modular composite method was not the result of advertising effort." Samadpour 2011 Decl. ¶ 44. Appendix H of the same declaration shows growing revenue for the modular compositing method, while revenue gradually decreased in the "classical" testing method that costs less and uses larger samples. *Id.* at ¶ 38. By 2008, revenue from the classical testing method was over 12 million dollars, while the modular compositing revenue was less than 1 million. By 2010, revenue for the modular compositing method was over 10 million, while the classical testing method had declined to less than 2 million.

Skepticism

Dr. Samadpour testified that he "was faced with a high degree of skepticism by experts in the field, and regulatory agencies (FSIS)." Samadpour 2011 Decl. ¶ 34.

> **It took years to overcome the skepticism of the experts in the field**. In my attempts to have USDA Food Safety Inspection Service (FSIS) accept the method and issue a letter of no objection, it became apparent that the agency was extremely apprehensive about the loss of sensitivity due to pooling, mainly masking a positive sample by a number of negative samples.

Id.

Dr. Samadpour described his efforts to gain acceptance of his method. *Id.* Dr. Samadpour testified that to get FSIS to accept the method, he had to modify the protocol as follows: "If the modular composite sample is negative, each individual enrichment component is tested individually before it is released into the chain of commerce." *Id.* Dr. Samadpour also described the skepticism of his clients. *Id.* at ¶ 35.

Dr. Samadpour's testimony was corroborated by Mr. James Byron who had been a competitor of IEH, but has since joined the company. Byron Decl. ¶ 3. For example, Mr. Byron testified that the method was "scoffed" at by the manager for food safety at Mr. Byron's former company because it was believed that the method would result in false negative results. *Id.* at ¶ 4. Mr. Byron also testified that he experienced the skepticism of customer's first hand. *Id.* at ¶ 7.

Mr. Warren Mirtsching, Chief Operating Officer at IEH, testified that while he was employed by Swift and Company, a meat producer, he was concerned about the sensitivity of Patent Owner's method. Mirtsching Dec. ¶¶ 4-5. To address these concerns, Mr. Mirtsching stated that he carried out detailed testing using the method and found that "it was sensitive enough to meet the requirements prescribed by Swift." *Id.* at ¶ 7. Mr. Mirtsching identified major customers of Swift, such as Tyson Company, that had initially challenged, but were later convinced that Patent Owner's method worked. *Id.* at ¶ 8-9.

Discussion

In order to establish commercial success, "[a] nexus between commercial success and the claimed features is required." *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). In this case, Patent Owner asserted that its commercial product embodying the claimed method has 30% of the cattle processing market in the US and 40% of the market in Canada. Furthermore, Patent Owner provided data that its product comprising the modular composite method in accordance with the claimed method had increased in revenue from 2008 to 2010 from less than 1 million to over 10 million dollars, while revenue of Patent Owner's second "classical testing" product declined from

over 12 million to under 2 million dollars. Patent Owner, however, did not provide an adequate explanation of the second "classical" product to understand the differences between the two and understand the reason for the success. For instance, was the success solely attributable to the post-enriching step e2 or to another step which was readily available in the prior art? As held in *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997), "the asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art."

All the data appears to involve testing of beef for contamination by at least *E. coli*. It is not clear from the evidence presented whether other bacterial contaminants are tested. It is also not clear from the evidence whether other food products had the same commercial success as that shown for the beef testing. Independent claims 1 and 17 are not limited to a specific food product, yet it appears that the commercial success was attributable to beef. Moreover, Patent Owner did not establish that its results for beef would be representative of results for other foods, such as other meats, dry foods and dry food materials, environmental samples, and pharmaceuticals covered by the claims. '584 patent, col. 1, ll. 18–31. Patent Owner did not separately argue claims limited to beef or other like meats.

Arguments were also made that lot sizes are smaller in the claimed method than in the prior art and "classical" method. Samadpour 2011 Decl. ¶ 8, 30, 36.[11]

[11] "In conducting my baseline studies, I found the unexpected result that while the number of positive findings increased due to increasing the number of lots tested (same production volume divided into more lots of smaller size) the overall amount of products destroyed is significantly less due to the fact that the lot sizes are much smaller."

See also Oral Hearing Transcript 16: 8–11; 17:1–5. However, the claims are not limited to a lot of a particular size. Thus, if this is a basis for patentability, the feature is not recited in the claim. It is well established that for evidence of secondary considerations to be accorded substantial weight, there must be a nexus between the claimed invention and what is relied upon as the secondary consideration. *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). A nexus is established when the secondary consideration is attributed to a feature of the claimed invention. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (2006).

Dr. Samadpour testified that to convince FSIS to accept the method, he had to modify the protocol by testing each individual enrichment component separately, even when the modular composite sample was negative. Samadpour 2011 Decl. ¶ 34. If the method responsible for the market share and increased revenue assays each test lot separately whether negative or positive, then it has not been established that the modular composite testing as claimed is responsible for the success. The commercial success must be due to a claimed feature.

The skepticism of the modular composite method established by the various declarants has the same flaws described above. The skepticism appears to be of a method for testing beef for bacterial contamination. The claims, however, include other meats, other foods, wet foods, and dry foods. Patent Owner did not establish this skepticism for the full breadth of the claim. In addition to this, according to Dr. Samadpour, he responded to FSIS skepticism by modifying the protocol to include testing of all samples. Thus, it has been clearly established on the record that, despite the skepticism, the claimed method in its entirely was adopted by the industry.

Summary

After considering the evidence before us, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, and Midura. Claim 17 has substantially the same language as claim 1 and is affirmed for the same reasons. Claims 2-4, 6-16, 18-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, and Midura were not separately argued by Patent Owner and thus are affirmed for the reasons given by the Examiner. RAN 10-14 and 22-26.

VI. REJECTIONS 2-4

Patent Owner made the same patentability arguments for dependent claims 5, 6, 21, 23, 24, 28-30, 32, and 33 cited in Rejections 2-4 (numbered 10, 11, 13, and 14 in the Appeal Brief) as they did for Rejection 1 (numbered 1 and 2 in the Appeal Brief). As we did not consider these arguments persuasive, we affirm the rejections for the reason set forth by the Examiner

VII. SUMMARY

As explained above, the Examiner's rejections 1, 2, 10, 11, 13, and 14 are affirmed, but designated new grounds of rejection 1-4 because the rationale and cited prior art differs from how the rejections were set forth in the RAN. Claims 1-33 are rejected under the new grounds of rejection 1-4.

NEW GROUND OF REJECTION

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.77(b) which provides that "[a]ny decision which includes a new ground of

rejection pursuant to this paragraph shall not be considered final for judicial review." Correspondingly, no portion of the decision is final for purposes of judicial review. A requester may also request rehearing under 37 C.F.R. § 41.79, if appropriate, however, the Board may elect to defer issuing any decision on such request for rehearing until such time that a final decision on appeal has been issued by the Board.

For further guidance on new grounds of rejection, see 37 C.F.R. § 41.77(b)-(g). The decision may become final after it has returned to the Board. 37 C.F.R. § 41.77(f).

37 C.F.R. § 41.77(b) also provides that the Patent Owner, WITHIN ONE MONTH FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected, or both.

(2) *Request rehearing.* The owner may request that the proceeding be reheard under § 41.79 by the Board upon the same record. ...

Any request to reopen prosecution before the examiner under 37 C.F.R. § 41.77(b)(1) shall be limited in scope to the "claims so rejected." Accordingly, a request to reopen prosecution is limited to issues raised by the new ground(s) of rejection entered by the Board. A request to reopen prosecution that includes issues other than those raised by the new ground(s) is unlikely to be granted. Furthermore, should the patent owner seek to substitute claims, there is a

presumption that only one substitute claim would be needed to replace a cancelled claim.

A requester may file comments in reply to a patent owner response. 37 C.F.R. § 41.77(c). Requester comments under 37 C.F.R. § 41.77(c) shall be limited in scope to the issues raised by the Board's opinion reflecting its decision to reject the claims and the patent owner's response under paragraph 37 C.F.R. § 41.77(b)(1). A newly proposed rejection is not permitted as a matter of right. A newly proposed rejection may be appropriate if it is presented to address an amendment and/or new evidence properly submitted by the patent owner, and is presented with a brief explanation as to why the newly proposed rejection is now necessary and why it could not have been presented earlier.

Compliance with the page limits pursuant to 37 C.F.R. § 1.943(b), for all patent owner responses and requester comments, is required.

The examiner, after the Board's entry of a patent owner response and requester comments, will issue a determination under 37 C.F.R. § 41.77(d) as to whether the Board's rejection is maintained or has been overcome. The proceeding will then be returned to the Board together with any comments and reply submitted by the owner and/or requester under 37 C.F.R. § 41.77(e) for reconsideration and issuance of a new decision by the Board as provided by 37 C.F.R. § 41.77(f).

AFFIRMED; § 41.77(b)

National Beef Ex. 1007
Page 1587

Appeal 2014-007983
Reexamination Control 95/001,294
Patent 7,534,584 B2

CC:

Patent Owner:

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, WA 98101-3045

Third Party Requester:

ROTHWELL, FIGG, ERNST, & MANBECK, P.C.
607 14th Street, N.W.
Suite 800
Washington, DC 20005

National Beef Ex. 1007
Page 1588

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 02/06/2015

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
02/06/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMERIEUX, INC.,
Third Party Requester,

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH INC.,
Patent Owner.

Appeal 2014-007983
Reexamination Control 95/001,294
Patent 7,534,584 B2
Technology Center 3900

Oral Hearing Held: December 17, 2014

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, Administrative Patent Judges.

APPEARANCES:

ON BEHALF OF THE PATENT OWNER:

BARRY L. DAVISON, Ph.D., ESQ.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045

and

MANSOUR SAMADPOUR, Ph.D.
IEH Laboratories & Consulting Group
15300 Bothell Way NE
Lake Forest Park, Washington 98155

ON BEHALF OF THIRD PARTY REQUESTER:
E. ANTHONY FIGG, ESQ.
SETH E. COCKRUM, Ph.D., ESQ.
Rothwell, Figg, Ernst & Manbeck, P.C.
607 14th Street, N.W., Suite 800
Washington, D.C. 20005

The above-entitled matter came on for hearing on Wednesday, December 17, 2014, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

- - - - -

USHER: Good morning, Calendar Number 47, Appeal Number 2014-007983, Mr. Davison and Mr. Figg.

JUDGE ROBERTSON: Thank you.

USHER: You're welcome.

JUDGE ROBERTSON: Okay, good morning, welcome to the Board.

MR. FIGG: Good morning.

JUDGE ROBERTSON: We are here for Appeal Number 2014-007983, Inter Partes re-exam 95/001294 and U.S. Patent 7534584.

Mr. Davison, you're for the Patent Owner?

MR. DAVISON: Yes.

JUDGE ROBERTSON: And you will have 30 minutes to argue your case. You may reserve some time for rebuttal, and if you would indicate to me when you get up how much time you would like to reserve for rebuttal, and Mr. Figg?

MR. FIGG: Yes, sir.

JUDGE ROBERTSON: You're for the Requester, you will have a 30-minute block to argue, no rebuttal.

MR. FIGG: But no rebuttal?

JUDGE ROBERTSON: Yes. So, Patent Owner, counsel for Patent Owner, when you're ready, please approach the podium and begin.

MR. FIGG: Your Honor, as a preliminary matter, may I make one comment? Mr. Davison has indicated that he and the inventor, Dr. Samadpour, are going to divide up the argument, and we didn't have a problem with that, but I guess I would like to preserve an objection that this is not an evidentiary hearing, and so I don't think it would be appropriate for Dr. Samadpour to be offering new opinions or new facts that are not part of the record that's before the Board.

JUDGE ROBERTSON: Okay, with respect to that, we make our decisions based on the arguments presented in the briefs. No new arguments are considered in terms of our decisionmaking process. So, with that in mind, we will proceed.

MR. FIGG: Thank you.

MR. DAVISON: So, I want to thank the Board for allowing us to have this opportunity. My name is Barry Davison, I am a patent attorney, I represent the inventor, Dr. Samadpour, he is the sole inventor of the patent in question, and we are here today because we think that the office got it wrong and that these claims are valid in view of the asserted art. And in particular, today, we want to focus on primarily two pieces of the asserted art, Jarvis and Price. And it's our contention that the other references have been used, as is clear in the record, for the reasons in the record, but that those are the primary references relied upon by the opposition.

JUDGE ROBERTSON: Okay, before you proceed, would you like to reserve -- further, would you like to reserve any time for rebuttal?

MR. DAVISON: Yes, 10 minutes, if possible. Excuse me.

JUDGE ROBERTSON: Ten minutes, go ahead.

MR. DAVISON: Now, because of these papers are rather complex pieces of science, and because the -- I think the crux of the issues are highly technical, Dr. Samadpour has requested that he be allowed to discuss the issues as are brought out by the respondent in the briefs. So, I would like to introduce him, he will stick to the record, and discuss Jarvis and Price, okay?

JUDGE ROBERTSON: Okay.

MR. DAVISON: And we have a slide deck. How do we get that going?

JUDGE ROBERTSON: Has the Requester seen your slide deck?

MR. DAVISON: Yes, we exchanged decks this morning.

JUDGE ROBERTSON: Did you have any chance to look at that, Requester?

MR. FIGG: We exchanged the slides. We do think there are new opinions, scientific opinions, that are presented in there. In view of Your Honor's comment at the beginning, I don't think it's feasible for me to object to every one of those, I just saw it 20 minutes ago or so.

JUDGE LEBOVITZ: Well, are the slides containing any new information that is not of record?

MR. DAVISON: Not in our opinion.

JUDGE LEBOVITZ: Because --

JUDGE ROBERTSON: Well, again, we emphasize that we make our decisions based on the arguments in the briefs of record.

JUDGE LEBOVITZ: I don't know if we have a projector set up here.

MR. FIGG: We had requested the video, but we have hard copies, so we don't need to use the projector.

JUDGE ROBERTSON: Do you both have hard copies?

MR. DAVISON: Do we have three hard copies? Ed?

JUDGE ROBERTSON: Can we go off the record for one second?

(Discussion off the record.)

JUDGE ROBERTSON: We are back on the record.

JUDGE LEBOVITZ: Okay, I want to ask a question.

JUDGE ROBERTSON: Go ahead.

JUDGE LEBOVITZ: We are on the record now. We have gone through the record thoroughly, okay, so we do have very specific questions that we would like to ask, and one thing I would like to say is that my reading of Jarvis and Price was that they were more focused on sample collection and they weren't really focused on where those samples came from. And it appeared that they were more focused on pre-enrichment, enrichment, and pooling, and not pooling samples, and the sensitivity involved with that. But if you go up in order, the secondary references, the -- one was the BAM reference, and the other was the FCIS reference, I think that was -- FSIS reference. Both those references are more telling you what the industry was doing at the time, and if you look at BAM and if you look at FSIS, what it looked like, they're talking about taking a production lot, which is probably five combo bins together, and then taking 60 samples out of them, okay? And then it looks like Price and Jarvis are talking about what you do with those 60 samples once they come out of it, okay? That's my understanding.

And if you look at a reference like Silliker and maybe some of the other references, they do talk about taking those 60 samples and breaking them up maybe into groups of 12. I know Silliker explicitly talks about taking them into groups of 12, okay?

So, if you've done that, that seems to us to be very much like what you're claiming, because it would be almost common sense that if you're going to be pulling 60 samples from a lot of five combo bins, and Silliker talks about 12 samples, then he would be talking about taking 12 samples from one combo bin, 12 samples from another combo bin, and then doing whatever -- doing the testing on those so you can go back to the combo bins and not have to throw them out.

Now, that might not be exactly what was being practiced in the industry, okay, I understand that, but however, we're looking at it from what would be obvious based on the references, okay? So, understand that perhaps the industry may not have been looking at different combo bins, but it seems to us that it's reasonable to -- that if you're taking 12 samples out, you go back to the combo bin so you don't have to throw them out. That's my question. And please correct me when I'm wrong, and talk loudly, et cetera.

MR. SAMADPOUR: Okay. So, first of all, thank you for allowing me the chance to be here. As you correctly stated, Price was the developing method, so Price purchased some dried milk, dry milk, powder, some cocoa powder, and some egg albumen and then

he inoculated these with the patency, with salmonella, and his intention was, okay, if you take 25-gram samples from this, you know, 15, 20, 25, whatever number, and then the methodology for salmonella was that you would get these independent 25-gram samples, you will pre-enrich them and then you would enrich them, and after that you would test.

So, Price said that if we get these 25-gram samples, we pre-enrich them, then before going to enrichment, why have like 60 pre-enrichments and 60 enrichments, we can now pool them in groups of five and have only 12 enrichments.

Now, this was in the context of having things from one lot of the product. What you correctly asserted was the beef industry situation where they had five combo bins, and they would take 12 samples from each of those five combo bins, 12 independent samples, and they would put it in a bag and send it to a lab. And the lab would test those and say, this lot of five combo bins is positive or negative. There is no going back to that situation.

And this would mimic the Silliker situation, which he was advocating that if you put all these samples, then you don't really need to do anything else. It's just as sensitive as -- so, all the work in the existing art was based on testing samples from one lot and then how do you save some lab time and some resources in the lab and save money by doing this.

Now, if I go through the introduction, it becomes clear, I can answer your question. May I do that? So, if you go to the first slide, that shows the invention, where you have five independent lots of products.

JUDGE LEBOVITZ: But those would be combo bins, they could be?

MR. SAMADPOUR: In this example, they are combo bins.

JUDGE LEBOVITZ: Yeah, okay.

MR. SAMADPOUR: They could be two hours of production from peanut butter, they could be two hours of production from bagging line from leafy greens.

JUDGE LEBOVITZ: Whatever?

MR. SAMADPOUR: Whatever. So it could be anything. Once you have this -- and lots are physical items, they are not virtual. Once you say this is a lot, you are separating them, you are segregating them, they are under control, and once you make a decision, it applies to that lot. You cannot reverse that, you go to jail.

So, from each one of these independent lots, we take a statistically significant number of samples, here it equals 60, okay? We dry composite that, this is something that Price did not do, and actually Price was teaching against that.

JUDGE LEBOVITZ: What do you mean dry composite it?

MR. SAMADPOUR: This 60 go into one bag. Price would get the 60 and would do 60 pre-enrichments on them. Aggregation of these 60 samples in one -- as it's depicted in the --

JUDGE DELMENDO: So, in your invention, you're aggregating them into one sample?

MR. SAMADPOUR: Exactly.

JUDGE DELMENDO: But I thought that you were saying that in the prior art that they were also throwing the meat samples into one bag.

MR. SAMADPOUR: In the prior art, from the same lot, they would get things and put them in the same bag, correct.

JUDGE DELMENDO: Yes. So, how would it work --

MR. SAMADPOUR: So, here, we are just doing the prior art.

JUDGE DELMENDO: Oh, okay.

MR. SAMADPOUR: In this step of the process over the prior art.

JUDGE LEBOVITZ: Oh, okay.

JUDGE DELMENDO: Okay.

MR. SAMADPOUR: So, we have, let's say for example, example here is five different distinct lots, could be spinach, could be beef, could be anything. We are taking our 60 samples, and we are aggregating them in one bag. Okay? Then we are enriching them individually, pooling the enrichments, and testing. If it's positive -- if

it's negative, the result is applicable to all five. We say that these five are negative, we will release them into chain of commerce.

If it's positive, we instantly have the enrichments, and this is not resampling, this is just the homogenous enrichment here. You go there, you take a sample and you test it. And we determine which ones are positive or which ones are negative. Positives are going to be -- go, you know, destroyed, negatives will be released into chain of commerce.

JUDGE DELMENDO: So, at this point, does it differ from the prior art?

MR. SAMADPOUR: That you have five different lots that are now getting pooled into one.

JUDGE LEBOVITZ: Well, wait a minute now, you're calling a lot here a bin, or a lot could be equivalent to a bin, correct?

MR. SAMADPOUR: Yes.

JUDGE LEBOVITZ: But the prior art, and I'm not talking about Jarvis or Price, I'm talking about BAM or FSIS, they were talking about a lot being five bins.

MR. SAMADPOUR: Correct.

JUDGE LEBOVITZ: So, and they were talking about sampling individually from the bins, which is sort of what you show here, in step one. So, that looks very similar.

MR. SAMADPOUR: And as I said --

JUDGE LEBOVITZ: Although they were taking 12 samples, not 60 samples.

MR. SAMADPOUR: In their mind, having five of these combos, taking 12 samples from each combo and combining them --

JUDGE LEBOVITZ: And aggregating them --

MR. SAMADPOUR: -- with 60 from this lot of five, okay?

JUDGE LEBOVITZ: Right. How does that differ from your invention?

MR. SAMADPOUR: We went from N60 from a lot of five, to N60 from each one of these lots of one.

JUDGE LEBOVITZ: Okay, but the claim doesn't require any particular number, right?

MR. SAMADPOUR: Statistically significant.

JUDGE LEBOVITZ: It's a statistically based standpoint.

MR. SAMADPOUR: Which the standard right now for rulings stands at 60 for the beef industry. So, whatever that statistical number is, it's now applying it to a broader number of -- let's say you had five combos in this example, you have let's say your N is 100, you would go and take 20 from each, you would put them in one bag, you would test it, there was no going back. Once you defined your lot, you cannot divide your lot into smaller portions. That's illegal. Okay?

JUDGE DELMENDO: So, you seem to be saying that there's a distinction there between your invention and the prior art, but I still, along Judge Lebovitz's question, I don't see a distinction.

MR. SAMADPOUR: The distinction is that the pooling methodology --

JUDGE DELMENDO: Yes.

MR. SAMADPOUR: -- that was used in Price, and in Silliker, was only applied to a single lot of product.

JUDGE DELMENDO: But --

MR. SAMADPOUR: Sixty or 30 samples taken from the production day, tested for salmonella. Once you have positive, any positive, that lot is destroyed. It doesn't matter whether one component was positive or 60 out of 60.

So, in Price, there was no remedy to go back and be able to release your product. We actually, we looked at about almost 63,000 lots of products, and we showed that, and it is very controversial, that by doing more sampling, by doing more testing, by increasing the lab costs, we saved the industry tons of money because less product was being destroyed --

JUDGE LEBOVITZ: Okay, that part we understand, but Silliker, for example, talks about 12, taking 12 samples individually, okay? So, what you seem to be saying is that the prior art taught aggregating all of them at once, so therefore you didn't have separate

identity going back to the different combo bins, right? But I think if you -- yeah, go ahead, then.

MR. SAMADPOUR: There's a distinction. Once you define your lot, you are stuck. You can define your lot as being one combo bin, if you want to stick with that example.

JUDGE LEBOVITZ: Yeah.

MR. SAMADPOUR: You can define your lot as 500 combo bins.

JUDGE LEBOVITZ: Yeah.

MR. SAMADPOUR: This goes to one of the articulations of why this was not an obvious thing to do.

JUDGE LEBOVITZ: Yeah.

MR. SAMADPOUR: The primary assumption in the food industry has been, an all statistical model that you have random distribution of the contaminants in the food.

JUDGE LEBOVITZ: That's why you sample.

MR. SAMADPOUR: It is a random distribution, then the size of the lot does make take a difference. Therefore, if that was true, we would not have been able to save any money, but going to larger number of lots and developing this methodology to trace them and be able to release them. If it was random -- we actually showed that it's not random, it's heterogenous, and before we showed that, it's because it's heterogenous, we can go to now if you have five and you are testing them together and you have a positive, this positive comes

from either one of the combos, two combos, three combos, four or five.

JUDGE LEBOVITZ: We don't know.

MR. SAMADPOUR: We show that in very small cases it's coming from five cases. In a set of 271 positives, this is part of the record, table 1 in the patent actually.

JUDGE LEBOVITZ: Yeah, I'm familiar with that.

MR. SAMADPOUR: Yeah. So, 271 positives, and we showed that 180 of those cases, it wasn't 10,000-pound bin contaminated, it was only 2,000 pounds.

JUDGE LEBOVITZ: It was only a particular bin?

MR. SAMADPOUR: Particular, yes.

JUDGE LEBOVITZ: And the bins were, I think, 2,000 pounds?

MR. SAMADPOUR: 2,000 pounds, exactly. So, by having this, we suddenly -- because no one in the food industry has any interest in taking more samples, doing more testing, because they think it's going to result into destruction of more products.

JUDGE LEBOVITZ: But -- okay, but what it sounds like you're saying is that the industry was aggregating bins together, so they could not go back to the -- so they -- so they were aggregating the bins together, so they did not go back to the individual bins when there was a positive. If they got a positive or a negative, it was throw

all of the bins out, because there's no separate identity here. Is that what you're saying?

MR. SAMADPOUR: Exactly. We just had the case, Peanut Corporation of America. These guys defined five days of production as being a lot. They would take a sample, and if that sample was positive, then they would say, oh, wait a minute, I am now going to test every day of production. And they were -- there was a criminal trial, and they were found guilty, and there's going to be sentencing later. Once you define your lot, you may not go back and resample, you may not divide it into sublots once it tests positive.

JUDGE LEBOVITZ: Who says that?

MR. SAMADPOUR: FDA and USDA.

JUDGE DELMENDO: So --

MR. SAMADPOUR: And there's case law now, it's Peanut Corporation of America.

JUDGE LEBOVITZ: Okay.

JUDGE DELMENDO: So, is it your discovery, then, to define the lots as small as possible, that that would be unobvious and surprising to one of skill in the art, at the outset, so as to avoid criminal prosecution?

MR. SAMADPOUR: Actually, we showed that by doing more testing, meaning having more lots, by making it smaller, okay, we -- taking more samples, doing more testing, we are actually saving money for the industry, and they just this mentality didn't exist,

because the assumption was homogenous distribution, and in homogenous distribution, it doesn't make a damn difference. If your 5,000, if your five combos tested positive, you tested the combos individually, each one would have tested positive.

JUDGE DELMENDO: But isn't there a trade-off in terms of cost of testing? You know, the more frequent testing for each batch or lot versus, you know, throwing away the tainted production? I mean, there seems to be -- it seems to me that one of skill in the art would be able to determine, you know, what is the trade-off.

MR. SAMADPOUR: Actually, no one was going there, because when you believe in homogenous distribution of the contaminants, then there is no need to go any further than having a production day, define it as a lot, take a few samples and say, we are good. It's after showing that this is not true, then we managed to convince many, many members of the food industry now to define their lots much smaller, they are doing much more -- we have one client that does 700 samples a day, each one a composite of 60, and -- and before, nothing.

JUDGE LEBOVITZ: Okay. Can I ask another question? Let me just shift gears for a little bit that there was another argument that was made, okay, and the other argument had to do with pooling the enriched samples, so this modular composite sample, okay? Now, the examiner seemed to be equating that with the step in Price where

you would pool the individual samples to get the individual pre-enriched samples together, and then test that pool. Do you understand?

MR. SAMADPOUR: Yes.

JUDGE LEBOVITZ: That's, I think, that would correspond to (d) and (e) of the claims, steps (d) and (e) of the claim. Can you address that?

MR. SAMADPOUR: Yes, I tried to address that in the deck that you have, in 5A. So, pre-enrichment and enrichment is terms of art. No microbiologist is going to tell you that pre-enrichment equates to enrichment.

JUDGE LEBOVITZ: Yes. Okay, the problem with that is, I understand those are terms of prior art, but the claim, here's my problem, and this is also --

MR. SAMADPOUR: Sure.

JUDGE LEBOVITZ: The claim says, in step (c), it doesn't say we're doing enrichment or pre-enrichment, it does say to create enriched samples, but then you get to claim 4, which depends on claim 1, where it talks about the enrichment medium. If claim 1 had enrichment medium in there, it would be 100 percent clear to me that you're talking about enrichment and not pre-enrichment.

MR. SAMADPOUR: Um-hmm.

JUDGE LEBOVITZ: But is your position that because step (c) says to provide a set of separate test samples enriched, that you're talking -- that must be talking about enrichment there?

MR. SAMADPOUR: Exactly. It's a one-step enrichment process, yes.

JUDGE LEBOVITZ: Because that's where the examiner disagreed.

MR. SAMADPOUR: Yeah. And we also have it in the patent description.

JUDGE LEBOVITZ: Requester, we will ask him that question, whether he disagreed.

MR. SAMADPOUR: Yes. And there's the issue of detectability that the examiner argued that Jarvis actually has a table and says that pre-enrichment turns out to be, you know, in 24 hours, we will give you ten to the eight cells.

JUDGE LEBOVITZ: Right.

MR. SAMADPOUR: And argues that Jarvis' pre-enrichment would overcome something of the claim.

JUDGE LEBOVITZ: Because you said you could use detection with PCR -- go ahead, sorry.

MR. SAMADPOUR: The reason -- I apologize.

JUDGE LEBOVITZ: No, go ahead.

MR. SAMADPOUR: The reason is that Jarvis is not a microbiologist, Jarvis is a mathematician. Mathematicians make

models, and if you go to that section of Jarvis' reference, okay, the one that has the table, okay, and that shows the ten to the eight, he says that if we assume a like phase of five hours and doubling time of 30 minutes, then this is what we get in 24 hours. Nothing is wrong with that, it's just a mathematical model, it doesn't work.

In the food sample that we receive in our labs, we have to be able to detect a pathogen with one pathogen in the 375-gram sample against the background of up to 100 million competitive organisms per gram. Once you put that in this pre-enrichment or enrichment situation, they do not behave as a mathematical model. So, that is a fictional thing that Jarvis just built to be able to have some numbers. It is not enabling, it is not telling you what pre-enrichment media you should use, this is a composition, which is where you buy it, none of that is there, and it's just purely what it states, a mathematical model. Jarvis goes on to say on page 141, first paragraph, he is defining what pre-enrichment is. It says, "The role of pre-enrichment is to allow the microbes to" -- okay, there are two types of pre-enrichment. The one that allows for growth to grow to a level, that's when you take one ML, when you take a portion, and you put that into an enrichment, that portion has at least one viable cell.

JUDGE LEBOVITZ: Did you --

MR. SAMADPOUR: And then he goes on to say that if the pre-enrichment is only for resuscitation, and does not allow for

multiplication, then the entire pre-enrichment has to be added to the enrichment medium, to ensure that you have at least one viable cell.

JUDGE LEBOVITZ: Did you address that in your declaration?

MR. SAMADPOUR: We have.

JUDGE LEBOVITZ: It was in one of your declarations, Dr. Samadpour?

MR. SAMADPOUR: Yes. Incessantly we have addressed these issues.

JUDGE DELMENDO: So, is it your position, then, that step (c) excludes pre-incubation step, or what is it, pre-enrichment?

MR. SAMADPOUR: Exactly, it does not include a pre-enrichment.

JUDGE DELMENDO: How so?

MR. SAMADPOUR: Because it says enrichment, enriched to a level, that's what we mean.

JUDGE DELMENDO: Okay.

MR. SAMADPOUR: Otherwise we would have said pre-enriched and enriched.

JUDGE DELMENDO: But the client -- the method recites comprising, which would not preclude a pre-enrichment step.

MR. SAMADPOUR: At that point then you have to have detectability, which you do not have, in Price, or in Silliker, because if they had detectability, they would not have added another

24 hours, and another media, enrichment media, to get to detectability to detect.

JUDGE DELMENDO: Okay.

MR. SAMADPOUR: Did that answer the question, sir?

JUDGE DELMENDO: It does, but I don't see how this claim would preclude pre-enrichment. You know, from a legal standpoint.

MR. SAMADPOUR: This claim precludes pre-enrichment, or compositing at -- pooling at pre-enrichment level by putting a limitation of detectability.

JUDGE LEBOVITZ: One more question I have, okay, and that relates to step (e), step (d) and (e), removing portions of each enriched test sample to form this composite -- interlocked composite and testing it. Where did the examiner say that step (d) and (e) were taught in the prior art? Do you recall?

MR. SAMADPOUR: They said that Price, by doing the pooling, at pre-enrichment, overcomes that.

JUDGE LEBOVITZ: Okay.

MR. SAMADPOUR: Because an argument was made that Price was actually pooling multiple lots into the same lot.

JUDGE LEBOVITZ: Okay.

MR. SAMADPOUR: Relying on figure 1 in Price, and I have an argument against that, which is -- should I go to that?

JUDGE ROBERTSON: Well, we are getting kind of short on time, so, you know, we've asked some questions.

MR. SAMADPOUR: These are good questions, I was going to cover them, so by all means, I can just go over that.

JUDGE LEBOVITZ: I think it was in the brief, but just quickly.

MR. SAMADPOUR: It was in the brief, also. So, Price presents his results in two tables. Price has three different types of commodities, dry milk, dried egg albumen, and cocoa. He is treating each one of them as being one lot. He's taking samples from each. He is -- so, he has so many samples from cocoa powder.

JUDGE LEBOVITZ: Right.

MR. SAMADPOUR: Correct. He pre-enriched those samples individually, pools them and he tests them. He never combines cocoa with egg albumen or with milk. This came from three different continents. No one does these things like this, okay?

JUDGE LEBOVITZ: I understand that.

MR. SAMADPOUR: This was within the lot, this was not within the lot, this was at the pre-enrichment level, and he had to go to another 24 hours of enrichment to get detectability.

Another erroneous argument has been made, but first let me complete that. The results in table 1 and table 2, in Price, clearly depict that these are different.

JUDGE LEBOVITZ: We understand that argument, right.

MR. SAMADPOUR: The argument that figure 1 shows anything different is erroneous, because any scientist can tell you that when we want to have an illustration, there is an art person that comes and listens to you and puts this abstract presentation of your materials and methods. The figure never overrides the text. The text is very clear, there was no pooling of anything within those, and even when we go --

JUDGE LEBOVITZ: We understand that argument, that was explained in the pre -- that this idea of pooling A plus B plus C and -- was not in the text.

MR. SAMADPOUR: Okay.

JUDGE LEBOVITZ: So, I don't think I have any further questions.

JUDGE ROBERTSON: Okay. We are sort of out of time. So, thank you very much, and now we will hear from Requester.

JUDGE LEBOVITZ: Thank you, Dr. Samadpour.

MR. SAMADPOUR: Thank you.

MR. FIGG: Good morning, Your Honors, thank you for your attention.

Referring to the first slide, it's very much like the first slide that Dr. Samadpour used to describe the invention, and I don't

think I need to go over this in any great detail, but I would like to emphasize the points that we think -- we think are important here.

The first -- this method defined by the claims involves two compositing steps. The first compositing step is in steps (a) and (b) and it's what's illustrated at the top of this figure. So, you've got something that's called a lot of material, and that then you can take multiple samples or portions from that such that what you end up with is representative of that lot. And that then is the first compositing step where you take those multiple portions, put them together, and the goal there is to have a statistically significant representative sample.

We heard Dr. Samadpour admit that that part and step (c) are in the prior art, and, indeed, they are, and the examiner cited references like the Midura reference, like the FSIS protocol, like the BAM reference, Silliker, Gabis, there were a number of references, all of which tell you that you have to have a representative sample. That's sort of common sense.

JUDGE DELMENDO: But what I heard the professor --

MR. FIGG: I'm sorry, Your Honor?

JUDGE DELMENDO: What I heard the professor to be saying, however, is that in the prior art, they weren't taking a sufficient number of samples so as to -- so as to meet the requirements for each -- what do you call -- each container.

MR. FIGG: I'm sorry, my hearing isn't the best, Your Honor.

JUDGE DELMENDO: I believe that what he was saying was that in the prior art, they were only taking samples of, say, 12, when 60 was required to meet the statistically significant number, and his belief is that by taking more tests, you're able to actually -- that was counterintuitive to what the prior art was teaching.

MR. FIGG: I'm sorry.

JUDGE DELMENDO: And you would be able to save more in the long run is his position, I believe.

MR. FIGG: I think there are actually two separate issues there.

JUDGE DELMENDO: Okay.

MR. FIGG: I think what the argument being made is that when you follow his overall process, not just the steps here at the top, but the overall process, you are able to make your test lots smaller, conduct more tests on this composite, and reject fewer lots. That may be true, that may be a result of this, it is not something that is in the claims. That ability to divide up what previously may have been considered a test lot into smaller lots, that's not in the claim.

What I was talking about here is this first step, how do you get a statistically representative sample from a batch of material? And there are numerous references that tell you how to do that. It is absolutely essential for testing that what you test is representative, and Dr. Samadpour admitted that was in the prior art, and it is in the prior

art, but that's the reason the examiner cited references like Midura and BAM and so forth, to show that that first step is in the prior art.

And as indicated here in step (c) of the claim, the next step is to place this composite that you have created in a nutrient medium and incubate it to increase the level of microorganisms that are in that sample.

And that was discussed also in the prior art, in the FSIS reference, in the Andrews reference, Silliker, Gabis, the BAM reference.

JUDGE LEBOVITZ: Do you -- the claim -- step (c).

MR. FIGG: Yes.

JUDGE LEBOVITZ: Is that a pre-enrichment step, or enrichment? What's your -- how do you come out on that issue?

MR. FIGG: As Your Honor pointed out in your earlier question, the claim doesn't distinguish between those two, all the claim says is that you inoculate to have a detectable level of microorganisms.

JUDGE LEBOVITZ: But it does say to produce an enriched sample.

MR. FIGG: Yes, but enriched sample, I think, is defined as meaning a sample in which the microorganisms are detectable, and that was -- that certainly is the way the examiner understood the claim, and concluded that the pre-enrichments that are discussed in Price and other references accomplish that.

Now, keep in mind, the claims -- the broad claims do not specify any particular means of detection. The old methods of detection were streaking on plates and observing this -- the colonies under a microscope, but newer methods, the so-called rapid methods, PCR and ELISA and so forth are extremely sensitive tests.

There really is no evidence in this record to rebut the examiner's conclusion that that pre-enrichment in Price leads to detectable levels of microorganisms, but in addition, I wanted to point out that on page 682 of Price, in the first column, it's the sentence that is just before the section that begins, Effect of Volume. It says, "Alternatively, problems with interfering organisms may warrant the use of direct selective enrichments."

So, Price does have the option there of using enrichment as opposed to pre-enrichment, but the examiner concluded pre-enrichment was -- was sufficient. The -- so, once we get to the -- these -- the step (c), what was called test lot samples, then --

JUDGE LEBOVITZ: Yeah, where do you get step (d)?

MR. FIGG: Pardon me?

JUDGE LEBOVITZ: Step (d), is that where you're going now?

MR. FIGG: That's where I'm going now.

JUDGE LEBOVITZ: Good. Sorry.

MR. FIGG: So, once we have those, then aliquots of each of them are combined into a single medium, which the patent

claim refers to as a modular composite sample. That modular composite sample is then tested, it either is positive, it has microorganisms in it, or it's negative. If it's negative, you have validated all of the lots that went into it. If it's positive, what the patent says you can do is go back and retest those individual test lot samples and figure out which ones contributed to the positive result, and you can discard them and salvage the others.

Now, if we go to the next slide, I wanted to talk about the Price reference first. Because all of these steps that I just described are in the prior art, and I would like to --

JUDGE LEBOVITZ: Except you haven't told us where (d) is.

MR. FIGG: I'm sorry?

JUDGE LEBOVITZ: You haven't told us where (d) is.

MR. FIGG: That's what I'm going to do right now. Thank you, Your Honor.

If we go to the second slide, I wanted to sort of start with how Price introduces his methodology, and this second slide is an excerpt from the opening paragraph of the Price reference. The first thing that he reserves is that positive results are relatively rare, and I guess we're all happy about that, most food products don't have microorganisms in them. And he says, "Therefore, a test procedure that gives a single negative answer for many negative samples offers an important saving in the analytical effort."

So, that's how he starts -- sets this -- the stage for his methods, which we submit is the same as the claimed method. And if we go to claim 3, this is the figure that Price uses to illustrate his method. And Price has these three samples at the top, he takes representative portions of them, puts them in pre-enrichment cultures and then makes a composite, wet composite, in the enrichment cultures, and then detects.

So, let's go to the next slide, and we compare this Price method to the claim. So, the claim method as illustrated by the Patent Owner's drawing is on the left, and Price is on the right. And you can see that what the Patent Owner illustrates the invention in this drawing with bins of beef trimmings, presumably. But the claims are not limited to that, obviously.

Price illustrates his method with dried powdered products like powdered milk and powdered cocoa and so forth. So, Price takes representative samples from each of those three and he puts them in these pre-enrichment broths. That corresponds -- the taking of the samples corresponds to steps (a) and (b) of the claim, putting them in the broths compares to claim (c).

Now he takes aliquots from each of those pre-enrichments and makes what the patent calls a modular composite sample. In this case, he used two, because he used selective enrichment media for salmonella, but each one of them is a composite sample.

JUDGE LEBOVITZ: That's the enrichment? The enrichment?

MR. FIGG: Yeah. Each one of them, though --

JUDGE LEBOVITZ: So, your position is that step (d) does not exclude enrichment?

MR. FIGG: That's right.

JUDGE LEBOVITZ: And that's what the examiner apparently said.

MR. FIGG: That's correct. It certainly doesn't exclude it in the claim, all the claim requires is detectable levels, and the examiner found that there were detectable levels, and as I mentioned, Price also tells you, you can go to direct enrichment if you choose to, to avoid the problem of competing organisms. So, Price gets you there.

Now, in the illustration of the Patent Owner's method, it doesn't tell you what was used for detection, it just says then you detect and you get an answer, it's either positive or negative. In the Price illustration, he shows you that detection is by selective plating, biochemical testing and serological testing. So, he goes into a little more detail, but the claims aren't limited to how you test, or most of them are not.

But both the Patent Owner and Price tell you you have two possibilities there, a negative result, and if you have a negative result, you now have validated all samples. In the case of the Patent

Owner, the five samples illustrated; in the case of Price, the three. But if you get a positive result, both the Patent Owner's method and the Price method says, now you can go back and look at the individual retained samples.

JUDGE LEBOVITZ: Okay.

MR. FIGG: And you can determine which of those three, in the case of Price, was responsible for the positive result.

JUDGE LEBOVITZ: Well, one thing, in -- excuse me, you show steps (a) and (b) as a first step of Price.

MR. FIGG: Yes.

JUDGE LEBOVITZ: But that doesn't show any compositing.

MR. FIGG: Yeah. Well, let me --

JUDGE LEBOVITZ: I mean, you've drawn it like it's a 102.

MR. FIGG: Yeah.

JUDGE LEBOVITZ: But I don't see compositing in step (a) and (b).

MR. FIGG: Well, I didn't draw this, Price drew this, so I'm working with what -- how Price illustrated his method, but this is -- basically I did want to address, in their briefs, the Patent Owner made three arguments about Price, and the one Your Honor just mentioned is the first one.

JUDGE LEBOVITZ: Right.

MR. FIGG: They said that Price does not describe the first what we call dry compositing steps.

JUDGE LEBOVITZ: Right.

MR. FIGG: There are two -- two or three answers to that. First of all, these are powdered products. So, powdered products are not like a 2,000-pound bin of beef trimmings, these are things that you can mix up and make homogenous and take a sample out, and that sample, the claim says multiple portions.

Well, that samples -- those samples of powdered material have multiple portions, meaning the different particles that you now have combined to make homogenous, but even if that were not the case, that's the reason the examiner cited references like FSIS and Midura, because those references tell you that if you have a material, a batch of material, you take multiple samples and you apply statistics so that you can get -- what you get is representative. That's what I was talking about earlier.

So, regardless of what Price tells you, the examiner used a combination of references here. And he said that's in the prior art. And we heard Dr. Samadpour candidly agree this morning that that part is in the prior art. So, that's not a distinction.

The second point that the Patent Owner makes, and I don't know if we heard this this morning or not, but the second point that the Patent Owner makes is that the Price reference actually teaches away from making a modular composite sample from separate

test lots. And what they refer to in making that argument is the article -- is a sentence on page 681 in the first column in the second full paragraph of Price, where it says, "If on the other hand the samples are individually pre-enriched, the actively growing salmonella might be expected to compete more favorably with organisms introduced from other samples when pooled at the enrichment stage. In addition, pooling pre-enrichment broths avoids the hazard and inconvenience of handling a very large flask."

I have struggled to try to figure out how that teaches away, because all Price is saying there is what his method is. He's saying, don't pool these three samples at this stage, at the top stage, put them individually in these first set of media, which is what he does, but pool them at the second composite step.

JUDGE LEBOVITZ: In the enrichment step?

MR. FIGG: Yeah, and that's what he does. So, I don't think this teaches away, in fact, what I think it does is it simply explains one of the rationales for price to have done this the way he did it.

Now, the argument that is I think the primary argument that the Patent Owner has made is that in Price, the samples come from the same "lot" as that's defined in the patent. And this is really, I think, the centerpiece of their case, and there are a number of reasons that that simply cannot be true.

First of all, I think he we need go back to the patent, because the -- the '584 patent, because the term "lot" is defined in that patent in a very general way, and it's basically saying a lot can be anything where the material has some commonality, proximity, time, process step, et cetera. And we heard this morning from Dr. Samadpour that what previously segments of the industry regarded as a lot, they can divide that up and it can be several lots.

So, this is a very arbitrary definition, what is a lot? Why should we say that Price's three samples are not lots, but dividing up peanut butter into multiple samples, you consider those lots.

JUDGE LEBOVITZ: The only issue I have is when you were talking about page 681 of Price?

MR. FIGG: Yes. Yes.

JUDGE LEBOVITZ: The claim requires aggregating -- under the examiner's interpretation, you aggregate a composite sample and then do a pre-enrichment step, but Price is saying, you don't aggregate samples and do a pre-enrichment step, because -- and he gives reasons why you don't want to do that.

So, to the extent that you say that it doesn't matter, I'm not quite -- I don't see that.

MR. FIGG: Well, I don't think that's what Price is saying, with respect, Your Honor.

JUDGE LEBOVITZ: Well --

MR. FIGG: What Price is saying is you don't put all three of these in the same pre-enrichment medium, you put them in separate media.

JUDGE LEBOVITZ: Yeah, but he's referring to a sample as a sample, he's not referring to the sample as a number of representative samples which have been aggregated together, it's pretty much vague, even what he means here by sample.

MR. FIGG: It's because Price is using as his illustrated method these powdered materials. So, he didn't have to go in like a bin of beef and take different samples from different -- or different portions from different locations in that bin to be sure he had a representative sample, but FSIS tells you that that's how you do it.

So, the examiner was, I think, absolutely correct, but these are representative samples even in Price, because they're powdered materials, but you could apply this to anything and you would follow the prior art teaching on how you get a representative sample, and that includes taking multiple portions.

JUDGE LEBOVITZ: Understood, thank you.

MR. FIGG: So, the -- let's look at this argument that you have to assume that these three samples came from the same lot. Price certainly doesn't say that.

JUDGE DELMENDO: I'm sorry, I want to go back to something you just said.

MR. FIGG: I'm sorry, Your Honor, can you speak up just a little bit?

JUDGE DELMENDO: In the Price method, would each of those bins, following the prior art, would they be statistically based sampling plan as required in step (a)?

MR. FIGG: Yes, that's precisely what Midura is all about, that's what FSIS is all about, that your test isn't of much value if what you're testing is not representative of the entire batch of material that you start with.

So, that's the whole point of Midura, how do you develop a sampling plan that gives you a representative sample that you can test and where that result will be representative of that entire batch of material. So, I think that was exactly the point the examiner was making and I think the examiner was correct about that.

So, the reason I started with the opening paragraph of Price is Price tells us why he is proposing doing this the way he describes, and it is to save the analytical effort, and having one negative result take the place of many. And if these were all from the same lot, then a negative result -- I mean, excuse me, a positive result would mean that that lot has to be discarded, or reprocessed or something, but you can't release it.

And we heard Dr. Samadpour say that here today, and the Patent Owner actually said that in their opening brief at page 26, that once you have a positive result for a lot, that lot is gone. You've

lost it. So, why would Price then say if you get a positive result you go back and look at the retained samples? That simply would make no sense. And Price says what you're trying to do is reduce workload. Well, if you had to -- if you had a positive result and you followed Price's method and you go back and retest the retained samples, that retesting is not going to do anything for you, because you have to reject that lot. If these all came from the same lot, you have to reject it.

So, you're now doing retesting that's going to increase your workload, it's not going to decrease it.

JUDGE LEBOVITZ: Well, I had made a comment about that at the beginning, Price doesn't really give you much information what he means about samples here, so the examiner went to BAM and the FSIS reference and Midura.

MR. FIGG: Midura, yeah. I'm sorry, were you done?

JUDGE ROBERTSON: Proceed.

MR. FIGG: I thought you were in the middle of your question.

JUDGE LEBOVITZ: No, I'm done.

MR. FIGG: You're exactly right. I would submit, Your Honor, that the definition of lot in the patent is very vague and general and it can be -- it's arbitrary. It can be whatever the analyst decides to call it. It might be 2,000 pounds of beef or it might be 500 pounds of

beef or it might be a week's production run of peanut butter or it might be one day's run. It's however they divide it up.

So, Price is no more arbitrary or general in that way than the patent is. It's just what you call it. And the whole point of Price is, here is a method where one negative result takes the place of several negative results, several tests. That saves work. That saves money. And but Price also says, just as the patent does, that if you get a positive result, we've got these retained samples from up here, so we can go back now and look at each sample individually, and if two of them were negative and one was positive, we've saved those two that were negative. We can release them. That's precisely what the patent says.

JUDGE DELMENDO: So, you're saying although it doesn't explicitly say that, you could infer it based on Price telling you to go back to the retaining samples? Is that your position?

MR. FIGG: I think it's explicit, Your Honor. I think that's why he's telling you to do that, to save time. And to be able to salvage those individual samples, or lots, that tested -- that would test negative.

Now, the other reference that the examiner relied on is Jarvis, and if we go to -- I won't spend a lot of time on this, but I think the point is, the examiner was correct in treating Jarvis and Price more or less as equivalent teachings. They both teach this wet compositing method, and using a single test to take the place of numerous tests.

And as Dr. Samadpour pointed out, Jarvis is a statistical teaching, it's teaching you how -- how do you get a result in which you have statistical confidence? And what Jarvis said was that when you do this compositing step, this step that creates what the patent calls a modular composite sample, you have the same level of statistical confidence in the result that you would have as if you had tested each sample separately. And that's an important point.

If we turn to slide 6, the critical part of the Jarvis reference is section 8.4, and section 8.4 of Jarvis is talking about how you test samples and analyze the results to get statistically significant results. And the title of 8.4 says, "Present or absent tests based on single or multiple samples," and in the opening sentence he says, "It's normal to inoculate one or more samples into a suitable selective or enrichment medium."

And then in the table in 8.4, table 8.4 in that section, which the examiner relied on, the examiner pointed out that what is described there is the testing of three separate lots, lots A, B and C. That testing, what is described on pages 135 and 136 of Jarvis, is how you do the testing of a separate lot, a separate sample. And remember, he started out by saying, testing single or multiple samples.

So, he describes how he tests single samples, and in 8.4, he gives the results of parallel testing of single samples. The examiner referred to that simply to show that Jarvis is talking about multiple lots. But then we get to section 8.4.2.1, and there, Jarvis

has -- is addressing an alternative to the separate testing of single lots. He's saying, we can composite, and by compositing, he says, we do that in order to reduce workload.

JUDGE LEBOVITZ: And that's just redundant to what Price tells you, so I think we understand that.

MR. FIGG: Well, I think the examiner has treated them as more or less the same teachings. And method 2 there is the wet compositing step of the claim, and at the bottom of the page there, on slide number 7, Jarvis tells us that by doing this, that if you get a positive result, you can go back and test the retained samples.

So, everything that's in the claim is there. I think I'm out of time.

JUDGE ROBERTSON: Yes, you are.

MR. FIGG: If you had any more questions.

(No response.)

JUDGE ROBERTSON: Patent Owner, you have a few minutes for rebuttal, I just want to emphasize that this time is to be used to respond to Requester's arguments and not to present a new argument.

MR. DAVISON: Thank you, Your Honor.

MR. SAMADPOUR: Thank you. So, one of the issues that was raised was what was the -- if Price wasn't doing multiple lots, then it didn't make sense. So I want to address that one. Price was not doing multiple lots. The reason Price has, you can go to the

pre-enrichment tubes and test them, twofold. It is customary for food industry that when you tell them if a sample was positive, they come back and say, how positive is positive? What's the extent of contamination?

So, if you have 60 tubes of pre-enrichment, you test them and say 50 of the 60 was positive or one of the 60 was positive. So, one driver is to show the extent of the contamination. The second driver, page 682. Once he does his pooling, and then he puts them on the plate, so 682, the second paragraph, states that once you look at the plates, if this plate has a lot of background colonies, it could mask your positive result, you could have a false negative. The second driver is that once you are looking at your plate, you can always go back to the pre-enrichment and do them individually and reduce the amount of background. There is nowhere in Price that it allows for going back and sorting out what's been different lots.

Another issue that Mr. Figg brought is virtual samples. The difference between a sample and samples. You may not take any sample, and once that sample is taken, say that it's -- this is samples. Not for dried products, not for liquid, not for anything.

For dried products, the protocol, you go to 60 different places, and each time grab a 25-gram sample. This is known in the art, no one would equate a 25-gram single sample to become composed of billions of particles, therefore I have anything close to a

billion. That's ridiculous. This is just one of those Lewis Black moments.

But the other issue to go to, samples versus samples. So, they are using figure 1, and saying that it has three different samples, therefore there are three different lots. So, I explained that, no, this is an abstract depiction of the materials and methods. These samples are all from the same batch of product, it's just depicting how this protocol is working.

They touched upon enrichment versus pre-enrichment, the same argument, we have a limitation to detection. If Price was at detection level, did not require a pre-enrichment -- enrichment, following enrichment protocol, of adding media, adding 24 hours more to the test. There is no evidence that Price at the pre-enrichment level was detectable at any point.

Jarvis. Jarvis is a statistical modeler. The examiner, Ryan Leach, adopted the view that table 8.8 is actually showing you statistical sampling. This is an MPN table. The most probable number method is a quantification method in which you get one sample, the sample is taken, you send it to a lab and you say, how many organisms do I have in this sample? They take three 100-gram portions, three 10-gram portions, three one-gram portions, they inoculate the media --

JUDGE LEBOVITZ: So, you're saying the MPN is the end testing, not obtaining representative samples.

MR. SAMADPOUR: End testing. There is no mixing of different lots.

JUDGE LEBOVITZ: Right, it's a different -- right.

MR. SAMADPOUR: And this idea that Jarvis is teaching multiple lots, testing is ridiculous. They're relying on this passage. Suppose that for a food product, okay, we have a limit of so many, and suppose that following results are obtained for three lots of products. You go to any food lab and say can you give me the results of testing of 10 different lots of products. These are lots of products that were sent to the lab, samples from different lots, sent to a lab, they were tested in a serial manner using the methodology, and the results are presented here. It's not teaching -- it's not going to overcome claim 1, because it's not teaching that you have five different lots, you apply statistical sampling to each one of these, you composite those, so on and so forth.

JUDGE ROBERTSON: Okay, I think you're about out of time. Judge Delmendo, any further questions?

JUDGE DELMENDO: No.

JUDGE ROBERTSON: Judge Lebovitz, any further questions?

JUDGE LEBOVITZ: No.

JUDGE ROBERTSON: Thank you all for coming in today, we will take the case under advisement and render a decision in due course. Thank you for participating.

MR. SAMADPOUR: Thank you.

MR. FIGG: Thank you, Your Honors.

(Whereupon, at 11:14 a.m., the hearing was adjourned.)

PATENT OWNER:

DAVIS WRIGHT TREMAINE, LLP/SEATTLE
IP DOCKETING DEPT.
DAVIS WRIGHT TREMAINE LLP
1201 THIRD AVENUE, SUITE 2200
SEATTLE, WA 98101-3045

THIRD PARTY REQUESTER:

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14TH ST., N.W.
SUITE 800
WASHINGTON, DC 20005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Mansour Samadpour
Control No.:	95/001,294
Confirmation No.:	1914
Filed:	05 April 2010
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Examiner:	Sharon Turner
Art Unit:	3991
Confirmation No.:	1914
Docket No.:	66090-008US2
Date:	20 February 2015

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

PATENT OWNER'S RESPONSE PURSUANT TO 37 C.F.R. § 41.77(b)(1) REQUESTING REOPENING OF PROSECUTION BEFORE THE EXAMINER

This Response Requesting Reopening of Prosecution is timely filed on 20 February 2015. No fee is deemed due under 37 C.F.R. § 41.20. If additional fees are necessary, Commissioner is authorized to charge any deficiency (or credit any overpayments) to Deposit Account No. 04-0258.

TABLE OF CONTENTS

AMENDMENTS TO THE CLAIMS ……..3

REMARKS…….....9

Patent Owner, pursuant to 37 C.F.R. § 41.77(b)(1), submits the following amendments to the claims:

1. (Thrice amended) A method of sampling, testing and validating a plurality of operationally-linked test lots of beef for release into commerce [[microbial contamination]], 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[[, according to a statistical sampling plan]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 lots [[samples]] are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots [[may nonetheless yet be]] are validated[[, according to the statistical sampling plan,]] 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).

2. (Amended) The method of claim 1, wherein each of the test lots is a single-unit production lot, comprised of operationally-linked product specimens.

3. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

4. (Original) 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. (Original) 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 microbial agent or organism.

6. (Original) 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. (Original) 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.

8. (Original) 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. (Original) 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. (Original) 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. (Original) The method of claim 1, wherein the number of separate test lots is from 3 to 10.

12. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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.

17. (Thrice amended) A method of sampling, testing and validating a plurality of operationally-linked test lots of meat or poultry for release into commerce [[microbial contamination]], 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[[, according to a statistical sampling plan for a particular microbial agent or organism,]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 [[may nonetheless yet be]] 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).

18. (Original) 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.

19. (Original) 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. (Original) 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. (Original) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

22. (Original) 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. (Original) 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.

24-25. (Cancelled)

26. (Original) The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.

27. (Original) The method of claim 2, wherein product specimens are synonymous with product portions.

28. (Original) The method of claim 4, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.

29. (Original) The method of claim 5 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

30. (Original) 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.

31. (Original) 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.

32. (Amended) The method of claim [[24]] 1, wherein the beef [[meat or poultry]] specimens are meat trim pieces [[or poultry trim pieces, respectively]].

33. (Amended) The method of claim [[24]] 17, wherein the meat is that of beef, pork, sheep or bison.

34-36. (Cancelled)

REMARKS

Claims 1-33 are pending re-examination, pursuant to 37 C.F.R. § 41.77(b)(1).

Claims 1, 17, 32, and 33 have been amended herein.

Claims 24 and 25 have been cancelled herein, without prejudice.

No new matter has been added.

Additional Declarations

Patent Owner attaches, for consideration by the Examiner, a further Declaration of Dr. Mansour Samadpour (EXHIBIT Z), which is incorporated by reference into this Response in its entirety in support of the rebuttal arguments presented herein.

The Declaration contains, *inter alia*, explanatory comments regarding the financial revenue data of record for marketed tests to further support and clarify the *nexus* between Patentee's patent claims and commercial success and the initial skepticism in the industry. The Declaration specifically addresses particular issues raised and discussed in the DECISION ON APPEAL (DOA).

Claim amendments and cancellations

Claim 1 has been amended to recite "test lots of beef" in place of "test lots" to clarify that the test lots are separate test lots of beef.

Explicit support for the Amendment is found in the originally filed specification, for example, at page 1, ll. 9 and 27; page 3, line 7; page 8, ll. 12 and 16; page 11, ll. 9 and 12; page 17, line 26; and page 18, ll. 3, 22, and 23.

Conforming amendments have been made to claim 32, which now directly depends from claim 1, instead of indirectly depending from claim 1 via claim 24, which is now cancelled.

Claim 17 has been amended to recite "test lots meat or poultry" in place of "test lots" to clarify that the test lots are separate test lots of meat or poultry.

Explicit support for the Amendment is found in the originally filed specification, for example, at page 19, ll. 24 and 27; page 20, ll. 9-10; page 1, ll. 9-10 and 27; page 3, line 7; page 8, ll. 12 and 16; page 11, ll. 9 and 12; page 17, line 26; and page 18, ll. 3, 22, and 23.

Claims 1 and 17 have additionally been amended to recite "operationally-linked" to clarify that the test lots, while separate, are nonetheless operationally-linked during a production run.

Explicit support for recitation of "operationally-linked" is found, for example, in original claims 2 and 3, and current claim 2; at page 8, ll. 3-10; page 11, ll. 21-26; page 14, ll. 4-13 and 21; page 15, ll. 13-14; and page 23, ll., 15-17 and 26-27.

No new matter has been added.

ARGUMENT SUMMARY

All art cited against this invention pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots, but not in the simultaneous fashion of Patent Owner's claims. The two references concerning "composite" (aggregated) samples contemplate that all samples come from the same food lot, where the sole motive for compositing is a desire to limit the number of samples to minimize testing costs. Nothing in the cited art motivates combination of samples from separate operationally-linked production lots within a production run of food within a single method. In fact the prior art at the time of filing contraindicated the claimed subject matter. No art, alone or in combination discloses or motivates performing the tasks of Patent Owner's independent claims 1 and 17; to simultaneously operate on a plurality of separate operationally-linked production lots within a production run, each to be validated for release into commerce, and involving creation of a modular composite sample from aliquots of separate enriched operationally-linked test lots each attributed to a particular corresponding separate operationally-linked test lot within a production run, and where each separate test lot is separately sampled from the respective plurality of separate test lots according to a statistical sampling plan, and **not** with a single-portion per pre-enrichment scheme as in Price or Jarvis (2).

NEW GROUNDS OF REJECTION

The Appeal Board in the DOA discussed and affirmed Rejections 1, 2, 10, 11, 13, and 14 (as numbered in the Appeal Brief), but interpreted Patent Owner's claims differently than the Examiner[1], and applied the prior art differently than did the Examiner. The rejections were

[1] "we interpret step c) of claim 1 to correspond to the prior art enrichment step aimed at growing the target organism in contrast to "pre-enrichment" which only resuscitates the target organism for subsequent growth in an enrichment media." (DOA at page 10, etc.)

modified by citing both Jarvis and Price, and Rejections 1, 2, and 13 were deemed to be similar and were combined. The new grounds of rejection were renumbered and are as follows:

1. Claims 1-4, 6-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (preAIA) as obvious in view of Jarvis, Price, FSIS, and Midura RAN 8, 22, 56;

2. Claims 5, 6, 23, 29, and 30 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Entis. RAN 50, 51, 53;

3. Claim 21 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Cousin. RAN 58, 60; and

4. Claims 24, 28, 32, and 33 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Gabis. RAN 62.

A. Ground 1 (REJECTION 1)

Appellant traverses the rejection of 1-4, 6-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (preAIA) as obvious in view of Jarvis, Price, FSIS, and Midura RAN 8, 22, 56.

For easier reference, the DOA numbered Applicant's claim 1 steps (a) – (e) as follows.

Step (a)

a1. "collecting a plurality of portions from each of a plurality of separate test lots"

a2. "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"

Step (b)

b1. "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"

Step (c)

c1. "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" or "enrichment"step

Step (d)

d1. "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample"

Step (e)

e1. "testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism"

e2. when testing is "negative," "all of said separate test lots are validated for release into commerce"

e3. when 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" of step (c)

e4. "obtaining a negative test result for each test lot"

a1. (plurality of samples/plurality of test lots) The DOA states that Jarvis teaches collecting a plurality of samples in method (2) on page 141, where separate pre-enrichment samples are prepared, and also describes a pre-enrichment step. The DOA states that Price also describes collecting a plurality of samples (Price at page 680; Figure 1). The DOA acknowledges (at page 13), however, that neither Jarvis nor Price describes collecting samples from more than one test lot as recited in Patent Owner's claims. The DOA, with respect to Jarvis Example 8.4 at page 136, stated that there is insufficient evidence that A, B, and C were used in the same method[2]. The DOA states (at page 14), however, that "collecting a plurality of portions from each of a plurality of separate test lots" would have been obvious based on FSIS and Midura.

Patent Owner points out, however, that such sampling in FSIS and Midura is done with respect to single lots that are each to be independently tested with separate assay applications. There is no teaching of the concept of jointly processing/assaying multiple lots in one application of an assay involving Patent Owner's unique modular composite sample.

a2. The DOA states (at page 15) that Jarvis teaches sampling of multiple tubes or from "test lots" (Jarvis at pages 136, 137). Patent Owner points out that this is incorrect as Jarvis at pages 136 and 137 only talks about taking a single sample from each of lots A, B, and C, and processing them independently using MPN methodology. The DOA, however, states that

[2] Patent Owner pointed out during Oral Arguments before the Appeal Board (see also Appeal Brief at page 12) that because of the nature/design of the MPN method (which involves a separate dilution matrix for each sample to be tested, with no mixing of any dilutions from different samples), it would be *impossible* that A, B, and C were used in the same method (see also Appeal Brief at page 12).

Midura teaches statistical sampling plans, and that the '584 patent teaches sample plans under the guidelines and directives from the USDA and FSIS.

b1. (combining/compositing) The DOA states (at page 16) that Jarvis describes compositing samples to reduce the number of samples tested. The DOA states that Price also teaches this concept (Price at page 679), and cites Silliker at page 475 ("Compositing of multiple subsamples (lumping) and wet compositing of pre-enrichment cultures have been tested as economical approaches to *Salmonella* control."). The DOA states that the purpose of Jarvis and Price was to determine whether pooling samples reduced the ability to detect contaminated food lots.

Patent Owner points out, however, that such sampling in Jarvis, Price, and Silliker is done with respect to single lots that are each to be independently tested with separate assay applications (no teaching of the concept of jointly processing/assaying multiple lots in one application of an assay involving Patent Owner's unique modular composite sample).

c1. (enrichment step) With respect to Patent Owner's step (c), the DOA states (at page 17) that there is a suggestion in Price (at page 682) and Gabis (at page 684) of direct enrichment.

Patent Owner points out, however, that both Gabis and Price would suggest to one of skill in the art that direct enrichment could ONLY be used in the context of non-lumped/non-composited single samples.

Specifically, Gabis (see Abstract at page 663) explicitly teaches that "in the analysis of 25g subsamples [unlumped] direct enrichment detected as many positive 'lots' as preenrichment, but in the analysis of lumped subsamples, direct enrichment gave dramatically reduced recovery," which is completely consistent with the data of Gabis Table 1, showing that lumping samples dramatically reduced detection in both direct selective enrichment protocols (i.e, the detection for the 108.3, 325, and 500g lumped samples in both the Tetrahtionate and the Slenite direct enrichment media was dramatically lower than in the corresponding unlumped 25g subsamples (13 of which 25g subsamples were independently tested); with the decrease in sensitivity increasing with increased lumping in going from 108.3, 325, and 500g lumped samples.

With respect to the DOA's comment (at pages 16-17, citing *In re ICON Health and Fitness Inc.,* 496 F.3d 1374, 1381 (Fed. Cir. 2007) that "there is a suggestion in Price (at page 682) and Gabis (at page 684) of direct enrichment. Even if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use "would render the result inoperable," Patent Owner points out (see also Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) that in fact, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols of Gabis) would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection methods inoperative in the food industry, which does not gamble with people's lives.

Patent Owner likewise points out that Price, in direct analogy to Gabis, would also suggest to one of skill in the art that direct enrichment could ONLY be used in the context of non-lumped/non-composited single samples. Price (page at page 682, ¶ 2) ***teaches away*** from the use of anything more than a single portion in each pre-enrichment:

> "*If many food samples are pooled at the pre-enrichment stage, the salmonellae face competition from the flora of all the samples in the pool. If, in the other hand, the samples are individually pre-enriched, the actively growing salmonella might be expected to compete more favorably with organisms introduced from other samples when pooled at the enrichment stage. In addition, pooling pre-enrichment broths avoids the hazards and inconvenience of handling very large flasks of culture.*"

(Note: Price uses the word "sample" to mean "portion," as defined in the '584 Patent.)

Since the problem being addressed by Price is to reduce the background of competing organisms, the statements by Price about the use of direct selective enrichments, two selective enrichments, or possibly even a reduction in the incubation time of the pre-enrichment cultures would be regarded by one of skill in the art, as being limited to the case of **non-lumped individual pre-enrichment cultures**, which would be expected to have fewer background/competitive organism problems; that is, one would not ***exacerbate*** the background problem by subjecting a *lumped* test sample to direct selective enrichments or two selective enrichments.

Again, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols) would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection methods inoperative in the food industry.

Patent Owner, therefore, contends that the DOA is in error on this this point.

d1. (forming a modular composite sample) With respect to Patent Owner's steps (d), the DOA acknowledges (at page 17, under discussion of step d1) that "[n]either Jarvis nor Price teaches combining samples after enrichment and testing them."

The DOA, however, *erroneously* states that that Jarvis does teach compositing both pre-enrichment and enrichment samples, while still attaining the "same degree of statistical confidence" (citing Jarvis method (3)). The DOA mistakenly interprets Jarvis method (3), which does NOT teach compositing enrichment samples. Jarvis method (3) is a combination of Jarvis methods (1) and (2). Jarvis method (1) is preparing 10 individual pre-enrichment cultures and testing each individually (no combining of either pre-enrichment cultures at all), and Jarvis method (2) is preparing 10 individual pre-enrichment cultures and then combining an equal volume of each to inoculate a 100ml enrichment broth (so this teaches combining pre-enrichment broths, but not combining enrichment cultures). In Jarvis method (3), which is a combination of Jarvis methods (1) and (2), 10 individual pre-enrichment cultures are prepared and then 5 of the individual pre-enrichment cultures are combined into a first combined pre-enrichment culture, and the other 5 of the individual pre-enrichment cultures are combined into a second combined pre-enrichment culture, then aliquots of the first and the second combined pre-enrichment cultures are combined at the point of inoculating the enrichment medium. Jarvis does not teach compositing enrichment cultures even with respect to samples taken from a single lot, much less separately taken from a plurality of separate test lots. The statistical significant comment about "same degree of accuracy" is with respect to combining pre-enrichment samples with respect to a single test lot, and does not teach, as mistakenly construed in the DOA, combining enrichment samples.

Patent Owner points out that a mere motivation to combine pre-enrichment samples to reduce workload does NOT make Patent Owner's step (d) (which requires removing portions of

each enriched separate test lot sample corresponding to the separate test lots, and combining the removed portions to provide a modular composite sample) obvious in view of the asserted art. Jarvis and Price deal with combining pre-enrichment samples derived from a single test lot, for the mere purpose of reducing the workload.

The DOA states (at page 18) that "[i]t is correct that the cited prior art, particularly Jarvis and Price, do not describe compositing samples from different enrichment samples, which themselves have been composited [from different separate test lots]. However, as indicated above, it would have been obvious to pool enriched samples together to reduce the number of tests that need be performed."

Patent Owner emphatically disagrees. First, as explicitly acknowledged in the DOA, pooling at the enrichment stage was not in the prior art. Second, even if it was, there is certainly no motivation in the art for compositing samples from different enrichment samples, which themselves have been composited [from different separate test lots]. In fact, there was a very strong counter motivation not to do this. Specifically, as discussed during Oral Hearing (see also Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) with respect to the explicit data of working Example 1 of Patent Owner's patent, prior to the present invention, and including for at least the last forty years there has been no such motivation because the food industry has widely assumed that contamination was, for purposes of production lot designation, uniform throughout a production run, which accordingly justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assay of any larger number of smaller separate operationally-linked production lots within a production run that might be formed[3]. Hence, prior to Patent Owner's invention, it has always been deemed sufficient to test one large lot (i.e., an entire production run), and thus no motivation to even form and define multiple separate operationally-linked production lots within a production run, **and thus no motivation to simultaneously/jointly test multiple separate operationally-linked**

[3] Obviously, if contamination is uniform, for purposes of lot designation, there would be no advantage to assaying multiple separate operationally-linked production lots within a production run in place of a lager production lot (the entire production run), because the positive detection results would be the same but would require a much larger number of samples, and in creased assay expense. By contrast, if contamination was non-uniform, Patent Owner hypothesized that some of the operationally-linked production lots within a production run would not be contaminated, while others would be.

production run lots within a production run. As discussed during Oral Hearing, Patent Owner hypothesized that the long-standing art assumption of contamination uniformity, for purposes of production lot designation, was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a production run, some of the operationally-linked production lots within the production run would not be contaminated, while others would be. Patent Owner's hypothesis and insight, therefore, was what provides the motivation (even for the Patent Owner) to pursue the presently claimed subject matter, which is entirely validated by the results of working Example 1 of Patent Owner's patent, and which, while engendering much initial skepticism, has led to rapid commercial success as amply evidenced in the record.

The originally filed specification of the '584 patent contained a working Example 1, which corroborated Patent Owner's hypothesis regarding non-uniformity of contamination, and that demonstrated the *nexus* between the invention as claimed and the related benefits which, despite the substantial disincentive of increased sampling and assay costs, have led to the current success of the '584 patent claimed subject matter (see Example 1 of the patent):

> Specifically, the individual single-unit production lot samples comprising the MWCS were analyzed separately following each *positive* MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a *positive* result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a *positive* result. If only the 391 individual single-unit production lots yielding a *positive* sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce.
>
> The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 1,9280,000 lbs of beef trim into commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in sensitivity relative to the MWCS testing) provides *substantial* additional assurance of the safety of the food products.
>
> ...

TABLE 1: Results of modular wet composite sampling of 62,919 multiple lots and number of Individual Production Unit Lot (IPUL) that tested positive when MWCS tested positive

Location	Total # Analyses	# Positives	1 IPUL	2 IPULs	3 IPULs	4 IPULs	5 IPULs
Est. A, B, C.	62,919	271	180	39	18	11	7

U.S. Patent No. 7,534,584, at Cols. 11 and 12.

The DOA's motivational analysis, therefore, is in error with respect to compositing samples from different enrichment samples, which themselves have been composited from different separate test lots. Prior to Patent Owner's invention, there was no such motivation, as corroborated by the absence of such modular compositing including over the last 40 plus years. Patent Owners hypothesis, and validation thereof by the Patent Owner, is what provided the motivation. In the presence of a pervasive assumption in the art that contamination was uniform for purposes of lot designation, and the counter motivation to avoid any increased sampling/testing costs, a mere motivation to composite pre-enriched or enriched samples in the context of a single lot does NOT provide motivation for Applicant's claimed subject matter. Moreover, Patent Owner notes that the biological and chemical arts are regarded as ***unpredictable*** by the Office. Patent Owner's claimed subject matter would have been contra-indicated in the art at the time of filing.

e1. and **e2**. (when testing is negative, all of said separate test lots are validated) With respect to Patent Owner's steps e1), the DOA states that testing is taught by Jarvis and Price (e.g., Price at page 680 (Figure 1)). The DOA states that step e2 involves obtaining a negative and "all of said separate test lots are validated for release, which it regards as a 'mental step.'"

Patent Owner strongly disagrees, because testing in e1 and e2 of the modular composite sample is a physical testing step, and not a mental step. Moreover, since the modular composite sample, by nature, is composited from different enrichment samples, which themselves have been composited from the different separate test lots, a negative tested modular composite sample is instantaneously a negative testing (validation) for all of the separate lots and is in fact an element of the claim. This is not a mental step, it is a physical assay/testing step of the modular composite sample.

Furthermore, for the reasons stated above with respect to that lack of motivation in the art for the limits of step d1, preparing and assaying such a modular composite sample is in fact not present or motivated in the art, including the very limited teachings of Jarvis and Price.

e3. (when the 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") With respect to Patent Owner's steps e1, the DOA states that Jarvis 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 assessed. (Jarvis at pages 141-142). The DOA states that "while it is true that Jarvis differs because Jarvis teaches going back to samples before enrichment, Jarvis still teaches concept of testing composited samples as in step e1 and going back to the sample before compositing it as in step e3." Since there is no compositing in e3, Patent Owner presumes that the DOA rather intended to state "Jarvis still teaches concept of testing composited samples as in step e1 and going back to test stored cultures as in step e3."

Patent owner points out, however, that the nature of the Jarvis stored sample is not only different because it is pre-enriched and not enriched, but also because the Jarvis pre-enriched samples are each from the same test lot, and each pre-enriched sample in not a statistical sample (only a single sample, and would not allow for validation). Not only is the motivation for going back to test the stored sample in Jarvis completely different than in the presently claimed subject matter, but the underlying utility is completely and fundamentally different. As recited in e3, "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)."

Furthermore, for the reasons stated above with respect to that lack of motivation in the art for the limits of step d1, preparing and assaying such a modular composite sample is in fact not present or motivated in the art, including the very limited teachings of Jarvis and Price.

Secondary Considerations

Patent Owner thanks the Appeal Board for its thoughtful analysis in the DOA of factual considerations (secondary considerations) that underlie the obviousness inquiry under *Graham*.

With respect to "Commercial Success," the DOA discusses (at pages 20-22) the Koohmaraie Declaration and the Samadpour 2010 Declaration. Patent Owner maintains the Declarations strongly support the underlying link/nexus of the commercial success of Patent Owner's methods to the elements of the presently claimed subject matter.

With respect to "Skepticism," the DOA discusses (at pages 22-23) the Mirtsching Declaration and the Samadpour 2011 Declaration. Patent Owner maintains the Declarations strongly support the underlying link/nexus of the commercial success of Patent Owner's methods to the elements of the presently claimed subject matter.

In the DOA "Discussion" (beginning at page 21 of the DOA), the DOA states that Patent Owner did not provide an adequate explanation of the second "classical" product to understand the differences between the two and understand the reason for success. The DOA states, "for instance, was the success solely attributable to the post-enriching step e2 or to another step in the prior art?"

Patent Owner points out that the Patent Owner's patent describes the "classical product" in detail in the '584 patent (see, e.g., Col. 2, line 46, through Col. 3, line 40; and see working Example 1). Additionally, the record of this *inter partes* re-examination and Appeal contains a detailed comparative description of the classical method relative to Patent Owner's new method. For example, Exhibit A and Exhibit B of Patent Owner's Appeal Brief show the classical assay method, and Patent Owner's new method, respectively:

Exhibit A: Figure 1 attached to and labeled as "Exhibit A" in the Response after non-final action filed via EFS-Web on July 26, 2010;

Exhibit B: Figure 2 attached to and labeled as "Exhibit B" in the Response after non-final action filed via EFS-Web on July 26, 2010;

As well established in the record, the classical approach did not simultaneous assay multiple operationally-linked production lots, but rather assayed a single production lot, which led to destruction loss of a large amount of product. Patent Owner's new method, despite increased sampling and assay costs, results in substantial overall financial savings directly because of the modular compositing approach (at least steps (c) through (e)) for simultaneously assaying multiple independent, operationally-linked lots in one application of the method, and whereby less product is diverted to waste and/or lower value products. The commercial success is clearly attributed to at least steps (c) though (e) that are not in the art, and are not motivated by the art for the reasons discussed herein. Working Example 1 of the '584 patent clearly shows why this is true:

> "Specifically, the individual single-unit production lot samples comprising the MWCS [modular composite sample] were analyzed separately following each

> positive MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a positive result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a positive result. If only the 391 individual single-unit production lots yielding a positive sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce."

Beginning at page 24 of the DOA, the DOA states that "[a]ll of the data appears to involve testing of beef, for contamination by E. coli. It is not clear whether other bacterial contaminants are tested, or whether other food products had the same commercial success."

Patent Owner (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) has, in addition to beef, successfully applied the presently claimed method (and in the context of using the assay as outlined for beef, and without the extra step of testing individual enriched samples if the modular composite sample tests negative), to a variety of food products tested, including but not limited to: meats (e.g., beef, pork, poultry, fresh and cured sausages, and the like), fresh agricultural commodities (e.g., leafy greens, vegetables, fruit, herbs, and the like), agricultural seeds, dried foods (e.g., spices, powders, flour, bakery mixes, and the like), pet foods, baked goods, processed meats, fermented foods, dairy products, nuts (both ground and tree), nut butters, trail mixes, compost, organic fertilizers, seafood, energy bars, cereals, sponge, and swap samples taken from food and food production environments, and including assaying for various pathogens (e.g., pathogenic *E. coli*, Salmonella, Listeria, Campylobacter, Vibrio, etc.) to obtain comparable commercial success to that corroborated in the record for beef and *E. coli*, and for the same reasons (i.e., destruction of less product with a production run), and due to the modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)). Moreover, as appreciated in the art, fabrication of meats such as pork sheep, bison, poultry, and the like, is analogous to beef fabrication in terms of art-recognized production runs and lots, and thus derives comparable commercial benefits from the same modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)).

Patent Owner, for procedural expediency and to facilitate prosecution of the present matter, has nonetheless amended claim 1 to recite "test lots of beef" in place of "test lots." Claim 17 has been amended to recite "test lots of meat and poultry" in place of "test lots."

The Amendments serve to narrow the scope of the claims to address the concern of the DOA with respect to the scope of the foods covered and the sufficiency of the secondary factor data.

Beginning at the bottom of page 24 of the DOA, the DOA states that "[a]rguments were also made that lot sizes are smaller in the claimed method than in the prior art and "classical" method. Samadpour 2011 Decl. ¶¶ 8, 30, and 36. See also Oral Hearing Transcript 16:8-11; 17:1-5. However, the claims are not limited to a lot of a particular size. Thus, if this is a basis for patentability, the feature is not recited in the claim."

Patent Owner, to further clarify this aspect has amended claims 1 and 17 to recite "operationally-linked test lots of beef" and "operationally-linked single-unit production lots of meat or poultry," respectively.

Patent Owner points out, as discussed above, that prior to the present invention, and including for at least the last forty years, there has been no such motivation because the food industry assumed that contamination was uniform, for purposes of production lot designation, throughout a production run, which justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assaying. Hence, prior to Patent Owner's invention, it has always been deemed sufficient to test one large lot (i.e., an entire production run), and thus there was no motivation to even form and define multiple separate operationally-linked production lots within a production run, and thus been no motivation to simultaneously/jointly test multiple separate operationally-linked production lots within a production run. As discussed during Oral Hearing, Patent Owner hypothesized that the long-standing art assumption of contamination uniformity for purposes of lot designation was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a production run (e.g., as was done in working Example 1 of Patent Owner's patent), some of the operationally-linked production lots within the production run would not be contaminated, while others would be.

Beginning at page 25 of the DOA, the DOA states that "Dr. Samadpour testified that to convince FSIS to accept the method, he had to modify the protocol by testing each individual enrichment component separately, even when the modular composite sample was negative. Samadpour 2011 Decl. ¶ 34. If the method responsible for the market share and increased revenue assays each test lot separately whether negative or positive, then it has not been established that the modular composite testing as claimed is responsible for the success. The commercial success must be due to a claimed feature."

Patent Owner points out (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) that the FSIS requirement for the extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applies to a small fraction of instances (at most 10-15% of the data used in the record to support commercial success) when the separate individual lots used to build the modular composite sample are sold to different entities. In 85-90% of the instances, when all the separate individual lots used to build the modular composite sample are sold to the same entity, there is no such requirement for assaying each individual enrichment component separately, even when the modular composite sample was negative. Patent Owner's commercial success data of record, therefore, clearly supports the nexus between commercial success and Patent Owner's claim elements, which are not in the prior art.

Furthermore, the initial FSIS skepticism outlined in the record applied to the assay, whether with or without the aspect of assaying each individual enrichment component separately, even when the modular composite sample was negative (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)).

In summary, Patent Owner contends that in view of the present claim amendments, there is a clear and sufficient *nexus* between Patent Owner's claim elements and the skepticism of the art, and the commercial success described in the record of this proceeding.

B. Grounds 2-4 (REJECTIONS 2-4)

The DOA (at page 26) states that "Patent Owner made the same patentability arguments for dependent claims 5, 6, 21, 23, 24, 28-30, 32, and 33 cited in Rejections 2-4 (numbered 10, 11, 13, and 14 in the Appeal Brief) as they did for Rejection 1 (numbered 1 and 2 in the Appeal

Brief). As we did not consider these arguments persuasive, we affirm the rejections for the reason set forth by the Examiner."

Patent Owner, based on the rebuttal arguments and amendments herein, contends that the rejections of the Examiner and Appeal Board have been overcome, including those for dependent claims 5, 6, 21, 23, 24, 28-30, 32, and 33 cited in Rejections 2-4 of the DOA (numbered 10, 11, 13, and 14 in the Appeal Brief).

Declarations

In addition to the current Declaration (Exhibit Z), Appellant's six (6) Declarations (Exhibits E-J), and comments regarding same in the Appeal Brief, are incorporated herein by reference, and should be carefully considered by the Examiner and the Board in support of the current Response.

Response to Declarations

Patent Owner incorporates by reference herein Patent Owner's comments in the Appeal Brief relating to various incorrect statements made in the RAN/ACP Section entitled "Response to Declarations."

EVIDENCE APPENDIX

Evidence required under 37 C.F.R. § 41.67(c)(1)(ix). Patent Owner relies upon evidence submitted and of record in the *inter partes* reexamination case, Control No. 95/001,294.

Evidence (Exhibits A-Y) used in the Appeal Brief, filed 07 May 2012, is incorporated by reference herein.

RELATED PROCEEDINGS APPENDIX

There are no decisions by a court or the BPAI pursuant the 37 C.F.R. § 41.67(c)(1)(x) that are submitted herein.

CERTIFICATE OF SERVICE

Timely service to the third party requester, bioMerieux, via their attorney E. Anthony Figg, at Rothwell, Figg, Ernst & Manbeck, P.C., 607 14th Street N.W., Suite 800, Washington, D.C. 20005 is being affected by first class mail sent on 20 February 2015.

CONCLUSION

For the reasons provided herein, Patent Owner submits the DOA rejections of the claims are overcome by the present Response, and that the claims are allowable as presently presented.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Patentee
Registration No. 47,309

EXHIBIT Z

Via Electronic Submission
Attorney Docket No.:66090-008US2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Mansour Samadpour
Control No.:	95/001,294
Confirmation No.:	1914
Filed:	05 April 2010
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Examiner:	Sharon Turner
Art Unit:	*3991*
Confirmation No.:	1914
Docket No.:	66090-008US2
Date:	20 February 2015

Attn: Mail Stop "Inter Partes Reexam"
Central Reexamination Unit
Commissioner for Patents
P. 0. Box 1450
Alexandria VA 22313-1450

DECLARATION OF MANSOUR SAMADPOUR UNDER 37 C.F.R. § 1.132
(IN SUPPORT OF PATENT OWNER'S RESPONSE PURSUANT TO 37 C.F.R. § 41.77(b)(1) REQUESTING REOPENING OF PROSECUTION BEFORE THE EXAMINER)

Madam:

I, Dr. Mansour Samadpour, being duly sworn, say:

1. I am familiar with and am the original inventor of the above-identified patent application, and am aware that it discloses and claims novel methods comprising sampling, testing, and validating test lots for microbial contamination. I am very familiar with the comments made by the Examiner in the *inter partes* reexamination proceeding in this case,

including the DECISION ON APPEAL (DOA), dated 20 January 2015. This supplemental declaration is in response to various issues raised in the DOA, including to further clarify and corroborate the nexus between the claimed invention (modular composite testing) and commercial success and skepticism in the art.

2. I am familiar with the amended claims in PATENT OWNER'S RESPONSE PURSUANT TO 37 C.F.R. § 41.77(b)(1) REQUESTING REOPENING OF PROSECUTION BEFORE THE EXAMINER, filed 20 February 2015, along with this Declaration.

3. I am the CEO and founder of the Institute of Environmental Health, the Assignee and owner of the subject patent application. My detailed *curriculum vitae* is attached hereto as APPENDIX A.

4. I am an author or co-author of at least 50 peer-reviewed research articles (citations for representative articles are included as part of APPENDIX A) in the field of food testing, analytical sampling, meat safety, and quality and my research has been presented at national and international meetings. I am an inventor on several granted United States and foreign patents and various pending domestic and international patent applications. I am an internationally recognized expert in food sampling, pathogen testing, and molecular epidemiology, with over 20 years academic and industry experience in this area.

5. In my capacity as CEO at Institute of Environmental Health, I am well versed and intimately aware of all aspects of the company and as such I am the person most acquainted with all functions of the company, including implementation of the statistical modular composite pooling procedure disclosed and claimed in the current patent, marketing of this procedure to others, and the surprising, rapid, and wide-spread acceptance of the claimed methods despite the fact that implementation of the methods increases the number of samples taken by about 300 to 500%, and the testing cost by about 30%. The acceptance of increased sampling is a surprising result since normally industry attempt to minimize sampling. Increasing sampling results in an increase in the number of positives found, with consequent requirements that product be diverted to an economically disadvantageous safe endpoint, such as rendering or cooking. However, my technique has actually resulted in saving of product, by permitting validation and release of smaller lots of product, even when testing of a composite enrichment encompassing several lots shows a positive result. Industry acceptance is particularly surprising in view of the increased testing cost, about 30% greater than with previous methods. Heretofore, the main goal of the industry has been to minimize testing costs, which were viewed as a dead loss.

6. I am familiar with the rejections asserted in DECISION ON APPEAL (DOA), dated 20 January 2015.

7. I am making this Declaration to support the PATENT OWNER'S RESPONSE PURSUANT TO 37 C.F.R. § 41.77(b)(1) REQUESTING REOPENING OF PROSECUTION BEFORE THE EXAMINER, to respond to the comments made by the DOA, and to Declare and corroborate the inventive and non-obvious nature of statistical wet composite pooling, as presently claimed, in the control of food-borne pathogens and the *nexus* between the claimed invention and the commercial success of the implemented procedures.

8. It is my position that ***ALL*** art cited against this invention pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots, but not in the simultaneous fashion of Appellant's claims involving a plurality of operationally-linked production lots within a production run. The two references concerning "composite" (aggregated) samples contemplate that all samples come from the same food lot, where the sole motive for compositing is a desire to limit the number of samples to minimize testing costs. Nothing in cited art motivates combination of samples from separate operationally-linked production lots within a production run of food within a single method. In fact the art at the time of filing contraindicated the claimed subject matter. No art, alone or in combination discloses or motivates performing the tasks of Appellant's independent claims 1 and 17; to simultaneously operate on a plurality of separate operationally-linked production lots within a production run, each to be validated for release into commerce, and involving creation of a modular composite sample from aliquots of separate enriched operationally-linked test lots each attributed to a particular corresponding separate operationally-linked test lot within a production run, and where each separate test lot is separately sampled from the respective plurality of separate test lots according to a statistical sampling plan, and **not** with a single-portion per pre-enrichment scheme as in Price or Jarvis (2).

9. With respect to the DOA's comment (page 16-17, citing *In re ICON Health and Fitness Inc.,* 496 F.3d 1374, 1381 (Fed. Cir. 2007) that "there is a suggestion in Price (at 682) and Gabis (at 684) of direct enrichment. Even if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use 'would render the result inoperable.'" I point out that in fact, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols of Gabis) would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection

methods inoperative in the food industry, which does not gamble with people's lives.

10. I likewise points out that Price, in direct analogy to Gabis, would also suggest to one of skill in the art that direct enrichment could ONLY be used in the context of non-lumped/non-composited single samples. Price (p. 682, ¶ 2) *teaches away* from the use of anything more than a single portion in each pre-enrichment:

> "*If many food samples are pooled at the pre-enrichment stage, the salmonellae face competition from the flora of all the samples in the pool. If, in the other hand, the samples are individually pre-enriched, the actively growing salmonella might be expected to compete more favorably with organisms introduced from other samples when pooled at the enrichment stage. In addition, pooling pre-enrichment broths avoids the hazards and inconvenience of handling very large flasks of culture.*"

(Note: Price uses the word "sample" to mean "portion", as defined in the Patent).

Since the problem being addressed by Price is to reduce the background of competing organisms, the statements by Price about the use of direct selective enrichments, two selective enrichments, or possibly even a reduction in the incubation time of the pre-enrichment cultures would be regarded by one of skill in the art, as being limited to the case of **non-lumped individual pre-enrichment cultures**, which would be expected to have fewer background/competitive organism problems; that is, one would not ***exacerbate*** the background problem by subjecting a *lumped* test sample to direct selective enrichments or two selective enrichments.

Again, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols) would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection methods inoperative in the food industry. I, therefore, contend that the DOA is in error on this this point.

11. The DOA states (at page 18) that "[i]t is correct that the cited prior art, particularly Jarvis and Price, do not describe compositing samples from different enrichment samples, which themselves have been composited [from different separate test lots]. However, as indicated above, it would have been obvious to pool enriched samples together to reduce the number of tests that need be performed.

I emphatically disagree. First, as explicitly acknowledged in the DOA, pooling at the enrichment stage was not in the prior, art. Second, even if it was, there is certainly no motivation in the art for compositing samples from different enrichment samples, which themselves have been composited [from different separate test lots]. In fact, there was a very strong counter motivation not to do this. Specifically, as discussed during Oral Hearing with respect to the explicit data of working Example 1 of the '584 patent, prior to the present invention, and including for at least the last forty years there has been no such motivation because the food industry has widely assumed that contamination was uniform, for purposes of production lot designation, throughout a production run, which accordingly justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assay of any larger number of smaller separate operationally-linked production lots within a production run that might be formed[1]. Hence, prior to Patent Owner's invention, it has always been deemed sufficient to test one large lot (i.e., an entire production run or a large segment of a production run), and thus no motivation to even form and define multiple separate operationally-linked production lots within a production run, **and thus been no motivation to simultaneously/jointly test multiple separate operationally-linked production run lots within a production run**. As discussed during Oral Hearing, Patent Owner/inventor hypothesized that the long-standing art assumption of contamination uniformity for purposes of production lot designation, was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a production run, some of the operationally-linked production lots within the production run would not be contaminated, while others would be. Patent Owner's/inventor's hypothesis and insight, therefore, was what provided the motivation (even for the Patent Owner/inventor) to pursue the presently claimed subject matter, which is entirely validated by the results of working Example 1 of the '584 patent, and which, while engendering much initial skepticism, has led to rapid commercial success as amply evidenced in the record.

The DOA's motivational analysis, therefore, is in error with respect to compositing samples from different enrichment samples, which themselves have been composited from different separate test lots. Prior to Patent Owner's invention, there was no such motivation, as

[1] Obviously, if contamination is uniform for purposes of lot designation, there would be no advantage to assaying multiple separate operationally-linked production lots within a production run in place of a larger production lot (the entire production run), because the positive detection results would be the same but would require a much larger number of samples, and assay expense. By contrast, if contamination was non-uniform, Patent Owner hypothesized that some of the operationally-linked production lots within a production run would not be contaminated, while others would be.

corroborated absence of such modular compositing including over the last 40 plus years. Patent Owners hypothesis, and validation thereof by the Patent Owner, is what provided the motivation. In the presence of a pervasive assumption in the art that contamination was uniform for purposes of lot designation, and the counter motivation/contraindication to avoid any increased sampling/testing costs, a mere motivation to composite pre-enriched or enriched samples in the context of a single lot does NOT provide motivation for Applicant's claimed subject matter. Applicant's claimed subject matter would have been contra-indicated in the art at the time of filing.

The original specification, for which I signed an inventor Oath/Declaration, of the current patent contained a working Example 1, which corroborated Patent Owner's hypothesis regarding non-uniformity of contamination, and that demonstrated the *nexus* between the invention as claimed and the related benefits which, despite the substantial disincentive of increased sampling and assay costs, have led to the current success of patent '584 (see Example 1 of the patent):

> Specifically, the individual single-unit production lot samples comprising the MWCS were analyzed separately following each *positive* MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a *positive* result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a *positive* result. If only the 391 individual single-unit production lots yielding a *positive* sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce.
>
> The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 1,9280,000 lbs of beef trim into commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in sensitivity relative to the MWCS testing) provides *substantial* additional assurance of the safety of the food products.
>
> …

TABLE 1: Results of modular wet composite sampling of 62,919 multiple lots and number of Individual Production Unit Lot (IPUL) which tested positive when MWCS tested positive

Location	Total # Analyses	# Positives	1 IPUL	2 IPULs	3 IPULs	4 IPULs	5 IPULs
Est. A, B, C.	62,919	271	180	39	18	11	7

U.S. Patent No. 7,534,584, at Cols. 11 and 12.

12. Beginning at page 24 of the DOA, the DOA states that "[a]ll of the data appears to involve testing of beef, for contamination by E. coli. It is not clear whether other bacterial contaminants are tested, or whether other food products had the same commercial success."

I have, in addition to beef, successfully applied the presently claimed method (and in the context of using the assay as outlined for beef, and without the extra step of testing individual enriched samples if the modular composite sample tests negative), to a variety of food products tested, including but not limited to: meats (e.g., beef, pork, poultry, fresh and cured sausages, and the like), fresh agricultural commodities (e.g., leafy greens, vegetables, fruit, herbs, and the like), agricultural seeds, dried foods (e.g., spices, powders, flour, bakery mixes, and the like), pet foods, baked goods, processed meats, fermented foods, dairy products, nuts (both ground and tree), nut butters, trail mixes, compost, organic fertilizers, seafood, energy bars, cereals, sponge, and swap samples taken from food and food production environments, and including assaying for various pathogens (e.g., pathogenic *E. coli*, Salmonella, Listeria, Campylobacter, Vibrio, etc.) to obtain comparable commercial success to that corroborated in the record for beef and *E. coli*, and for the same reasons (i.e., destruction of less product within a production run, and increased confidence in negative results, brand protection, etc.), and due to the modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)). Moreover, as appreciated in the art, fabrication of meats such as pork sheep, bison, poultry, seafood and the like, is analogous to beef fabrication in terms of art-recognized production runs and lots, and thus derives comparable commercial benefits from the same modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)).

13. Beginning at the bottom of page 24 of the DOA, the DOA states that "[a]rguments were also made that lot sizes are smaller in the claimed method than in the prior art and "classical" method. Samadpour 2011 Decl. ¶ 8, 30, 36.[11] See also Oral Hearing Transcript 16: 8-11; 17:1-5. However, the claims are not limited to a lot of a particular size. Thus, if this is a basis for patentability, the feature is not recited in the claim.

I note that claims 1 and 17 have been amended to recite "operationally-linked test lots of beef" and "operationally-linked single-unit production lots of meat or poultry," respectively.

I further point out, as discussed above, that prior to the present invention, and including for at least the last forty years, there has been no such motivation because the food industry assumed that contamination was uniform, for purposes of production lot designation, throughout a production run, which justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assaying. Hence, prior to Patent Owner's invention, it has always been deemed sufficient to test one large lot (i.e., an entire production run), and thus there was no motivation to even form and define multiple separate operationally-linked production lots within a production run, and thus been no motivation to simultaneously/jointly test multiple separate operationally-linked production lots within a production run. As discussed during Oral Hearing, Patent Owner hypothesized that the long-standing art assumption of contamination uniformity, for purposes of production lot designation, was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a production run (e.g., as was done in working Example 1 of the '584 patent), some of the operationally-linked production lots within the production run would not be contaminated, while others would be.

14. Beginning at page 25 of the DOA, the DOA states that "Dr. Samadpour testified that to convince FSIS to accept the method, he had to modify the protocol by testing each individual enrichment component separately, even when the modular composite sample was negative. Samadpour 2011 Decl. ¶ 34. If the method responsible for the market share and increased revenue assays each test lot separately whether negative or positive, then it has not been established that the modular composite testing as claimed is responsible for the success. The commercial success must be due to a claimed feature."

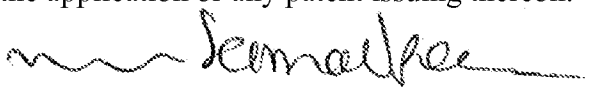
I point out, however, that the FSIS requirement for the extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applies to a small fraction of instances (at most 10-15% of the data in the record used to support commercial success) where the separate individual lots used to build the modular composite sample <u>are sold to different entities</u>. In 85-90% of the instances, where all the separate individual lots used to build the modular composite sample are sold to the <u>same entity</u>, <u>there is no such requirement for assaying each individual enrichment component separately, even when the modular composite sample was negative</u>. Patent Owner's data of record, therefore, clearly supports the nexus between commercial success and Patent Owner's claim elements,

which are not in the prior art.

Furthermore, I point out that the initial FSIS skepticism outlined in the record applied to the assay, with or without, the aspect of assaying each individual enrichment component separately, even when the modular composite sample was negative.

In summary, in view of the present claim amendments, there is a clear and sufficient *nexus* between Patent Owner's claim elements and the skepticism of the art, and the commercial success described in the record of this proceeding.

15. I further 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 that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and may jeopardize the validity of the application or any patent issuing thereon.



Mansour Samadpour, Ph.D.
20 February 2015

APPENDIX A
CURRICULUM VITAE

MANSOUR SAMADPOUR, PH.D.
Principal

SUMMARY

Dr. Samadpour is a food microbiologist with extensive experience in food safety, food production, and epidemiology of foodborne illnesses. He is currently President of Molecular Epidemiology and IEH Laboratories & Consulting Group (IEH), who together employ upwards of 300 personnel. IEH initially focused on providing services to the beef harvesting and grinding industries, and currently IEH conducts testing for about 1/3 of the U.S. market. Since the spinach outbreak of 2006 services have expanded into the produce sector and now IEH serves major clients in fresh cut produce (lettuce, tomatoes, and green onions), apples, sprouts, and tree nuts. In this capacity Dr. Samadpour has been intimately involved in defining and developing microbiological testing programs for food safety management of *E. coli* O157, *Salmonella*, EHEC, *Shigella* and *L. monocytogenes* testing plans as well as the evaluation of the efficacy of microbial interventions. Dr. Samadpour's expertise has been sought in most of the major foodborne illnesses that have occurred since the Jack In The Box *E. coli* O157 episode of 1993, and he as served as expert witness on numerous occasions.

Currently Dr. Samadpour has over 50 scientific publications, over 50 abstracts, 12 popular press and trade articles and more than 200 research reports. He is also the inventor on over 14 patent applications involving aspects of food testing and foodborne illness risk analysis.

EDUCATION

1990	**Ph.D.**, Food Science and Technology, minor in Molecular Biology; University of Washington, Seattle, WA
1987	**M.S.**, Microbiology University of Washington, Seattle, WA
1981	**B.S.**, Microbiology University of Washington, Seattle, WA

PROFESSIONAL POSITIONS

2001-Present	**Principal**, Molecular Epidemiology, also dba IEH Laboratories & Consulting Group, Seattle, WA
1993-2003	**Assistant Professor**, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington,

Seattle, WA

1991-1993 **Research Associate**, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

1990-1991 **Post-Doctoral Research Associate**, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

1988-1990 **Pre-Doctoral Fellow**, School of Fisheries, University of Washington, Seattle, WA

1978-1980 **Graduate Research Assistant**, Department of Microbiology, University of Washington, Seattle, WA

SELECTED PUBLICATIONS

1. Czaja CA, Stamm WE, Stapleton AE, Roberts PL, Hawn TR, Scholes D, **Samadpour M,** Hultgren SJ, Hooton TM. "Prospective Cohort Study of Microbial and Inflammatory Events Immediately Preceding *Escherichia coli* Recurrent Urinary Tract Infection in Women." J Infect Dis. 2009 Aug 15;200(4):528-536.

2. Kulasekara BR, Jacobs M, Zhou Y, Wu Z, Sims E, Saenphimmachak C, Rohmer L, Ritchie JM, Radey M, McKevitt M, Freeman TL, Hayden H, Haugen E, Gillett W, Fong C, Chang J, Beskhlebnaya V, Waldor MK, **Samadpour M**, Whittam TS, Kaul R, Brittnacher M, Miller SI. "Analysis of the genome of the *Escherichia coli* O157:H7 2006 spinach-associated outbreak isolate indicates candidate genes that may enhance virulence." Infect Immun. 2009 Jun 29. [Epub ahead of print].

3. Stopforth JD, Kottapalli B, **Samadpour M**. "Sterility testing of a dispensing valve for aseptic function in food service applications." J Food Prot. 2008 Mar;71(3):653-6.

4. Stopforth JD, Mai T, Kottapalli B, **Samadpour M**. "Effect of acidified sodium chlorite, chlorine, and acidic electrolyzed water on *Escherichia coli* O157:H7, *Salmonella* and *Listeria monocytogenes* inoculated onto leafy greens." J Food Prot. 2008 Mar;71(3):625-8.

5. Field KG, **Samadpour M**. "Fecal source tracking, the indicator paradigm, and managing water quality." Water Res. 2007 Aug;41(16):3517-38. Epub 2007 Jun 27. Review.

6. Stopforth JD, O'Connor R, Lopes M, Kottapalli B, Hill WE, **Samadpour M**. "Validation of individual and multiple-sequential interventions for reduction of microbial populations during processing of poultry carcasses and parts." J Food Prot. 2007 Jun;70(6):1393-401.

7. Meays CL, Broersma K, Nordin R, Mazumder A, **Samadpour M**. "Spatial and annual variability in concentrations and sources of *Escherichia coli* in multiple watersheds." Environ Sci Technol. 2006 Sep 1;40(17):5289-96.

8. Lopes M., Stopforth J.D., Sucre K., Miksch R.R., Giddens E., Reddy M.C.S., Yemm R.S. and **Samadpour, M**. "Alternative Cutting Methods to Minimize Transfer of Nervous System

Tissue During Steak Preparation from Bone-in Short Loins", J Food Prot. 2006 Jun;69(6):1456-9.

9. Stopforth J.D., Lopes M., Shultz J.E., Miksch R.R., and **Samadpour M.** "Microbiological Status of Fresh Beef Cuts", Research Note, J Food Prot. 2006 Jun;69(6):1388-92.

10. Stopforth J.D., Lopes M., Shultz J.E., Miksch R.R., and **Samadpour M**. "Location of Bung Bagging During Beef Slaughter Influences the Potential for Spreading Pathogen Contamination on Beef Carcass", J Food Prot. 2006 Jun;69(6):1452-5.

11. **Samadpour M**, Barbour MW, Nguyen T, Cao TM, Buck F, Depavia GA, Mazengia E, Yang P, Alfi D, Lopes M, Stopforth JD. "Incidence of enterohemorrhagic *Escherichia coli*, *Escherichia coli* O157, *Salmonella*, and *Listeria monocytogenes* in retail fresh ground beef, sprouts, and mushrooms." J Food Prot. 2006 Feb;69(2):441-3.

12. Hooton TM and **Samadpour M.** "Is acute uncomplicated urinary tract infection a foodborne illness, and are animals the source?" Clin Infect Dis. 2005 Jan 15;40(2):258-9

13. **Samadpour M**, Roberts MC, Kitts C, Mulugeta W, Alfi D. "The use of ribotyping and antibiotic resistance patterns for identification of host sources of *Escherichia coli* strains" Lett Appl Microbiol. 2005;40(1):63-8

14. ***Samadpour M.***, *Evans PS, Everett KDE, Ghatpande P, Ma G and Miksch RR "Occupational and Environmental Exposures to Waterborne Microbial Diseases" in* Textbook of Clinical Occupational and Environmental Medicine, 2nd Ed. Rosenstock et al (eds). , Philadelphia: Elsevier Saunders, 2004

15. Stoeckel DM, Mathes MV, Hyer KE, Hagedorn C, Kator H, Lukasik J, O'Brien TL, Fenger TW, **Samadpour M**, Strickler KM, Wiggins BA. "Comparison of seven protocols to identify fecal contamination sources using *Escherichia coli*" Environ Sci Technol. 2004 Nov 15;38(22):6109-17

16. Keene WE, Markum AC, and **Samadpour M**. "Outbreak of *Pseudomonas aeruginosa* infections caused by commercial piercing of upper ear cartilage." JAMA. 2004 Feb 25;291(8):981-5.

17. Wilkerson C, **Samadpour M**, van Kirk N, and Roberts MC. "Antibiotic resistance and distribution of tetracycline resistance genes in *Escherichia coli* O157:H7 isolates from humans and bovines." Antimicrob Agents Chemother. 2004 Mar;48(3):1066-7.

18. Harwood VJ, Wiggins B, Hagedorn C, Ellender RD, Gooch J, Kern J, **Samadpour M**, Chapman AC, Robinson BJ, Thompson BC. "Phenotypic library-based microbial source tracking methods: efficacy in the California collaborative study" J Water Health. 2003 Dec;1(4):153-66.

19. Myoda SP, Carson CA, Fuhrmann JJ, Hahm BK, Hartel PG, Yampara-Lquise H, Johnson L, Kuntz RL, Nakatsu CH, Sadowsky MJ, **Samadpour M**. "Comparison of genotypic-based microbial source tracking methods requiring a host origin database" J Water Health. 2003 Dec;1(4):167-80

20. Davis MA, Hancock DD, Besser TE, Rice DH, Hovde CJ, Digiacomo R, **Samadpour M**, and Call DR. "Correlation between geographic distance and genetic similarity in an international collection of bovine faecal *Escherichia coli* O157:H7 isolates." Epidemiol Infect. 2003 Oct;131(2):923-30.

21. Zhang C, Zhang M, Ju J, Nietfeldt J, Wise J, Terry PM, Olson M, Kachman SD, Wiedmann M, **Samadpour M**, and Benson AK. "Genome diversification in phylogenetic lineages I and II of *Listeria monocytogenes*: identification of segments unique to lineage II populations." J Bacteriol. 2003 Sep;185(18):5573-84.

22. Davis MA, Hancock DD, Rice DH, Call DR, DiGiacomo R, **Samadpour M**, and Besser TE. "Feedstuffs as a vehicle of cattle exposure to *Escherichia coli* O157:H7 and *Salmonella enterica*." Vet Microbiol. 2003 Sep 1;95(3):199-210.

23. Renter DG, Sargeant JM, Oberst RD, and **Samadpour M**. "Diversity, frequency, and persistence of *Escherichia coli* O157 strains from range cattle environments." Appl Environ Microbiol. 2003 Jan;69(1):542-7.

24. **Samadpour M**, Kubler M, Buck FC, Depavia GA, Mazengia E, Stewart J, Yang P, and Alfi D. "Prevalence of Shiga toxin-producing *Escherichia coli* in ground beef and cattle feces from King County, Washington." J Food Prot. 2002 Aug;65(8):1322-5.

25. **Samadpour M**, Stewart J, Steingart K, Addy C, Louderback J, McGinn M, Ellington J, and Newman T. "Laboratory investigation of an *E. coli* O157:H7 outbreak associated with swimming in Battle Ground Lake, Vancouver, Washington." J Environ Health. 2002 Jun;64(10):16-20, 26, 25.

26. Farag AM, Goldstein JN, Woodward DF, and **Samadpour M.** "Water quality in three creeks in the backcountry of Grand Teton National Park, USA." Journal Fresh Water Ecology 2001. 16:135-143.

27. Hooton TM, Scholes D, Stapleton AE, Roberts PL, Winter C, Gupta K, **Samadpour M**, and Stamm WE. "A prospective study of asymptomatic bacteriuria in sexually active young women." N Engl J Med. 2000 Oct 5;343(14):992-7.

28. Jackson LA, Keene WE, McAnulty JM, Alexander ER, Diermayer M, Davis MA, Hedberg K, Boase J, Barrett TJ, **Samadpour M**, and Fleming DW. "Where's the beef? The role of cross-contamination in 4 chain restaurant-associated outbreaks of *Escherichia coli* O157:H7 in the Pacific Northwest." Arch Intern Med. 2000 Aug 14-28;160(15):2380-5.

29. *Morbidity and Mortality Weekly Report.* Center for Disease Control. "Outbreak of Salmonella Serotype Muenchen Infections Associated with Unpasteurized Orange Juice -- United States and Canada." MMWR, July 16, 1999. 48:577-600.

30. Grimm LM, Goldoft M, Kobayashi J, Lewis JH, Alfi D, Perdichizzi AM, Tarr PI, Ongerth JE, Moseley SL, and **Samadpour M**. "Molecular epidemiology of a fast-food restaurant-associated outbreak of *Escherichia coli* O157:H7 in Washington State." J Clin Microbiol. 1995 Aug;33(8):2155-8.

31. **Samadpour M**. "Molecular epidemiology of *Escherichia coli* O157:H7 by restriction fragment length polymorphism using Shiga-like toxin genes." J Clin Microbiol. 1995 Aug;33(8):2150-4.

32. Kim HH, **Samadpour M**, Grimm L, Clausen CR, Besser TE, Baylor M, Kobayashi JM, Neill MA, Schoenknecht FD, and Tarr PI. "Characteristics of antibiotic-resistant *Escherichia coli* O157:H7 in Washington State, 1984-1991." J Infect Dis. 1994 Dec;170(6):1606-9.

33. **Samadpour M**, Ongerth JE, Liston J, Tran N, Nguyen D, Whittam TS, Wilson RA, and Tarr PI. "Occurrence of Shiga-like toxin-producing *Escherichia coli* in retail fresh seafood, beef, lamb, pork, and poultry from grocery stores in Seattle, Washington." Appl Environ Microbiol. 1994 Mar;60(3):1038-40.

34. *Morbidity Mortality Weekly Report*. Center for Disease Control. "*Escherichia coli* O157:H7 outbreak linked to commercially distributed dry-cured salami-Washington and California, 1994". MMWR March 10,1994. 44:157-160

35. **Samadpour M**, Grimm LM, Desai B, Alfi D, Ongerth JE, and Tarr PI. "Molecular epidemiology of *Escherichia coli* O157:H7 strains by bacteriophage lambda restriction fragment length polymorphism analysis: application to a multistate foodborne outbreak and a day-care center cluster." J Clin Microbiol. 1993 Dec;31(12):3179-83.

36. Coyle MB, Carlson LC, Wallis CK, Leonard RB, Raisys VA, Kilburn JO, **Samadpour M**, and Bottger EC. "Laboratory aspects of "Mycobacterium genavense," a proposed species isolated from AIDS patients." J Clin Microbiol. 1992 Dec;30(12):3206-12.

37. Duguay SJ, Park LK, **Samadpour M**, and Dickhoff WW. "Nucleotide sequence and tissue distribution of three insulin-like growth factor I prohormones in salmon." Mol Endocrinol. 1992 Aug;6(8):1202-10.

38. Riley DE, **Samadpour M**, and Krieger JN. "Detection of variable DNA repeats in diverse eukaryotic microorganisms by a single set of polymerase chain reaction primers." J Clin Microbiol. 1991 Dec;29(12):2746-51.

39. Stibbs HH, **Samadpour M**, and Ongerth JE. "Identification of *Giardia lamblia*-specific antigens in infected human and gerbil feces by western immunoblotting." J Clin Microbiol. 1990 Oct;28(10):2340-6.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In *Inter Partes* Reexamination of	:	Examiner: Sharon Turner
Mansour SAMADPOUR	:	Group Art Unit: 3991
Patent No.: 7,534,584 B2	:	**Control No.: 95/001,294**
Issued: May 19, 2009	:	

Reexam Request Filed: April 5, 2010

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THIRD-PARTY REQUESTER COMMENTS PURSUANT TO 37 CFR § 41.77 (c) ON THE PATENT OWNER'S REQUEST TO REOPEN PROSECUTION

These Comments are submitted in response to the Patent Owner's Response Pursuant to 37 CFR § 41.77 (b)(1) Requesting Reopening of Prosecution Before the Examiner filed and served February 20, 2015. Accordingly these Comments are timely filed if submitted on or before March 20, 2015. Entry and consideration of these Comments are therefore respectfully requested. It is not believed that any fees are necessary in conjunction with the filing of these Comments; however, to the extent that any fees are deemed necessary, the Commissioner is authorized to charge any required fees to Counsel's Deposit Account Number 02-2135.

National Beef Ex. 1007
Page 1674

Comments on the Claim Amendments

"Operationally-Linked"

Patent Owner has amended claims 1 and 17 to include the limitation "operationally-linked" purportedly to "clarify that the test lots, while separate, are nonetheless operationally-linked during a production run." PO Response at 9. However, the Patent Owner fails to note that as defined in the '584 patent specification test lots are already "operationally-linked." In support for the claim amendment "operationally-linked," the Patent Owner cites to the following passage in the '584 specification:

> The term "test 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 product 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 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.

(Response at 10)(citing application at 8:3-10) (emphasis added). The other portions of the specification cited by Patent Owner in support of the "operationally-linked" amendment also define a test lot as consisting of operationally-linked specimens. *See e.g.,* (Response at 10) (citing application at 11:21-26, "...a test lot...is defined and taken as one or more operationally-linked specimens of a medium or process...") (citing application at 14:4-13, which refers to "operationally-linked portions of production (e.g., test lots...")

(citing application at 14:21, "test lots each comprising an assemblage of one or more operationally-linked specimens ... "). Because the claim term "test lot" is defined as consisting of operationally-linked the specific inclusion of the words "operationally-linked" does not serve to meaningfully limit the claim.

To the extent that Patent Owner asserts that this amendment limits the size of the test lost, then that assertion must fail. As described in the '584 patent specification, the term "operationally-linked" does not have a size component. ('584 patent at 5:21-30). Indeed, as acknowledged by Patent Owner during the hearing, the definition of what constitutes the size of a lot is arbitrary. (Hearing Transcript at 14) (in discussing what defines a test 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). Thus, the claim term as amended does not recite a lot size feature.

"Test Lots of Beef"

The Patent Owner has amended claim 1 to specify "test lots of beef" purportedly to "clarify that the test lots are separate test lots of beef." (Response at 9). This appears to be in response to the Decision on Appeal ("DOA") pointing out that all evidence of commercial success and skepticism that was put forth by the Patent Owner is limited to beef, but the claims are not limited to beef products. (DOA at 24-25). However, this amendment does nothing to establish a nexus between the claimed method and the alleged secondary considerations. For example, although the claim may now be limited to beef products, the amendment does not serve to link the alleged success of the method to a particular step that is not found in the prior art.

Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731, 740 (Fed. Cir. 2013) ("If the feature that creates the commercial success was known in the prior art, the success is not pertinent.") (citing *Ormco Corp. v. Align Tech., Inc.* 463 F.3d 1299, 1311-12 (Fed. Cir. 2006)). It also does not clarify how the claimed method is different from the "classical" method, which is also used on test lots of beef. For these reasons, Requester submits that the claimed method does not alter the DOA's finding that the claims are obvious.

"Tests Lots of Meat or Poultry"

The Patent Owner has amended claim 17 to specify "test lots of meat or poultry" purportedly to "clarify that the test lots are separate test lots of meat or poultry." (Response at 9). The purpose of the amendment again seems to be an attempt to correlate evidence of commercial success to a particular type of food product. However, the amendment fails to provide an adequate nexus for "meat or poultry" for the same reasons discussed with respect to "beef." Moreover, there is even less evidence to support Patent Owner's claims that "meat or poultry" is commercially successful than there is for test lots of beef.[1] The only support for this statement is a conclusory paragraph in the Samadpour declaration that cites to no evidence to support its claims. Such evidence should be accorded little or no weight. *See* MPEP 716.01(c).

Rejection 1 Should Be Affirmed

In its DOA, the PTAB concluded that claims 1 – 4, 6 – 16, 18 – 20, 22, 24 – 27, 31 and 32 are invalid as obvious in view of Jarvis, Price, FSIS and Midura for essentially the same reasons that the Examiner had previously found those claims obvious. (DOA at 3). However, the PTAB interpreted the claims differently from the Examiner, and also combined the Price and

[1] The Patent Owner also appears to define "beef" as a subset of the "meat" category. (Response at 21).

Jarvis references into a single rejection. As a result, the PTAB designated its rejection a new ground of rejection, *i.e.,* Rejection 1. Third-Party Requester respectfully requests affirmance of Rejection 1.

The Patent Owner's Response Fails to Overcome the Basis for Rejection 1.

For ease of reference, the DOA numbered the various limitations of the '584 patent claims. The Patent Owner adopted the notation used by the DOA, and so Requester will also use this notation.

Step (a)(1) is obvious in view of the cited prior art

The DOA defined step (a)(1) as "collecting a plurality of portions from each of a plurality of separate test lots." (DOA at 11). The DOA correctly states that Jarvis and Price both teach collecting a plurality of samples. (DOA at 12 – 13). The DOA notes that Jarvis also teaches a pre-enrichment step that is not recited in claim 1. (DOA at 13). But the DOA also correctly notes that the claimed method uses the open ended term "comprising" and so does not exclude the use of pre-enrichment.

Jarvis and Price Both Teach Multiple Test Lots

The DOA states that neither Jarvis nor Price describes the collection of samples from more than one test lot. (DOA at 13). Requester respectfully disagrees with this interpretation of the references. Both Jarvis and Price teach the use of multiple test lots. With respect to the Jarvis reference, the DOA notes that the Examiner did not provide sufficient evidence that test lots A, B, and C in example 8.4 were used in the same method. (DOA at 13). However, the DOA overlooks the teachings of Jarvis method (2).

Jarvis Example 8.4 describes a method for determining if food product test lots should be accepted or rejected. (Jarvis at 136). In this example, Jarvis states "[s]uppose the following results are obtained on three lots of product." (*Id.*). Example 8.4 then lists theoretical data for each test lot and indicates that a decision to reject the lot, repeat the test, or accept the lot can be made. (*Id.*). Thus, it is clear that the Jarvis reference teaches the testing of a plurality of separate test lots. It is also clear that the test lots were used in the same method, and this is evidenced by Jarvis method (2) in section 8.4.2.1.

Jarvis method (2) involves incubating 10 separate samples in 10 separate pre-enrichment media, and then compositing the pre-enrichment media in an enrichment medium. A negative test on the enrichment medium validates all 10 samples. If the enrichment medium tests positive, then the stored pre-enrichment media can be tested separately "so that some indication of the proportion of contaminated samples can be obtained." (Jarvis at 141-42). If all 10 of Jarvis' samples were from a single lot of food product, then Jarvis' teaching that the stored pre-enrichment media can be tested separately would make no sense, and it would not achieve Jarvis' stated purpose of "reduc[ing] the work load on the laboratory." (Jarvis at 141). *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (noting that in an obviousness analysis it is inappropriate to modify a prior art reference in a manner that leaves it inoperable for its intended purpose); *See also* MPEP 2143.01 (V) – (VI). If any one of the samples from a single lot tested positive for contamination, then the entire lot would have to be destroyed or otherwise disposed of. The more logical reading of Jarvis – and the reading that would be apparent to a person of ordinary skill at the time – is that the 10 samples are from individual lots, such that retesting of individual pre-enrichment media would identify those lots that are contaminated (and thereby must be destroyed) and those that are not.

Importantly, the disclosure of Jarvis Example 8.4 and Jarvis method (2) are found within the same subsection of the Jarvis reference, i.e., section 8.4 "Presence or absence tests based on single or multiple samples." (Jarvis at 135 – 142). A person of ordinary skill in the art would have recognized the relationship between those passages, separated by a mere five pages, that appear in the same section of a textbook devoted to statistical sampling methods for food validation. Thus, a person of ordinary skill in the art would have recognized that the use of separate test lots – specifically mentioned in Example 8.4 – are used in the same method – method (2) so that the stated purpose of reducing the work load can be achieved.

The Price reference also teaches the use of multiple test lots, and interpreting Price differently would defeat the purpose of the enrichment culture pooling procedure of Price. Pooling of pre-enrichment cultures of multiple samples derived from a single lot would be of no value, because a positive result would invalidate the entire lot in any event. Even Patent Owner agrees that a single positive sample would invalidate the entire test lot. (Hearing Transcript at 13) ("Once you have a positive, any positive, that lot is destroyed. It doesn't matter whether one component was positive or 60 out of 60"). However, Price teaches that, if the composited enrichment culture tests positive, then the retained samples are to be tested individually. (*see* Price Fig. 1 and text at 681). Such re-testing would only make sense and would only achieve Price's objective of "saving in the analytical effort required for quality control" (Price at 679) if a negative result on an individual retained culture would allow validation of the test lot from which the sample corresponding to that retained culture was derived. If the enrichment cultures were all derived from the same lot, a positive result for the composited culture would require rejection of the lot, regardless of whether individual pre-enrichment cultures tested negative. Thus, interpreting Price to require that all samples be taken from the same lot would defeat the purpose

of the method and is contrary to its teachings. Moreover, the Price reference would not have been so interpreted by person of ordinary skill.

The DOA is Correct that FSIS and Midura Teach Testing Multiple Test Lots

Setting aside the DOA's finding that Jarvis and Price do not teach testing a plurality of test lots, the DOA correctly finds that collecting samples from a plurality of separate test lots would have been obvious in view of the FSIS and Midura references. (DOA at 13). The DOA correctly states that the term "test lot" is defined in the '584 patent as "an assemblage of one or more specimens of a medium or process ... where the one or more specimens of the assemblage are operationally linked in a matter ..." (DOA at 13) (citing '583 patent, 5:21-28). The DOA also correctly notes that a "test lot can be a single production unit, such as a combo or bin.) (*Id.*) (citing '584 patent, 5:32-36). The DOA then correctly identifies representative disclosures in the FSIS and Midura references that teach step (a)(1). (DOA at 13-14). Requester agrees with the DOA regarding the teachings of FSIS and Midura.

In response, the Patent Owner merely makes a conclusory statement that "sampling in FSIS and Midura is done with respect to single lots that are each to be independently tested with separate assay applications." (Response at 12). In reaching this conclusion, the Patent Owner fails to discuss the FSIS and Midura references, and explain why the DOA is incorrect on this point. As such, the Patent Owner's conclusion should be accorded no weight, and the DOA should be affirmed with respect to the obviousness of step (a)(1).

Step (a)(2) is obvious in view of the cited prior art

The DOA defined step (a)(2) as "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." (DOA at 11). The DOA notes that step (a)(2) involves statistical sampling from a test lot, and correctly found that Jarvis and Midura teach statistical sampling plans. (DOA at 14). The DOA further notes that Patent Owner appeared to concede that statistical-based sampling plans from a test lot were known in the prior art. (*Id.*). The DOA also found Appellant's challenge of the obviousness of using statistical sampling in a method for testing food lots for contamination to be baseless in view of the overwhelming evidence of record. (DOA at 15). Requester agrees with the DOA's assessment.

In response, the Patent Owner first refers to the teaching of the Jarvis reference cited in the DOA in relation to step (a)(1). (Response at 12). Patent Owner argues that Jarvis does not teach sampling from multiple lots, and references Example 8.4 of the Jarvis method. (*Id.*). It is unclear why Patent Owner refers to this section of Jarvis, since it was not cited by the DOA in relation to step (a)(2). As explained above, Requester believes that the Jarvis method does teach sampling from multiple test lots. In any event, Jarvis is also a reference devoted to the teaching of statistical based sampling plans. (*See* Jarvis). Accordingly, Jarvis teaches statistical based sampling plans.

However, despite its unfounded criticism of Jarvis, Patent Owner appears to concede that statistical-based sampling plans were known in the art. (Response at 12-13). Specifically, Patent Owner states that "[t]he DOA ... states that Midura teaches statistical sampling plans, and that the '584 patent teaches sample plans under the guidelines and directives from the USDA and FSIS," and offers no argument to the contrary. Thus, the findings of the DOA should be affirmed with respect to step (a)(2).

Step (b)(1) is obvious in view of the cited prior art

The DOA defined step (b)(1) as "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." (DOA at 11). The DOA finds that Jarvis and Price both teach compositing samples to reduce the number of samples tested. (DOA at 16). The DOA also notes that "it was an art-recognized goal to make food testing more efficient by reducing the number of samples test [sic] to be tested," and this goal was accomplished by pooling. (*Id.*). Finally, the DOA states that "[i]t would have been common sense 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.*). Requester agrees with the DOA on these points. Requester agrees with the DOA that step (b)(1) would have been obvious.

In response to the DOA, the Patent Owner states that "sampling in Jarvis, Price, and Silliker is done with respect to single lots that are each to be independently tested with separate applications..." (Response at 13). Again, Patent Owner merely makes this conclusory statement without any discussion of the references to indicate a rational basis for the conclusion. Accordingly, Patent Owner's statement should be accorded no weight. Moreover, as discussed above, the Jarvis and Price references do disclose testing separate test lots. In addition, the Silliker reference also teaches the use of separate test lots.

Silliker's purpose was to compare various analytical methods for detecting *Salmonella* contamination. The results of this comparison are shown in Table 1. (Silliker at 477). The data in this table explicitly shows that product from different test lots was tested, e.g., Tests 19 – 20, 22 representing fish meal lots 1 – 3. (Silliker at Table 1). Nor can Patent Owner argue that these

tests are serial dilutions of the same test lot, or retesting of the same test lot, because when Silliker does retest the same lot it says so explicitly, e.g., Tests 2 – 4 representing dilutions of the same test lot. (*Id.*).

Setting the disclosures of Jarvis, Price, and Silliker aside, Patent Owner has failed to consider the teachings of FSIS and Midura. As correctly noted by the DOA, both of those references teach the testing of multiple test lots. (DOA at 13-14). Since Patent Owner failed to address the disclosures of those references in any way other than a conclusory statement, the finding in the DOA with respect to those references should be affirmed by the Examiner. Thus, for all of the reasons discussed above, the findings of the DOA should be affirmed with respect to step (b)(1).

Step (c)(1) is obvious in view of the cited prior art

The DOA defined step (c)(1) as "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." (DOA at 11). The DOA also refers to this as the "enrichment step." (*Id.*). Requester respectfully submits that step (c)(1) should not be interpreted as requiring enrichment media.

Enrichment Media is Not Required for the Target Agent to Reach Detectable Levels

The language of step (c)[2] provides that the purpose of the step is "to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples

[2] The DOA addresses this step in the context of claim 1, but also notes that similar language is recited by claim 17. DOA at 6. These Comments adopt the DOA's approach of referring only to claim 1, but notes that comments made with respect to claim are equally applicable to claim 17.

to reach detectable levels..." '584 patent, claim 1. Modern diagnostic methods such as PCR are capable of detecting the target organism at levels as low as one organism. The Berri reference previously submitted by the Requester and considered by the Examiner exemplifies this method. Berri discloses the detection of a single *C. burnetii* cell in 1 mL of liquid. (Berri at 292). Berri's detection method involves the use of common laboratory techniques, such as PCR, that are equally applicable to any DNA-containing sample. (*Id.*). Thus, even in the most extreme case, where only a single organism is present in the sample, the bacteria may be present in detectable levels within the meaning of the '584 patent claims without requiring the use of enrichment media. In addition, as stated in Dr. Bailey's Declaration it was well known that pre-enrichment media would both resuscitate the target microorganism and cause it to grow to detectable levels and become substantially uniform within the liquid pre-enrichment culture. (Bailey Dec, ¶9d). This evidence was not rebutted. Accordingly, Requester maintains that this step is satisfied by pre-enrichment media, and does not require enrichment media.

The Claims Do Not Exclude a Pre-Enrichment Step

The DOA is also correct that the claim does not exclude a pre-enrichment step, and that direct enrichment is also taught in the Price and Gabis references. (DOA at 17). In response to the Patent Owner's argument that direct enrichment was disfavored, the DOA points out that "[e]ven if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use would render the result inoperable." (*Id.*) (internal citation omitted). Accordingly, Requester agrees that step (c)(1) is obvious in view of the prior art.

The Patent Owner Fails to Rebut the DOA's Findings

In response to the DOA, the Patent Owner asserts that "Gabis and Price would suggest to one of skill in the art that direct enrichment could only be used in the context of non-lumped/non-composited samples." (Response at 13). With respect to Gabis, the Patent Owner cites a sentence in the abstract that states "in the analysis of lumped subsamples, direct enrichment resulted in a significantly lower rate of recovery than preenriched subsamples." (*Id.*). However, Patent Owner fails to acknowledge that even if the direct enrichment step produces a lower rate of recovery, it still results in the detection of salmonellae. (Gabis at 668) (noting that pre-enrichment resulted in 50.2% of the samples testing as positive, whereas direct enrichment resulted in 34.1% of the samples testing positive.). In other words, it does not render the result inoperable.

With respect to the Price reference, the Patent Owner repeats the same unpersuasive argument that Price teaches away from using direct enrichment with lumped samples because it may create a "background problem" with other flora present in the sample. (Response at 14). Patent Owner's interpretation of this passage is incorrect. In the Patent Owner cited passage, Price cautions against the lumping of many separate test lots into a single pre-enrichment culture. However, that is not what Price is discussing while suggesting direct selective enrichment media may be used. In teaching the use of direct selective enrichment, Price 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. Price also makes clear that the samples incubated in each individual jar should be drawn from same individual test lots. (Price at 681). In other words, Price teaches that samples from separate test lots should not be mixed in an

initial composite sample – which is precisely what Patent Owner contends is required by the claims. Therefore, Price does not teach away from using selective enrichment media by incubating in a lumped sample as the Patentee suggests.

The Patent Owner also overlooks that the claim does not exclude the use of a pre-enrichment step. Accordingly, both references, which teach the pre-enrichment of lumped samples followed by direct enrichment, render the step obvious.

The Patent Owner also argues that "regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols of Gabis) would in fact lead to false negatives, which would render such lumped/direct enrichment detection methods inoperative in the food industry..." (Response at 14). The Patent Owner supports this statement by reference to the Declaration of Mansour Samadpour. Leaving aside that the claims are not limited to such regulatory requirements, the declaration itself cites to no authority for this position. Instead, the declaration merely repeats the same self-serving statement as reflected in the Response. Such statements should be accorded little or no weight. *See* MPEP 716.01(c).

The Patent Owner's position also overlooks that modern diagnostic methods, such as the PCR method taught in the Berri reference, are capable of detecting even a single organism in a sample. (Berri at 292). In view of such methods, there is no danger in any perceived loss of sensitivity caused by lumping as argued by the Patent Owner. Indeed, the Entis reference teaches that although direct detection without the need for an enrichment step is possible with PCR based methods, "a preliminary enrichment culture step to increase target levels is common

in PCR detection protocols." (Entis at 94). Thus, Patent Owner's concerns are unfounded, and finding of the DOA with respect to step (c)(1) should be affirmed.

Step (d)(1) is obvious in view of the cited prior art

The DOA defines step (d)(1) as "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample." (DOA at 11). The DOA asserts that neither Jarvis nor Price teach compositing samples from different enrichment samples, which themselves have been composited. (DOA at 18). Requester submits this assertion is based on the incorrect finding that neither Jarvis nor Price teach the testing of multiple test lots. As addressed above in connection with step (a)(1), the Jarvis and Price references both teach the testing of multiple lots, and so Jarvis and Price also teach compositing samples from different enrichment samples, which have themselves been composited.

Moreover, the DOA correctly finds that the requirement of step (d)(1) is obvious in view of the cited prior art. (DOA at 17-18). The DOA concludes that Jarvis teaches methods of compositing pre-enrichment and enrichment samples that attain the "same degree of statistical significance." (DOA at 17) (citing Jarvis at 141). The DOA further notes that Jarvis discloses that compositing samples reduces the workload on the laboratory, and that Price contains a similar teaching. (DOA at 17). Based on these disclosures, the DOA correctly finds that "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. (DOA at 17-18). In addition, "it would have been reasonably expected that pooling samples at two different steps ... would have the requisite sensitivity in detecting positives for contamination." (DOA at 18). Finally, the DOA correctly concludes that "compositing in two stages as described in Jarvis provides the motivation to have

carried out the second compositing step recited in step d1." (DOA at 18-19). Thus, Requester agrees that step (d)(1) is obvious in view of the prior art.

In response, the Patent Owner first argues that Jarvis does not teach compositing both pre-enrichment and enrichment samples. (Response at 15). In doing so, Patent Owner appears to concede that Jarvis method (3) does in fact teach two compositing steps as was noted in the DOA. (*Id.*) Specifically, the Patent Owner notes that "5 of the individual pre-enrichment cultures are combined into a first combined pre-enrichment culture, and the other 5 of the individual pre-enrichment cultures are combined into a second combined pre-enrichment culture, then aliquots of the first and the second combined pre-enrichment cultures are combined at the point of inoculating the enrichment medium." (*Id.*). Thus, according to Patent Owner, the first compositing step involves compositing samples into a pre-enrichment culture, and the second involves taking those composited pre-enrichment cultures, and compositing them into an enrichment culture. Thus, Patent Owner agrees that the Jarvis reference teaches compositing at the pre-enrichment stage and the enrichment stage –as was found in the DOA.

Patent Owner did not address the DOA's finding that Price also teaches testing pooled enrichment samples. (DOA at 18). Figure 1 of Price clearly teaches compositing samples at the enrichment stage, and subsequently testing them. (Price at Fig. 1). Accordingly, the Price reference further buttresses the conclusion that step (d)(1) was obvious.

The Patent Owner devotes the majority of its discussion of step (d)(1) to argue against a motivation to combine enriched samples corresponding to separate test lots. (Response at 15-18). As an initial matter, neither the Response nor the Samadpour declaration cite to any evidence to

support the conclusory statements they contain. Thus, these statements should also be accorded little or no weight. *See* MPEP 716.01(c).

In addition, Patent Owner's arguments with respect to lack of motivation fail to take into account the teachings of Jarvis and Price to reduce workload. Instead, the Patent Owner simply argues that "there is certainly no motivation in the art for compositing samples from different enrichment samples, which themselves have been composited from different separate test lots." (Response at 16). This argument is nothing more than a rehash of Patent Owner's previously asserted position that the prior art does not teaching testing multiple separate test lots. However, the DOA correctly found that both Midura and FSIS teach multiple test lots. (DOA at 13-14). As noted above, the Patent Owner's only response to this finding was to assert – without explanation – that FSIS and Midura only involve single lot testing. (Response at 12). This conclusory statement should be accorded no weight, and the DOA's finding in this regard should be affirmed. Because the prior art clearly taught the use of multiple test lots, Patent Owner's assertion that there was no motivation to composite samples from multiple test lots should be disregarded for the reasons given above.

In addition, the Patent Owner fails to address in any way the DOA's finding that "it would have been reasonably expected that pooling samples at two different steps ... would have the requisite sensitivity in detecting positives for contamination." (DOA at 18). Indeed, the Jarvis reference makes it clear that compositing at two different stages as done in method (3) results in the same degree of statistical significance. (Jarvis at 141). Accordingly, this conclusion is unrebutted, and should be affirmed.

Steps (e)(1) and (e)(2) are obvious in view of the cited prior art

The DOA defines step (e)(1) as "testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism." (DOA at 12). The DOA correctly concludes that this testing is taught by Price and Jarvis. (DOA at 19). With respect to step (e)(2), the DOA defines it as "when testing is 'negative,' all of said separate test lots are validated for release into commerce." (DOA at 12). The DOA also found that this testing is disclosed in the Jarvis and Price references, because they will also obtain negatives. (DOA at 19). Requester agrees with the DOA that this step is disclosed in the prior art.

The DOA has interpreted step (e)(2), which uses the term "validate" to be a mental step. Specifically, the DOA notes that the patent does not define "validate" to require a physical or manipulative step. *Id.* Instead, the patent defines "validate" or "validation" as "determining that a particular sample tests negative using [a] detection assay." DOA at 10 (citing '584 patent at 7:1-10). As a result, the DOA interprets "validate" in accordance with its broadest reasonable interpretation 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." DOA at 10. Requester agrees with this interpretation, and agrees that use of the term "validate" does not limit the claim.

Patent Owner disagrees and asserts that validation "is not a mental step, it is a physical assay/testing step of the modular composite sample." (Response at 18). However, the Patent Owner did not make any amendments to the claim to require a physical step, and, as noted in the DOA, the '584 patent does not define the term to require a physical step. (DOA at 10). Accordingly, the Patent Owner's argument must fail in this regard, and as such the term

"validate" does not limit the scope of the claim. Accordingly, the DOA's findings with respect to step (e)(1) and (2)(2) should be affirmed.

Step (e)(3) is obvious in view of the cited prior art

The DOA defines step (e)(3) as "when 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 of step c." (DOA at 12). The DOA correctly concludes that Jarvis teaches in method (2) "the concept of testing composited samples as in step e1 and going back to the sample before compositing as in step e3." (DOA at 19). Accordingly, the DOA correctly found that "it would have been obvious to one of ordinary skill in the art to have saved the samples prior to compositing and then to return to them, if the composited sample tests positive in order to determine which samples were positive." (*Id.*). The DOA also notes that the Price reference teaches this same step in Figure 1. (DOA at 20). Requester agrees this step is disclosed in the cited references.

In response the Patent Owner repeats its previous argument that Jarvis only discloses using a single test lot. (Response at 19). As addressed above, Requester disagrees that Jarvis (and Price) only teach a single test lot. Nonetheless, the use of multiple test lots are clearly disclosed by the FSIS and Midura references. To the extent the Patent Owner argues that the stored samples in Jarvis will not produce a statistically significant result, this is patently false. Both the Jarvis reference and the Midura reference are devoted to statistical sampling methods, and thus those references would have taught the taking of sufficient samples so that each separate test lot could be "validated."

The Samadpour Declaration Fails to Overcome the Obviousness Rejection

Throughout the course of the reexamination, Patent Owner submitted numerous declarations alleging that secondary considerations of commercial success and skepticism in the field weigh against a finding of obviousness. The DOA addressed this evidence, and correctly found that it was lacking. (DOA at 23-25).

There is no nexus between the claimed method and commercial success

With respect to commercial success, the DOA concludes that although Patent Owner provided data indicating its claimed method showed an increase in revenue over the "classical" method, the Patent Owner did not provide an adequate explanation of the "classical" method so that the differences between the two could be understood. (DOA at 23-24). The DOA specifically notes that it was unable to determine whether the claimed success was due to a specific feature of the claimed method, or whether it resulted from another step that was readily available in the prior art. (DOA at 24).

In response, the Patent Owner seems to argue that the distinction between the two methods is that "the classical approach did not simultaneous [sic] assay multiple operationally-linked production lots, but rather assayed a single production lot," but the claimed method uses a "modular compositing approach (at least steps (c) through (e)) for simultaneously assaying multiple independent, operationally-linked lots in one application of the method..." (Response at 20). But this argument overlooks that the prior art taught these steps.

As detailed in the DOA, the Midura and FSIS references (and Jarvis and Price) taught that statistically significant samples from multiple test lots should be collected. (DOA at 12 – 15). The Jarvis and Price references taught that the collected samples can be composited in order

to reduce the workload on the laboratory. (DOA at 15-16). The DOA also finds that the claims do not exclude a pre-enrichment step, so that even if the DOA's interpretation of step (c) is affirmed that step is obvious in view of the prior art. (DOA at 17). The Jarvis and Price references also teach the testing of pooled enrichment samples. (DOA at 18). In addition, these references also teach compositing in two stages (Jarvis at 141 (method 3)), and the Patent Owner apparently agrees that Jarvis teaches a two-tiered compositing step. (Response at 15). Finally, the validation steps recited in step (e) do not limit the claim because they recite a mental step. (DOA at 19). Moreover, the Price and Jarvis references both teach retaining stored samples for the purpose of retesting in the event of a positive test results. (DOA at 19-20). Accordingly, the Patent Owner's claimed method is simply an aggregate of steps that were known in the prior art. Thus, the Patent Owner cannot show that any commercial success was due to a particular feature of the claimed method that was not independently known in the art.

The Patent Owner also cites to the Samadpour Declaration as evidencing alleged commercial success of the method across a range of food products. (Response at 21). As previously noted, the Samadpour Declaration contains citation to no evidence to support its claims, and thus should be accorded little to no weight. *See* MPEP 716.01(c). Moreover, the Patent Owner has amended the claims to exclude food products except for beef, meat or poultry. (Response at 9). Thus, any alleged evidence of commercial success that may result from application of the method to lots of fresh agricultural commodities, agricultural seeds, dried foods, pet foods, baked goods, processed meats, fermented foods, dairy products, nuts, nut butters, trail mixes, compost, organic fertilizers, seafood, energy bars, cereals, sponge, and swap samples taken from food and food production environments is irrelevant. (Response at 21).

Accordingly, the Patent Owner has failed to show there is a nexus between any alleged commercial success and the claimed method.

The Claims Are Not Limited to a Particular Lot Size

The DOA also address various arguments that were made by Patent Owner that "lot sizes are smaller in the claimed method than in the prior art and 'classical' method." (DOA at 24). Specifically, the DOA holds that "the claims are not limited to a lot of a particular size," and "if [that] is a basis for patentability, the feature is not recited in the claim." (DOA at 25). Accordingly, there is no nexus between the claim and the secondary consideration proffered by the Patent Owner. (*Id.*).

In response, the Patent Owner argues that amending the claim to recite "operationally-linked" solves this problem. (Response at 22). But Patent Owner is incorrect. As discussed above with respect to this claim amendment, the term "operationally-linked" does not connote a lot size. Rather it refers to a proximity, time, or processing step. ('584 patent at 5:27-28). Moreover, the definition of test lot set forth in the '584 patent already notes that the specimens in a test lot are operationally-linked. ('584 patent at 5:21-30). Accordingly, the addition of the words "operationally-linked" does not meaningfully limit the claim, and the claim is still not limited by a particular lot size.

Modification of the Claimed Method to Gain Acceptance Nullifies Any Nexus Between the Claims and Evidence of Secondary Considerations

The DOA also addressed the allegations that the Patent Owner had to overcome skepticism in the field to convince FSIS to accept the claimed method. (DOA at 25). Specifically, the DOA noted that Patent Owner testified that in order to convince FSIS to accept the method, the Patent Owner had to modify his protocol to test individual enrichment

component samples separately, even when the claimed modular composite sample was negative. (*Id.*). Because the method responsible for the increased market share requires testing each individual test lot separately regardless of whether the modular composite sample tests negative or positive, the DOA found that the Patent Owner had failed to establish that the modular composite sample testing is responsive for the claimed commercial success. (*Id.*). Requester agrees with the DOA's assessment of the flaws in the Patent Owner's alleged evidence of secondary considerations. In particular, Requester agrees that the Patent Owner has failed to establish a nexus between any supposed secondary considerations and the claimed methods.

In rebuttal to the DOA's finding that in order to gain acceptance of the claimed method the protocol was modified to require testing individual enrichment samples even with the modular composite sample tested negative, the Patent Owner asserts the extra step is only necessary in certain instances where the separate individual lots to build the modular composite sample are sold to different entities. (Response at 23). Again, the Samadpour Declaration cites to no evidence to support this position. *See* MPEP 716.01(c). Moreover, even taking as true that the extra step is only needed in certain instances, the fact remains that the extra step is still needed. Accordingly, a nexus between the claimed method and any alleged secondary considerations has still not been established.

Rejections 2 – 4 Should Be Affirmed

The PTAB affirmed Rejections 2 – 4 (covering dependent claims 5, 6, 21, 23, 24, 28 – 30, 32, and 33) because the Patent Owner made the same unpersuasive patentability arguments for these Rejections as it made for Rejection 1. DOA at 26. In its Response, Patent Owner has not argued these Rejections separately, and instead relies on the arguments it made in relation to Rejection 1. Response at 23-24. Because those arguments fail to overcome Rejection 1, and

Patent Owner has set forth no additional argument to overcome Rejections 2 – 4, the Examiner should also maintain the PTAB's rejections under Rejections 2 – 4.

Conclusion

In view of the above comments, it is respectfully requested that the PTAB's Rejections 1 – 4 be affirmed.

Date: March 20, 2015

Respectfully submitted,

By: _____
E. Anthony Figg
Reg. No. 27,195

Rothwell, Figg, Ernst & Manbeck
1425 K. Street, N.W., #800
Washington, D.C. 2005
(202) 783-6040

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 06/05/2015

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
06/05/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMÉRIEUX, INC.
Requester and Respondent

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH INC.
Patent Owner and Appellant

Appeal 2014-007983
Reexamination Control 95/001,294
Patent 7,534,584 B2
Technology Center 3900

Before RICHARD M. LEBOVITZ, *Administrative Patent Judge*.

LEBOVITZ, *Administrative Patent Judge*.

ORDER REMANDING INTER PARTES REEXAMINATION
UNDER 37 C.F.R. § 41.77(d) TO THE EXAMINER

Patent Owner requests reopening of prosecution under 37 C.F.R. § 41.77(b)(1) (Request to Reopen Prosecution Before the Examiner, filed February 20, 2015) ("Request") in response to the PTAB ("the Board") Decision on Appeal entered January 20, 2015 ("DOA") in which Rejections 1, 2, 10, 11, 13, and 14 were affirmed, but designated as new grounds of rejection because the Board's

claim interpretation and application of the cited prior art differed from the Examiner's. The Requester filed comments pursuant to 37 C.F.R. § 41.77(c) on Patent Owner's Request ("Comments," dated March 20, 2015).

PATENT OWNER'S REQUEST

37 C.F.R. § 41.77(b)(1) states:

> The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected or both.

Claims 1 and 17

1) In the Request, Patent Owner proposes to amend independent claims 1 and 17 by reciting that the test lots are "beef" and "meat or poultry," respectively. Request 9. These amendments directly address the discussion of secondary considerations in the DOA in which the Board noted that the rejected claims were not limited to meat. DOA 24.

2) Patent Owner also proposes to amend claims 1 and 17 to recite that the lots are "operationally-linked" to clarify that the test lots are operationally-linked during a production run. Request 9. This amendment is responsive to statements in the DOA on page 18 about compositing enriched samples.

In sum, because Patent Owner's proposed amendments to claims 1 and 17 relate to the claims so rejected by the Board under 37 C.F.R. § 41.77(b) and otherwise comply with the requirements of 37 C.F.R. § 1.530, the amendments to the claims are entered.

Claim 32

Patent Owner proposes to amend claim 32 by making it dependent on claim 1 and limiting it where the beef specimens are meat rim pieces. The proposed amendment relates to the claims so rejected and thus will be entered.

Declaration

Patent Owner provides a new Declaration by Dr. Mansour Samadpour (Exhibit Z) said to specifically address particular issues raised and discussed in the DOA. Request 2. Our review of the declaration finds it consistent with Patent Owner's characterization of it as a rebuttal to issues discussed in the DOA concerning the claims so rejected. Accordingly, Exhibit Z will be entered.

Remand

The case is remanded to the Examiner for a determination pursuant to 37 C.F.R. § 41.77(d). Under 37 C.F.R. § 41.77(d), the Examiner is to consider Patent Owner's Request and Requester's Comments and issue a determination as to whether the Board's new grounds of rejection as designated in the Decision have been overcome. Following the Examiner's determination, the proceeding will be returned to the Board together with any comments and reply submitted by Patent Owner and/or Requester under 37 C.F.R. § 41.77(e) for reconsideration and issuance of a new decision by the Board as provided by 37 C.F.R. § 41.77(f).

It is ORDERED that Patent Owner's Request to reopen prosecution before the Examiner is GRANTED, and the proceeding is hereby remanded to the Examiner for a determination pursuant to 37 C.F.R. § 41.77(d).

GRANTED

Patent Owner:

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, WA 98101-3045

Third Party Requester:

ROTHWELL, FIGG, ERNST, & MANBECK, P.C
607 14th Street, N.W.
Suite 800
Washington, DC 20005

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 07/20/2015

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
07/20/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Transmittal of Communication to Third Party Requester *Inter Partes* Reexamination	Control No.	Patent Under Reexamination	
	95/001,294	7534584	
	Examiner	Art Unit	
	SHARON TURNER	3991	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th Street, N.W.
Suite 800
Washington, D.C. 20005

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination prceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

Inter Partes Reexamination: 41.77(d) Determination

Prosecution History

The Decision by the Patent Trial and Appeal Board (PTAB) dated 1/20/15 is noted.

The Decision sets forth new grounds of rejection as summarized at 1/20/15 pp. 3-4.

41.77(c) Submissions and Evidence

Patent Owner's request to reopen prosecution was received 2/20/15. The request is accompanied by claim amendments, argument and a further declaration of Dr. Mansour Samadpour.

Requester's comments were received 3/20/15.

Consistent with the Remand by the PTAB mailed 6/5/15, the above submissions have been entered and fully considered.

Grounds of Rejection set forth by the PTAB

The following grounds of rejection were set forth in the 1/20/15 Decision (summarized II., pp. 3-4) (detailed reasoning IV., Ground 1, pp. 10-20), (VI., Grounds 2-4, p. 26).

1. Claims 1-4, 6-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, and Midura.

2. Claims 5, 6, 23, 29, and 30 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Entis.

3. Claim 21 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Cousin.

4. Claims 24, 28, 32, and 33 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, FSIS, Midura, and Gabis.

Claim Amendments

Claim 1 is amended to specify test lots, "of beef," and claim 17 is amended to specify test lots, "of meat or poultry."

Claim 1 and 17 are further amended to recite within the preamble, "operationally-linked test lots," and within step a), "operationally-linked single-unit production lots."

Claim Interpretation

The claim interpretation of the 1/20/15 Decision, particularly pp. 9-10 is adopted.

The term, "test lot," is defined within the '584 patent as follows.

Description Paragraph - DETX (4):
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.

The amendment to claim 1 specifies the test lots as beef, and claim 17 specifies the test lots as meat or poultry.

While claim 1 refers to, "operationally-linked," test lots throughout, claim 17 refers to, "operationally-linked," test lots within the preamble, but in the body of the claim this element is referred to as, "operationally-linked single-unit production lots."

The term, "single-unit production lot," is defined and utilized within the '584 patent as follows.

Description Paragraph - DETX (5):
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).

The term, "operationally-linked," is not defined, but it is utilized within the '584 patent as follows.

Description Paragraph - DETX (20):
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.

Description Paragraph - DETX (28):
The methods of the present invention provide substantial economic savings to the food and pharmaceutical industries, because of the precision in detecting in the context of operationally-linked portions of production (e.g., test lots; single production units; single-unit production lots) which are contaminated. The inventive methods prevent unnecessary destruction of negative lots that are condemned because of guilt by association (e.g., simply because they were grouped with a contaminated composite prior art multiple production unit lot in a prior art testing protocol). Where a positive finding is obtained, a smaller quantity of material is diverted to an economically undesirable end use. The proposed invention has substantial utility (e.g., bringing savings, accuracy and precision in pinpointing problems) in the environmental industry.

Description Paragraph - DETX (31):
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; incubating the set of test lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched test lot samples; removing, aseptically, equal portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all test lot samples are validated, and wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

Description Paragraph - DETX (32):
In particular aspects, the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof. In particular aspects, the test lot is a single-unit production lot, comprised of operationally-linked product specimens. In particular aspects, product specimens are synonymous with product portions. In particular aspects, the methods further comprise incubating the modular composite sample prior to testing it. In particular aspects, incubating each test lot sample comprises adding an amount of enrichment medium to the sample, and removing enriched sample portions comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample. In particular aspects, testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

Description Paragraph - DETX (64):
Sterility testing of food and pharmaceuticals, or purity testing of fermentation processes often involves compositing a number of samples to form a composite test lot. Detection of microbial contamination in the composite sample, as discussed in detail herein above, results in rejection of the whole production. Practically speaking, often a pinpoint contaminant enters production at a given time point, and then clears within a few minutes. Aspects of the present invention allow for identifying the time of entry, and informed elimination of products (operationally linked test lots) flanking the contamination event.

Description Paragraph - DETX (67):
In the context of environmental monitoring, when several samples (water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids) are composited and subjected to enrichment, followed by testing to detect environmental contamination, the current invention allows for pinpointing the test lots (e.g., operationally-linked unit(s)) that are positive for the microbe of concern.

Patent owner asserts (2/20/15 p. 9) that the changes, "clarify that the test lots, while separate, are nonetheless operationally-linked during a production run, and imply (2/20/15 p. 22) that the terms clarify the invention with respect to (smaller) lot sizes.

Requester asserts (3/20/15 p. 2) that test lots as defined in the '584 patent are already operationally-linked, and therefore (3/20/15 p. 3) the limitation does not serve to meaningfully limit the claims, particularly with respect to size.

The definition of 'test lot' and 'single-unit production lot' are delineated above as set forth in the '584 patent. This guidance describes a system for testing lots by collecting samples, portions or specimens such that the test results may be linked to the originating lot, thereby giving information about the lot. While the specification discusses the characteristics of samples, portions, specimens and/or lots particularly with respect to proximity, time and process step, the specification does not limit the samples, portions, specimens or lots by number or size. Accordingly, while the claim limitation operationally-linked test lots, or operationally-linked single-unit production lot clarify that the samples, portions or specimens are collected in a manner that preserves the linkage of production processing information (for example with respect to proximity, time, and/or process step) to the respective originating lot, the limitation does not serve to limit the samples, portions, specimens or lots with respect to any particular number and/or size.

Declaration of Mansour Samadpour (Exhibit Z)

The declaration of Mansour Samadpour submitted 3/20/15 has been entered and fully considered but is not persuasive and fails to overcome the obviousness rejection set forth by the Board. The declaration is further addressed below.

Response to Argument

The 1/20/15 Decision at pp. 11-12 outlines the claim limitations with respect to the separate element steps. Patent owner and Requester adopt this delineation and address the claim elements in the same manner.

With respect to element a1), Patent owner and Requester raise the issue of whether the prior art adequately renders obvious the collecting step from a plurality of separate (multiple, additional) test lots.

Patent owner argues (2/20/15 p. 12) that FSIS and Midura only sample single lots for independent testing and do not teach the concept of processing multiple lots. The Samadpour declaration states that the cited art, "pertains to sampling of a single lot of food or serial application of the respective methods to additional single lots…," (¶8).

Requester argues (3/20/15 p. 5-8) that in contrast to the 1/20/15 Decision, both Jarvis and Price teach testing multiple lots and also agree with the 1/20/15 Decision that FSIS and Midura render obvious testing multiple lots

The statements in the Samadpour declaration noted above is taken as an admission that element a1) is met. The serial testing of additional single lots adequately acknowledges the concept of testing of additional lots or multiple separate lots as was well recognized in the art. For example, Midura (p. 13) explains the objective and general considerations for submitting samples of a food lot to a lab for testing, and include distinguishing the lot by pertinent

information such as lot number, date, place, and time of collection which elements are critical in any chosen sampling plan (Midura pp. 14-15), with the ultimate goal being accepting or rejecting any defective lot(s) being tested (Midura pp. 16-23).

With respect to the claim amendments it is further noted that FSIS is additionally on point to beef (meat) samples taken during an operationally-linked production run, in particular the procedures notes sampling under a, "Randomized or Representative Sampling," procedure based on either, "1. Time: Throughout the production lot," or, "2. Space: At or toward the end of the production lot." (FSIS p. 27). Implicit in the, "FSIS Directive," issued by the United States Department of Agriculture Food Safety and Inspection Service is the practice of the disclosed procedure for any and all lots of, "RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENETS AND BEEF PATTY COMPONENTS," entering the market. Moreover, Midura is also on point to microbiological testing of different food lots and such testing is indicated for sampling (p. 16 col. 1) raw and processed meats (p. 18 col. 1), and specifically in testing for *E. coli* contamination (p. 19 col. 1) as in the FSIS testing of beef production lots. Midura also adequately teaches the considerations for operationally-linked lots, particularly the variables of proximity, time and process step within the development of representative sampling plans for testing different lots (p. 14 col. 2-p. 16 col. 1). Accordingly, the examiner agrees that the rejection set forth in the 1/20/15 Decision adequately renders obvious element a1).

Regarding a2) requiring sampling from each lot according to a statistically based sampling plan, Patent Owner argues (2/20/15 p. 12) that Jarvis at p. 136-137 only talks about taking a single sample from each of lots A, B, and C, and processing them independently using

MPN methodology whereas Midura and the '584 patent teach such statistically based sampling plans consistent with the guidelines and directives from the USDA and FSIS.

Requester in contrast agrees (3/20/15 p. 9) that the Decision correctly found statistical sampling in Jarvis and Midura and that such was conceded by Patent Owner.

The Examiner also agrees with the basis set forth in the 1/20/15 Decision that Jarvis, the '584 patent, Midura and FSIS acknowledge statistically based sampling plans including as noted above for a1) testing beef production lots (FSIS) and raw and processed meats for E. coli or other pathogens (Midura).

Regarding b1), this step requires combining the a1) portions to form a set of separate test lot samples, which the 1/20/15 Decision notes is taught in Jarvis and Price. Patent Owner argues (2/20/15 p. 13) that such sampling in Jarvis, Price (and Silliker) is with respect to single lots to be independently tested with no teaching of the concept of the modular composite sample. Patent Owner's modular composite sample is however the subject of step d1) and thus this argument is misplaced.

Requester agrees with the 1/20/15 Decision noting Jarvis and Price teach pooling thereby motivating the artisan to combining samples for example from different bins representative of the lot. This is essentially the practice taught in the FSIS sampling plan to form a set of combined portions representative of the lot of beef from the production run. It is also agreed that Jarvis and Price teach such combining for the benefit of reducing the number of samples required to be tested for any lot. Moreover as noted in the 1/20/15 Decision, these references with the teachings of FSIS and Midura render obvious combining such collected portions for testing multiple different lots.

Step c1), as interpreted by the 1/20/15 Decision pp. 9-10, is an enrichment step and not a pre-enrichment step. The Decision notes that Jarvis teaches pre-enrichment then combining portions of the pre-enrichment broth for incubation in enrichment broth, while Price also teaches compositing samples and an enrichment step. The 1/20/15 Decision determined that Jarvis and Price with FSIS and Midura render obvious step c1), incubation testing of separate test different test lot samples.

Patent Owner argues (2/20/15 p. 13) the art teaches that direct enrichment can only be used in the context of non-lumped/non-composited single samples, as direct enrichment of lumped samples reduces recovery (referring to Gabis and Price). Patent owner additionally argues (2/20/15 p. 14) that the Samadpour declaration (¶9-10) notes that food regulatory methods require testing able to detect a single organism and that any loss in sensitivity would render the detection method inoperative (referring to Gabis and Price) and thus teach away from lumped direct enrichment cultures.

Requester argues (3/20/15 pp. 11-12) that the incubating step is under conditions suitable to allow levels of target microbial agent or organism to be detectable and uniform or substantially uniform, and does not require enrichment media (arguing that the pre-enrichment culture is sufficient for detection and to achieve substantial uniformity). Requester also argues that the claims do not exclude pre-enrichment. Further, while Gabis notes a lower rate of recovery in lumped direct enrichment samples, (particularly in tetrathionate vs. selenite Tables 1-2), Requester notes that this method (as is claimed) nonetheless still detects contamination, and thus is not inoperative.

The results of different sample testing for detection of Salmonella is taught in Tables 1-2 of Gabis. Such variable testing would be well recognized by the artisan based upon the different samples to be tested, the subject organism to be detected and other variables such as media, culture conditions, optional pre-enrichment and/or direct enrichment procedures as well as detection methods such as optical density, streak plates, slide agglutination or other methods for detection including as noted by Requester (3/20/15 p. 14), detection by PCR (Berri p. 292). Gabis teaches that inclusion of the pre-enrichment step increases the number of samples testing positive, an improvement of the supposed direct enrichment procedure. In addition Gabis indicates that analysis of a single lumped 325 g pre-enriched subsample was as efficient in the recovery of salmonellae as the analysis of thirteen 25 g pre-enriched subsamples. The reference concludes that for detection of Salmonella, pre-enrichment of high-moisture foods is recommended over direct enrichment (Discussion p. 668). Gabis' testing is of frozen raw products of skeletal meat obtained from human food processors, including poultry, eggs, beef, pork, hog, chicken, and egg albumen.

As noted in the 1/20/15 Decision, the presence of such pre-enrichment procedures is not precluded. Moreover, the fact that the pre-enrichment cultures are subsequently transferred for enrichment confirms that the claim limitations are met, the portions merely being combined in a different way prior to the incubation step. Thus, the testing alternatives in Gabis do not teach away. Indeed Gabis concludes that the results clearly indicate that lumping 25-g subsamples is as sensitive as the analysis of individual 25 g subsamples (Discussion p. 668 col. 1). The artisan with knowledge of such alternative testing procedures would incorporate such steps for example where contamination detection was deemed more critical than cost.

Price pools multiple pre-enrichment broth cultures into single enrichment broths and specifically compares the pooled samples vs. the pooled pre-enrichment broths. Price shows that a higher number of positives were recovered by pooling pre-enrichments rather than by pooling samples (p. 679-681). In addition, pooling pre-enrichment broth cultures permits small portions of each individual culture to be retained for subsequent testing in the event of positive samples, whereas pooling of food samples results in the loss of individual identity. Price recommends when numerous interfering organisms are present, that retained pre-enrichment cultures be tested or alternatively the use of direct selective enrichments, two selective enrichments or reduced incubation in pre-enrichment broth (Price 681-682). Such alternatives were well within the skill of the artisan based upon the samples tested, the organism to be detected, the presence or absence of other organisms as well as the media and testing procedures utilized.

Accordingly, Gabis and Price do not teach away from the claimed procedures, but instead motivate to such alternative testing procedures when warranted, to increase sensitivity of detection and/or reduce testing costs. Consistent with the 1/20/15 Decision, the claims do not preclude the additional step of pre-enrichment cultures, nor do they teach away from the prior art procedures of incubating or enriching a set of separate test lot samples as taught by Jarvis, Gabis and Price. Such compositing steps and advantages are art acknowledged testing procedures.

Step d1) recites removing portions each of the separate test lot samples and combining the removed portions to provide a modular composite sample. The 1/20/15 Decision notes that Jarvis teaches combining both pre-enrichment and enrichment samples, similar to the pooling of samples in Price to reduce workload, increase testing capacity and also to preserve individual portions representative of the originating individual samples identity for subsequent testing (p.

681). These teachings render obvious the (second) combining step of element d1) particularly as the artisan would have a reasonable expectation that pooling at two different steps would have the requisite sensitivity in detecting contamination.

Patent Owner disputes (2/20/15 p. 15-16) that Jarvis teaches compositing pre-enrichment and enrichment samples and argues that the reference fails to motivate the artisan to combine such samples as in d1) to reduce workload. Patent Owner also argues (2/20/15 p. 16-18) that there was counter-motivation in the art as supported by the Samadpour declaration (¶11), which attests that the art widely (and incorrectly) assumed that contamination was uniform for the purposes of production lot designation throughout an entire production run. This error supposedly justified and led to large lot designations in contrast to increased sampling or sampling smaller lots which was counter-motivated due to increased testing costs.

Requester argues (3/20/15 pp. 15-17) that Jarvis and Price do teach two-tiered compositing (both at the pre-enrichment and enrichment stages) of multiple test lots, with the same degree of statistical significance, and agree with the 1/20/15 Decision that these teachings with FSIS and Midura render obvious step d1).

As above, it is agreed that the teachings in Jarvis, Price, FSIS and Midura render obvious step d1). The statistical methods of compositing, as well as two-tiered compositing were well understood and practiced by the artisan at the time of the invention, particularly for the noted advantages of reducing workload, increasing testing capacity and preserving portions from different sample lots for repeat testing. Such statistical methods were well known and would be employed for essentially any and all lots of meat, beef and/or poultry as required by USDA policy (FSIS for beef) and testing procedures.

The elements which Patent Owner argues are different, and render the invention nonobvious, (operationally-linked lot units of smaller size) are elements related to steps a1)-a2) and b1) directed to the delineation of sample size, sampling plans and lot designation and/or size, rather than d1) combining. The weighing of such variables as addressed above were however well known and commonly practiced as acknowledged by the principles taught in Jarvis, Price and Midura, but also by the FSIS particularly for sampling beef. In contrast to Patent Owner's arguments, Midura specifies additional variables considered in the designation of any lot(s) including the variables of time, proximity and process step (Midura pp. 13-16, 20-21). Accordingly, the prior art renders obvious selection of smaller lot sizes, in particular when increased sampling and more rigorous testing for contamination is desired.

Moreover, the selection of such methods based upon a cost analysis, rather than for example maximizing detection of contaminating events, is merely an alternative or different motivating factor well recognized by the artisan during selection and design of any particular testing procedure. Midura pp.13-16 reflects the consideration of such cost factors in the statistical definitions provided including the acceptance number, acceptance quality level, average outgoing quality limit, consumer protection, consumer risk, destructive testing, limiting quality, operating characteristic, probability, and producer's risk amongst others. While Patent Owner argues that increased sampling and testing was counter-motivated by the increased cost associated with such testing, such argument merely identifies alternative motivations for selecting any suitable testing procedure. As in Midura, the art well recognized the cost associated with destruction testing. Moreover, the FSIS directives, while USDA policy, are not recognized as the most accurate, sensitive or cost-effective procedures. The artisan most

interested in preventing contamination would maximize the acceptance quality level in any testing procedure, whereas the artisan most interested in containing cost would select alternative testing procedures accordingly. Jarvis and Price also acknowledge the art recognized advantages of combining (or compositing) to preserve units for subsequent retesting and either subsequent validation or destruction. Subsequent testing was already known to save those lots that might be subsequently validated while controlling those lots which retest positive and should be subsequently destroyed. Thus Patent Owner's argument of non-obviousness based upon a desire to contain costs is not persuasive and merely points to alternative motivations in the selection of any testing procedure (including lot number and/or size), which were well known in the art.

Step e) is delineated as having four separate elements. Step e1) directs testing, steps e2) and e3) delineate when testing is negative or positive respectively and e4) delineates obtaining a negative test. The 1/20/15 Decision pp. 9-10 interprets step e) to encompass a mental step or process as the '584 patent does not define validate to require a physical or manipulative step, but rather a determination not translated into a required physical act. Nonetheless, the 1/20/15 Decision sets forth specific teachings of the prior art which render obvious elements e1)-e4).

Regarding e1)-e3) the 1/20/15 Decision p. 19 notes that Jarvis and Price teach testing in which a negative finding validates the samples as not containing contamination, and when testing is positive the methodology allows retesting of individual samples from the prior composite to verify the origin of contamination. Regarding e4), as noted for e1)-e3) Jarvis and Price teach that a negative test is obtained for each sample or lot to be validated and released.

Patent Owner argues (2/20/15 pp. 18-19) that element e) is not a mental step and argues that Jarvis fails to teach a second composite from enrichment broth and testing of different lots.

However as addressed above, the teachings of Jarvis and Price of two compositing steps as well as the teachings of FSIS and Midura specific to testing different lots together render obvious the dual compositing procedure, particularly from enrichment broth, which is acknowledged in the art as suitable for microbial testing and validation of different lots.

Requester agrees (3/20/15 pp. 18-19) with the 1/20/15 Decision that elements e1)-e3) are met particularly by Jarvis and that the term validate within elements e2) and e3) should be interpreted as a mental step. Requester disagrees however that Jarvis and Price are limited to testing of a single test lot. Nonetheless, Requester agrees that Midura renders obvious such multiple lot testing as well as the respective results and actions.

The Examiner agrees that the teachings of Jarvis, Price, FSIS and Midura render obvious step e) and all limitations of elements e1)-e4) as delineated in the 1/20/15 Decision. In particular, Jarvis and Price teach dual-tier compositing steps for the benefit of reducing testing as well as enabling retesting positive samples to determine the origin of contamination, and as discussed above such teachings are applicable to the testing of multiple lots as is particularly reflected in FSIS and Midura. Similar to the testing in Jarvis, Price, FSIS and Midura, and on point to meat, beef and/or poultry samples, a negative result for Salmonella indicates a suitability for release to commerce whereas a positive result indicates contamination. As in Jarvis and Price, positive results are followed up with additional testing of the originating samples, with negative samples being released to commerce and positive samples being retained and/or destroyed. All lots for release are required to obtain a negative test for each lot to be released.

Regarding secondary considerations, Patent Owner argues (2/20/15 pp. 19-21) that the claimed invention's success is due to multiple operationally linked lots and the modular

composite sampling approach of steps c)-e), which provide the advantages of allowing retesting of lots when the composite tests positive, resulting in a savings due to retention of those underlying lots subsequently retesting free of contamination. Patent owner argues (2/20/15 p. 21-22) that the Samadpour declaration (¶12) supports that the invention has been successfully applied to beef and other samples although the claims have been limited to beef, meat and/or poultry. Patent Owner argues (2/20/15 p. 22) that there was no motivation to test multiple separate operationally linked production lots of smaller size, and that the claim as amended to operationally-linked units are directed to lots of smaller size, see also Samadpour declaration (¶13). Patent owner (2/20/15 p. 23) and the Samadpour declaration (¶14) also argue that the requirement for retesting each lot (regardless of result) only applies to a small fraction of instances i.e., when separate lots are sold to different entities, and that the skepticism applied to the assay with or without the requirement to test each individual component separately, even when the composite sample was negative. Patent Owner thus concludes the Samadpour declaration supports sufficient nexus to the claims.

Regarding secondary considerations, Requester argues (3/20/15 pp. 20-23) that there is insufficient nexus between any claim element, as all elements were already known in the art, that the claims are not limited to a smaller lot size, and that the modification of the testing procedure to include testing of all lot samples regardless of the composite result, nullifies any nexus with the two-tier testing procedure of the claims.

As discussed above, the secondary considerations and declaration of Samadpour are not sufficient to overcome the rejection set forth in the 1/20/15 Decision. The art suitably motivates to testing multiple lots in a two-tier composite procedure. The art further evidences that

selection of sampling plans and lot sizes are standard within the art. The artisan aimed towards maximizing consumer protections and minimizing release of contaminated material over any concern for testing costs, would employ such suitable methods as was well within the skill of the art at the time of the invention. While USDA policy may set minimal testing standards, such policies are not recognized as the most efficient or rigorous approach available. Moreover, as discussed above, the instant claims are not limited to any particular sampling plan or lot size.

Regarding rejections 2-4, neither Patent Owner nor Requester argue these rejections separately.

41.77(d) Determination by the Examiner

41.77 Decisions and other actions by the Board
(d) Following any response by the owner under paragraph (b)(1) of this section and any written comments from a requester under paragraph (c) of this section, the proceeding will be remanded to the examiner. The statement of the Board shall be binding upon the examiner unless an amendment or new evidence not previously of record is made which, in the opinion of the examiner, overcomes the new ground of rejection stated in the decision. The examiner will consider any owner response under paragraph (b)(1) of this section and any written comments by a requester under paragraph (c) of this section and issue a determination that the rejection is maintained or has been overcome.

The Examiner finds that the response by Patent Owner fails to overcome the obviousness rejections of Grounds 1-4 set forth by the 1/20/15 PTAB Decision. In particular, the 1/20/15 Decision found that the Grounds 1-4 as set forth establish obviousness, and also found that Patent Owner's original arguments and evidence of secondary considerations were insufficient to overcome the rejections. Patent Owner has introduced amendments which limit the subject matter to beef, meat or poultry and to operationally-linked units, however such limitations fail to provide sufficient nexus to the claims to overcome the prior art rejections of record.

The Examiner's review of Patent Owner's 41.77(c) response finds the new amendments, argument and evidence (including of secondary considerations) to be insufficient to overcome the Ground 1-4 rejections set forth by the PTAB.

The Examiner finds Requester's reply and arguments, sufficient to support the rejections set forth by the PTAB. Requester's reply and arguments also adequately counter Patent Owner's asserted evidence of secondary considerations.

Time Period for Response

Periods for response to this determination are identified in 37 CFR 41.77(e). Following expiration of those time periods, the proceeding will be returned to the Board for reconsideration under 37 CFR § 41.77(f). Note that under 37 CFR § 41.77(e), patent owner and third party requester responsive comments are due one month from the mailing date of this determination, and both third party requester and patent owner replies to those comments are then due one month from date of service of the comments. These time periods cannot be extended. See 37 CFR § 41.77(g).

Inter Partes Duty to Disclose

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,534,584 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding.

Inter Partes Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.903.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

By EFS to: Registered users may submit via the electronic filing system EFS-Web at https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html

By U.S. Postal Service Mail to:
Mail Stop *Inter partes* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

/Sharon Turner/
Patent Reexamination Specialist
CRU 3991

Conferees:

/Padmashri Ponnaluri/
Patent Reexamination Specialist
CRU 3991

/Jean C. Witz/
Supervisory Patent Reexamination Specialist
CRU 3991

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Mansour Samadpour
Control No.:	95/001,294
Confirmation No.:	1914
Filed:	05 April 2010
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Examiner:	Sharon Turner
Art Unit:	3991
Confirmation No.:	1914
Docket No.:	0066090-008US2
Date:	20 August 2015

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

PATENT OWNER'S RESPONSE TO INTER PARTES REEXAMINATION DETERMINATION UNDER 37 C.F.R. § 41.77(d)

This Response is timely filed on 20 August 2015. No fee is deemed due under 37 C.F.R. § 41.20. If additional fees are necessary, Commissioner is authorized to charge any deficiency (or credit any overpayments) to Deposit Account No. 04-0258.

TABLE OF CONTENTS

CLAIMS ……..3

REMARKS…….....9

Patent Owner, pursuant to 37 C.F.R. § 41.77(b)(1), submits the following amendments to the claims:

No claims are amended with this Response.

1. (Thrice amended) A method of sampling, testing and validating a plurality of operationally-linked test lots of beef for release into commerce [[microbial contamination]], 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[[, according to a statistical sampling plan]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 lots [[samples]] are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots [[may nonetheless yet be]] are validated[[, according to the statistical sampling plan,]] 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).

2. (Amended) The method of claim 1, wherein each of the test lots is a single-unit production lot, comprised of operationally-linked product specimens.

3. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

4. (Original) 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. (Original) 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 microbial agent or organism.

6. (Original) 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. (Original) 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.

8. (Original) 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. (Original) 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. (Original) 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. (Original) The method of claim 1, wherein the number of separate test lots is from 3 to 10.

12. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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.

17. (Thrice amended) A method of sampling, testing and validating a plurality of operationally-linked test lots of meat or poultry for release into commerce [[microbial contamination]], 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[[, according to a statistical sampling plan for a particular microbial agent or organism,]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 [[may nonetheless yet be]] 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).

18. (Original) 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.

19. (Original) 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. (Original) 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. (Original) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

22. (Original) 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. (Original) 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.

24-25. (Cancelled)

26. (Original) The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.

27. (Original) The method of claim 2, wherein product specimens are synonymous with product portions.

28. (Original) The method of claim 4, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.

29. (Original) The method of claim 5 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

30. (Original) 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.

31. (Original) 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.

32. (Amended) The method of claim [[24]] 1, wherein the beef [[meat or poultry]] specimens are meat trim pieces [[or poultry trim pieces, respectively]].

33. (Amended) The method of claim [[24]] 17, wherein the meat is that of beef, pork, sheep or bison.

34-36. (Cancelled)

REMARKS

This is a Response to the 41.77(d) Determination, dated 20 July 2015 (hereinafter "Determination").

Claims 1-23 and 26-33 are pending.

No claims have been amended herein.

No new matter has been added.

ARGUMENT SUMMARY

All art cited against this invention pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots, but not in the simultaneous fashion of Patent Owner's claims. The two references concerning "composite" (aggregated) samples contemplate that all samples come from the same food lot, where the sole motive for compositing is a desire to limit the number of samples to minimize testing costs. Nothing in the cited art motivates combination of samples from separate operationally-linked production lots within a production run of food within a single method. In fact the prior art at the time of filing contraindicated the claimed subject matter. No art, alone or in combination discloses or motivates performing the tasks of Patent Owner's independent claims 1 and 17; to simultaneously operate on a plurality of separate operationally-linked production lots within a production run, each to be validated for release into commerce, and involving creation of a modular composite sample from aliquots of separate enriched operationally-linked test lots each attributed to a particular corresponding separate operationally-linked test lot within a production run, and where each separate test lot is separately sampled from the respective plurality of separate test lots according to a statistical sampling plan.

NEW GROUNDS OF REJECTION

The Appeal Board in the DOA (1/20/15 Decision) discussed and affirmed Rejections 1, 2, 10, 11, 13, and 14 (as numbered in the Appeal Brief), but interpreted Patent Owner's claims

differently than the Examiner[1], and applied the prior art differently than did the Examiner. The rejections were modified by citing both Jarvis and Price, and Rejections 1, 2, and 13 were deemed to be similar and were combined. The new grounds of rejection were renumbered and are as follows:

1. Claims 1-4, 6-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (preAIA) as obvious in view of Jarvis, Price, FSIS, and Midura RAN 8, 22, 56;

2. Claims 5, 6, 23, 29, and 30 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Entis. RAN 50, 51, 53;

3. Claim 21 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Cousin. RAN 58, 60; and

4. Claims 24, 28, 32, and 33 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Jarvis, Price, PSIS, Midura, and Gabis. RAN 62.

A. Ground 1 (REJECTION 1)

Appellant traverses the rejection of 1-4, 6-20, 22, 24-27, 31, and 32 under 35 U.S.C. § 103(a) (preAIA) as obvious in view of Jarvis, Price, FSIS, and Midura RAN 8, 22, 56.

For easier reference, the DOA numbered Applicant's claim 1 steps (a) – (e) as follows.

Step (a)

a1. "collecting a plurality of portions from each of a plurality of separate test lots"

a2. "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"

Step (b)

b1. "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"

Step (c)

[1] "we interpret step c) of claim 1 to correspond to the prior art enrichment step aimed at growing the target organism in contrast to "pre-enrichment" which only resuscitates the target organism for subsequent growth in an enrichment media." (1/20/15 Decision at page 10, etc.)

c1. "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" or "enrichment"step

Step (d)

d1. "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample"

Step (e)

e1. "testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism"

e2. when testing is "negative," "all of said separate test lots are validated for release into commerce"

e3. when 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" of step (c)

e4. "obtaining a negative test result for each test lot"

a1. (plurality of samples/plurality of test lots) The DOA states that Jarvis teaches collecting a plurality of samples in method (2) on page 141, where separate pre-enrichment samples are prepared, and also describes a pre-enrichment step. The DOA states that Price also describes collecting a plurality of samples (Price at page 680; Figure 1). The DOA acknowledges (at page 13), however, that neither Jarvis nor Price describes collecting samples from more than one test lot as recited in Patent Owner's claims. The DOA, with respect to Jarvis Example 8.4 at page 136, stated that there is insufficient evidence that A, B, and C were used in the same method[2]. The DOA states (at page 14), however, that "collecting a plurality of portions

[2] Patent Owner pointed out during Oral Arguments before the Appeal Board (see also Appeal Brief at page 12) that because of the nature/design of the MPN method (which involves a separate dilution matrix for each sample to be tested, with no mixing of any dilutions from different samples), it would be *impossible* that A, B, and C were used in the same method (see also Appeal Brief at page 12).

from each of a plurality of separate test lots" would have been obvious based on FSIS and Midura.

At page 6 of the present Determination, the Examiner states whereas Patent Owner maintains that the asserted art only teaches sampling of a single lot, Requester argues, **in contrast to the 1/20/15 Decision**, that both Jarvis and Midura teach testing multiple lots. The Examiner states that the Samadpour declaration is taken as an admission that element a1 is met.

Patent Owner disagrees. First, the 1/20/15 Decision agrees with Patent Owner that both Price and Jarvis are limited to sampling of independent lots; **not sampling of multiple lots in the context of a single assay procedure as claimed**. *Second*, Patent Owner disagrees that **testing** multiple lots independently by sampling from a single lots and independently testing solely with respect each single lot (i.e., serial independent testing of single lots) is equivalent to, or motivates Patent Owner's claimed methods. The fundamental difference is that the prior art does NOT teach or motivate construction of Patent Owner's modular composite sample as in step d1.

Patent Owner points out, as stated in the Samadpour declaration, that such sampling in Jarvis, Price, FSIS and Midura is done with respect to single lots that are each to be independently tested with separate assay applications. There is no teaching of the concept of jointly processing/assaying multiple lots in one application of an assay involving Patent Owner's unique modular composite sample as in step d1, which is fundamental to Patent Owner's methods.

While the serial testing of additional single lots may adequately acknowledge the concept that testing of additional lots or multiple separate lots ***independently of one another*** was well recognized in the art, such serial testing does NOT acknowledge or motivate the concept of combining samples from separate operationally-linked production lots within a production run of food within a single method. Just because Midura, as urged by the Examiner at page 7 of the Determination, may have taught distinguishing separate lots by lot number, date, place and time, does not teach or motivate anything about constructing Patent Owner's unique modular composite sample as in step d1. Steps

Likewise, the Examiner's statements (Determination at p.7) that "FSIS in additionally on point to beef (meat)", that "Midura is also on point to microbiological testing of different food lots and such testing is indicated for sampling (p.16 col 1) raw and processed meats", and that "Midura adequately teaches the considerations for operationally linked lots" do NOT teach or motivate anything about constructing Patent Owner's unique modular composite sample as in step d1, because each lot in the context of FSIS, Midura, Jarvis and Price is tested independently, and there is never any teaching or motivation to construct Patent Owner's unique modular composite sample, **which is a claim element NOT taught in the prior art**. The art does not teach or motivate sampling of multiple lots in the context of a single assay procedure as claimed.

a2. The Examiner maintains that "the '584 patent, Midura and FSIS acknowledge statistically based sampling plans… including for beef…and raw and processed meats", but this is in the context of serial testing individual lots independently of one another.

Patent Owner maintains that none of the art teaches statistical sampling in the context of combining samples from separate operationally-linked production lots within a production run of food within a single method (i.e., formation of Patent Owner's modular composite sample.

b1. (combining/**compositing**) The Determination states that the 1/20/15 Decision stated that Jarvis and Price taught combining portions to form a set of separate test lot samples, and that Patent Owner's rebuttal, that such sampling/compositing in Jarvis, Price (and Siliker) is with respect to single lots to be independently tested with no teaching of the concept of the modular composite sample, is misplaced because that is the subject of step d1. Patent Owner agrees that mere compositing (combining multiple samples taken from a single test lot to form a test lot sample) was known in the art.

With respect to the Examiner's position and the 1/20/15 Decision, while the references, as noted in the 1/20/15 Decision, may render obvious combining collected portions from each of a number separate test lots, and forming separate respective test lot samples for testing of multiple separate lots ***independently of one another*** such serial testing does NOT acknowledge or motivate the concept of combining samples from separate operationally-linked production lots within a production run of food within a single method for the purpose of formation of Patent Owner's modular composite sample. Patent Owner disagrees that step b1 is properly considered

in isolation of step d1, given the context of Patent Owner's claimed invention as a whole (jointly processing/assaying multiple lots in one application of an assay involving Patent Owner's unique modular composite sample).

c1. (enrichment step) With respect to Patent Owner's step (c), Patent Owner points out, as recognized by the Examiner and the 1/20/15 Decision at pp.9-10, that step c1 is an enrichment step not a pre-enrichment step, and more importantly the 1/20/15 Decision acknowledges that Patent Owner's meaning is no different than how it is used in the art in term of allowing the target agent/organism to reach detectable levels (Decision p. 8), and growing the target organism under suitable conditions to recover sufficient amounts to enable detection (Decision pp. 10). The Decision concludes that "[a]ccordingly, we interpret step c) of claim 1 to correspond to the prior art enrichment step aimed at growing the target organism in contrast to "pre-enrichment" which only resuscitates the target organism for subsequent growth in an enrichment media.

The Examiner Acknowledges that step c1 is an enrichment step, and thus also msut acknowledge that pre-enrichment does not provide for detection of the target microorganism in the meaning of the art (as explicitly supported by the 1/20/15 Decision). The Requestor's argument that pre-enrichment culture is sufficient for detection and to achieve substantial uniformity is thus not supportable, according to the 1/20/15 Decision. Moreover, an argument that Patent Owner's claims do not exclude pre-enrichment does not change this conclusion.

Additionally, as already stated in the record, both Gabis and Price teach to one of ordinary skill in the art that direct enrichment could ONLY be used in the context of non-lumped/non-composited single samples.

Specifically, Gabis (see Abstract at page 663) explicitly teaches that "in the analysis of 25g subsamples [unlumped] direct enrichment detected as many positive 'lots' as preenrichment, but in the analysis of lumped subsamples, direct enrichment gave dramatically reduced recovery," which is completely consistent with the data of Gabis Table 1, showing that lumping samples dramatically reduced detection in both direct selective enrichment protocols (i.e, the detection for the 108.3, 325, and 500g lumped samples in both the Tetrathionate and the Selenite direct enrichment media was dramatically lower than in the corresponding unlumped 25g subsamples (13 of which 25g subsamples were independently tested); with the decrease in

sensitivity increasing with increased lumping in going from 108.3, 325, and 500g lumped samples.

With respect to the DOA's comment (at pages 16-17, citing *In re ICON Health and Fitness Inc.,* 496 F.3d 1374, 1381 (Fed. Cir. 2007) that "there is a suggestion in Price (at page 682) and Gabis (at page 684) of direct enrichment. Even if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use "would render the result inoperable," Patent Owner points out (see also Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) that in fact, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols of Gabis) **would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection methods inoperative in the food industry**, which does not gamble with people's lives.

Patent Owner likewise points out that Price, in direct analogy to Gabis, would also suggest to one of skill in the art that direct enrichment could ONLY be used in the context of non-lumped/non-composited single samples. Price (page at page 682, ¶ 2) ***teaches away*** from the use of anything more than a single portion in each pre-enrichment:

> "*If many food samples are pooled at the pre-enrichment stage, the salmonellae face competition from the flora of all the samples in the pool. If, in the other hand, the samples are individually pre-enriched, the actively growing salmonella might be expected to compete more favorably with organisms introduced from other samples when pooled at the enrichment stage. In addition, pooling pre-enrichment broths avoids the hazards and inconvenience of handling very large flasks of culture.*"

(Note: Price uses the word "sample" to mean "portion," as defined in the '584 Patent.)

Since the problem being addressed by Price is to reduce the background of competing organisms, the statements by Price about the use of direct selective enrichments, two selective enrichments, or possibly even a reduction in the incubation time of the pre-enrichment cultures would be regarded by one of skill in the art, as being limited to the case of **non-lumped individual pre-enrichment cultures**, which would be expected to have fewer

background/competitive organism problems; that is, one would not ***exacerbate*** the background problem by subjecting a *lumped* test sample to direct selective enrichments or two selective enrichments.

Again, as widely recognized in the regulatory and food production art, regulatory methods require that the testing method must be able to detect a single organism in the sample, and that any loss of sensitivity (e.g., as reflected by the loss of sensitivity caused by lumping in the context of the direct enrichment protocols) would, in fact, lead to *false negatives*, which would render such lumped/direct enrichment detection methods inoperative in the food industry.

Patent Owner, therefore, maintains that the Determination is in error on this this point.

Additionally, Patent Owner contends that the Examiner's statement (Determination p. 10) that "Moreover, the fact that the pre-enrichment cultures are subsequently transferred for enrichment confirms that the claim limitations are met, the portions merely being combined in a different way prior to the incubation step" is not only misleading, but fundamentally in error.

First, the prior art, including that presently asserted only teaches combining portions of pre-enrichment samples, and not enriched samples.

Second, the "merely" in the phrase "merely being combined in a different way prior to the incubation step" is misleading and in error because it mischaracterizes Patent Owner's claimed invention, wherein the step c1 samples are enriched "to reach detectable levels" prior removing portions to for form the modular composite sample of d1. This is fundamentally important, because it allows, in the case of e3, when testing is positive, for testing 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" of step (c), "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)" (emphasis added by Patent Owner).

The position of the 1/20/15 Decision and the Determination, therefore, effectively ignore Patent Owner's claim limitations, and the testing alternatives in Gabis do ***teach away***, because pre-enrichment pooling would effectively preclude Patent Owner's claimed invention. Moreover, the alleged alternative of Price discussed by the Examiner at Determination p.11 that "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" (Price at page 682, first full paragraph), would only be reasonably understood to a situation where the individual selective enrichment cultures were not pooled. There is absolutely **no** teaching in Price that if there are problems with interfering organisms, a culture would directly selectively enriched followed by pooling of such culture. Price does not teach pooling of enriched cultures, even in the case where there are problems with interfering organisms.

Patent Owner maintains that Gabis and Price do teach away because they teach pooling at the pre-enrichment stage only, there are not teachings to pool enriched cultures, and certainly not in the context of combining samples from separate operationally-linked production lots within a production run of food within a single method for the purpose of formation of Patent Owner's modular composite sample.

d1. (forming a modular composite sample) With respect to Patent Owner's steps (d), the 1/20/15 Decision acknowledges (at page 17, under discussion of step d1) that **"[n]either Jarvis nor Price teaches combining samples after enrichment and testing them**."

The 1/20/15 Decision, reiterated in the Determination, however, *erroneously* states that that Jarvis does teach compositing both pre-enrichment and enrichment samples, while still attaining the "same degree of statistical confidence" (citing Jarvis method (3)). The DOA mistakenly interprets Jarvis method (3), which does NOT teach compositing enrichment samples. Jarvis method (3) is a combination of Jarvis methods (1) and (2). Jarvis method (1) is preparing 10 individual pre-enrichment cultures and testing each individually (no combining of either pre-enrichment cultures at all), and Jarvis method (2) is preparing 10 individual pre-enrichment cultures and then combining an equal volume of each to inoculate a 100ml enrichment broth (so this teaches combining pre-enrichment broths, but not combining enrichment cultures). In Jarvis method (3), which is a combination of Jarvis methods (1) and (2), 10 individual pre-enrichment cultures are prepared and then 5 of the individual pre-enrichment cultures are combined into a first combined pre-enrichment culture, and the other 5 of the individual pre-enrichment cultures are combined into a second combined pre-enrichment culture, then aliquots of the first and the second combined pre-enrichment cultures are combined at the point of inoculating the enrichment medium. Jarvis does not teach compositing enrichment cultures even with respect to samples taken from a single lot, much less separately taken from a

plurality of separate test lots. The statistical significant comment about "same degree of accuracy" is with respect to combining pre-enrichment samples with respect to a single test lot, and does not teach, as mistakenly construed in the DOA, combining enrichment samples.

Patent Owner points out that a mere motivation to combine pre-enrichment samples to reduce workload does NOT make Patent Owner's step (d) (which requires removing portions of each enriched separate test lot sample corresponding to the separate test lots, and combining the removed portions to provide a modular composite sample) obvious in view of the asserted art. Jarvis and Price deal with combining pre-enrichment samples derived from a single test lot, for the mere purpose of reducing the workload.

Requestor argues Requester argues (3/20/15 pp. 15-17) that Jarvis and Price do teach two-tiered compositing (both at the pre-enrichment and enrichment stages) of multiple test lots, with the same degree of statistical significance, and agree with the 1/20/15 Decision that these teachings with FSIS and Midura render obvious step d1.

Patent Owner emphatically disagrees. First, as explicitly acknowledged in the 1/20/15 Decision, pooling at the enrichment stage was not in the prior art. Second, even if it was, there is certainly no motivation in the art for compositing samples from different enrichment samples, which themselves have been composited [from different separate test lots]. **In fact, there was a very strong counter motivation not to do this**. Specifically, as discussed during Oral Hearing (see also Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) with respect to the explicit data of working Example 1 of Patent Owner's patent, prior to the present invention, and including for at least the last forty years there has been no such motivation because the food industry has widely assumed that contamination was, for purposes of production lot designation, uniform throughout a production run, which accordingly justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assay of any larger number of smaller separate operationally-linked production lots within a production run that might be formed[3]. Hence, prior to Patent Owner's invention, it has always been deemed

[3] Obviously, if contamination is uniform, for purposes of lot designation, there would be no advantage to assaying multiple separate operationally-linked production lots within a production run in place of a lager production lot (the entire production run), because the positive detection results would be the same but would require a much larger number of samples, and increased

sufficient to test one large lot (i.e., an entire production run), and thus no motivation to even form and define multiple separate operationally-linked production lots within a production run, **and thus no motivation to simultaneously/jointly test multiple separate operationally-linked production run lots within a production run**. As discussed during Oral Hearing, Patent Owner hypothesized that the long-standing art assumption of contamination uniformity, for purposes of production lot designation, was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a production run, some of the operationally-linked production lots within the production run would not be contaminated, while others would be. Patent Owner's hypothesis and insight, therefore, was what provides the motivation (even for the Patent Owner) to pursue the presently claimed subject matter, which is entirely validated by the results of working Example 1 of Patent Owner's patent, and which, while engendering much initial skepticism, has led to rapid commercial success as amply evidenced in the record.

The originally filed specification of the '584 patent contained a working Example 1, which corroborated Patent Owner's hypothesis regarding non-uniformity of contamination, and that demonstrated the *nexus* between the invention as claimed and the related benefits which, despite the substantial disincentive of increased sampling and assay costs, have led to the current success of the '584 patent claimed subject matter (see Example 1 of the patent):

> Specifically, the individual single-unit production lot samples comprising the MWCS were analyzed separately following each *positive* MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a *positive* result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a *positive* result. If only the 391 individual single-unit production lots yielding a *positive* sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce.
>
> The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 1,9280,000 lbs of beef trim into

---

assay expense. By contrast, if contamination was non-uniform, Patent Owner hypothesized that some of the operationally-linked production lots within a production run would not be contaminated, while others would be.

> commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in sensitivity relative to the MWCS testing) provides *substantial* additional assurance of the safety of the food products.
>
> …

TABLE 1: Results of modular wet composite sampling of 62,919 multiple lots and number of Individual Production Unit Lot (IPUL) that tested positive when MWCS tested positive

Location	Total # Analyses	# Positives	1 IPUL	2 IPULs	3 IPULs	4 IPULs	5 IPULs
Est. A, B, C.	62,919	271	180	39	18	11	7

U.S. Patent No. 7,534,584, at Cols. 11 and 12.

The motivational analyses of the 1/20/15 Decision and the Determination, therefore, are in error with respect to compositing samples from different enrichment samples, which themselves have been composited from different separate test lots. Prior to Patent Owner's invention, there was no such motivation, as corroborated by the absence of such modular compositing including over the last 40 plus years. Patent Owner's hypothesis, and validation thereof by the Patent Owner, is what provided the motivation. In the presence of a pervasive assumption in the art that contamination was uniform for purposes of lot designation, and the counter motivation to avoid any increased sampling/testing costs, a mere motivation to composite pre-enriched or enriched samples in the context of a single lot does NOT provide motivation for Applicant's claimed subject matter. Moreover, Patent Owner notes that the biological and chemical arts are regarded as ***unpredictable*** by the Office. Patent Owner's claimed subject matter would have been contra-indicated in the art at the time of filing.

The Examiner's statement (Determination p. 12) that "[t]he statistical methods of compositing, as well as two-tiered compositing were well understood and practiced by the artisan at the time of the invention, particularly for the noted advantages of reducing workload, increasing testing capacity and preserving portions from different sample lots for repeat testing" is misleading because it appears to equate mere compositing and pooling of pre-enrichment cultures (all corresponding to a single test lot), with Applicants two-tiered testing which comprises compositing and pooling of enriched culture portions corresponding to different

separate test lots, which certain was not well understood and practiced in the art. The Examiner's conclusions, and those of the 1/20/15 Decision, are NOT supportable in this regard.

Moreover, Patent Owner disagrees with the Examiner's statement (Determination p. 13 with respect to size of the test lot, implying that Patent Owner's claims need to describe a small lot and/or that even so small lots are concepts known in the art. Patent Owner has not made that argument. Patent Owner has, in the above discussion of working Example 1, however, tried to place the teachings of the patent in the context of the relevant art, especially the art clearly disclosed in the background section of the patent. This is the technical field in which the skilled person operates and in which they would read the claim to make sense. That art does, indeed, deal with production lots, or test lots, which are of significant size – this is the technical field in which the method is intended to be applied. However, Patent Owner has not argued that the claim is specifically limited to "large" or "small" test lots. Rather, Patent Owner has emphasized that invention enables analysis of multiple separate operationally linked test lots (e.g., opposed to an entire production run), with a single application of the methods as claimed. A lot is a unit of production, defined by the worker in the specific relevant production technology. Logically therefore, and certainly in the context of the particular technical field described in the background section of the patent, a "test lot" is the lot, or unit of production, that is being tested. Of course, that test lot will be defined by the skilled person undertaking the relevant testing for safety and quality, dependent on the product, production process and the nature of the specific test required. There is no single structural or numeric definition of such a test lot that will suit all the potential applications of the method. The size of the test lot will be defined by the skilled person in the context of each test procedure, dependent on the purpose of that test.

The patentability of Patent Owner's claims do not depend on any particular lot size, but rather on the presently recited elements, including the formation of a modular composite sample, and that the test lots are operationally linked.

Moreover, Patent Owner disputes the Examiner arguments (Determination p. 13) that "[w]hile Patent Owner argues that increased sampling and testing was counter-motivated by the increased cost associated with such testing, such argument merely identifies alternative motivations for selecting any suitable testing procedure. As in Midura, the art well recognized the cost associated with destruction testing."

Patent Owner points out that while the art may well have recognized the cost associated with *destruction* testing (having to throw away contaminated product), as outlined in the discussion of working Example 1 of Patent Owner's patent, **the art presumed that contamination was uniform, and thus had no conception or motivation that destruction costs could be minimized** by simultaneously analyzing multiple separate operationally linked test lots as presently claimed, which methods would involve substantial increased sampling costs. The Examiner's position in this regard is, therefore, unsupportable. Patent Owner's arguments do not merely identify alternative motivations as urged by the Examiner.

For example, the Examiner's arguments (Determination at p. 14) that "Jarvis and Price also acknowledge the art recognized advantages of combining (or compositing) to preserve units for subsequent retesting and either subsequent validation or destruction" even if presumed to be correct, does not change the fact that that while the art may well have recognized the cost associated with *destruction* testing (having to throw away contaminated product), as outlined in the discussion of working Example 1 of Patent Owner's patent, **the art presumed that contamination was uniform, and thus had no conception or motivation that destruction costs could be minimized** by simultaneously analyzing multiple separate operationally linked test lots as presently claimed.

e1. and **e2**. (when testing is negative, all of said separate test lots are validated) Patent Owner objects to the characterization of step e as a mental step, because it is not; it involves testing whether the result is negative or positive, and even retesting when the result is positive. The testing in e1 and e2 of the modular composite sample is a physical testing step, and not a mental step. Moreover, since the modular composite sample, by nature, is composited from different enrichment samples, which themselves have been composited from the different separate test lots, a negative tested modular composite sample is instantaneously a negative testing (validation) for all of the separate lots **and is in fact an element of the claim**. This is not a mental step, it is a physical assay/testing step and **result** of testing of the modular composite sample.

Furthermore, for the reasons stated above with respect to that lack of motivation in the art for the limits of step d1, preparing and assaying such a modular composite sample is in fact not present or motivated in the art, including the very limited teachings of Jarvis and Price.

e3. (when the 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") With respect to Patent Owner's steps e1, the 1/20/15 Decision states that Jarvis 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 assessed. (Jarvis at pages 141-142). The 1/20/15 Decision states that "while it is true that Jarvis differs because Jarvis teaches going back to samples before enrichment, Jarvis still teaches concept of testing composited samples as in step e1 and going back to the sample before compositing it as in step e3." Since there is no compositing in e3, Patent Owner presumes that the 1/20/15 Decision rather intended to state "Jarvis still teaches concept of testing composited samples as in step e1 and going back to test stored cultures as in step e3."

Patent Owner points out, however, that the nature of the Jarvis stored sample is not only different because it is pre-enriched and not enriched, but also because the Jarvis pre-enriched samples are each from the same test lot, and each pre-enriched sample in not a statistical sample (only a single sample, and would not allow for validation). Not only is the motivation for going back to test the stored sample in Jarvis completely different than in the presently claimed subject matter, but the underlying utility is completely and fundamentally different. As recited in e3, "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)."

Furthermore, for the reasons stated above with respect to that lack of motivation in the art for the limits of step d1, preparing and assaying such a modular composite sample is in fact not present or motivated in the art, including the very limited teachings of Jarvis and Price.

Secondary Considerations

The Examiner states that "the secondary considerations and declaration of Samadpour are not sufficient to overcome the rejection set forth in the 1/20115 Decision. The art suitably motivates to testing multiple lots in a two-tier composite procedure. [Patent Owner points out that this statement by the Examiner is erroneous an unsupportable as discussed herein above]

The art further evidences that selection of sampling plans and lot sizes are standard within the art. The artisan aimed towards maximizing consumer protections and minimizing release of contaminated material over any concern for testing costs, would employ such suitable methods as was well within the skill of the art at the time of the invention. While USDA policy may set minimal testing standards, such policies are not recognized as the most efficient or rigorous approach available. Moreover, as discussed above, the instant claims are not limited to any particular sampling plan or lot size.

Patent Owner disagrees. *First*, the Examiner's statement that two-tiered compositing was motivated and practiced by the artisan at the time of the invention is misleading because it appears to equate mere compositing and pooling of pre-enrichment cultures (all corresponding to a single test lot), with Applicants testing which comprises compositing and pooling of enriched culture portions corresponding to different separate test lots, which certain was not well understood, motivated or practiced in the art. The Examiner's position in this regard is NOT supportable.

Second, despite the Examiner's urging, and as stated in the Samadpour declaration, there was a profound cost disincentive in the art with respect to anything that would increase sampling and associated costs above what was required by the regulatory agencies. Moreover, the art presumed that contamination was uniform, and thus had no conception or motivation that destruction costs could be minimized by simultaneously analyzing multiple separate operationally linked test lots as presently claimed.

Patent Owner also strongly disagrees with the Requestor's urging (3/20/15 pp. 20-23) "that there is insufficient nexus between any claim element, as all elements were already known in the art, that the claims are not limited to a smaller lot size, and that the modification of the testing procedure to include testing of all lot samples regardless of the composite result, nullifies any nexus with the two-tier testing procedure of the claims".

First, as discussed above at page 20-21 of this Response, there is no need for the claims to define a particular lot size as large or small. The patentability of Patent Owner's claims do not depend on lot size, but rather the presently recited elements, including the formation of a modular composite sample, and that the test lots are operationally linked.

Second, the Requestor's statement that "the modification of the testing procedure to include testing of all lot samples regardless of the composite result, nullifies any nexus with the two-tier testing procedure of the claims" is erroneous on its face.

Specifically, as reiterated below, Patent Owner points out (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) that the FSIS requirement for the extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applied to a small fraction of instances (at most 10-15% of the data used in the record to support commercial success) when the separate individual lots used to build the modular composite sample are sold to different entities. In 85-90% of the instances, when all the separate individual lots used to build the modular composite sample are sold to the same entity, **there is no such requirement for assaying each individual enrichment component separately, even when the modular composite sample was negative**.

Patent Owner's commercial success data of record, therefore, clearly supports the nexus between commercial success and Patent Owner's claim elements, because the alleged extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applied to a small fraction of instances (at most 10-15%) is not only not in the claims, but was also not required as recognized by the consumer's purchasing the claimed testing methods.

If anything, the requirement for an additional step for 10-15% of cases, would be a disincentive, and despite that disincentive consumers have overwhelming adopted Patent Owner's methods. The commercial success nexus is thus even stronger, because of this aspect.

Furthermore, the initial FSIS skepticism outlined in the record applied to the assay, whether with or without the aspect of assaying each individual enrichment component separately, even when the modular composite sample was negative (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)).

Patent Owner maintains that the Koohmaraie Declaration and the Samadpour 2010 Declaration strongly support the underlying link/nexus of the commercial success of Patent Owner's methods to the elements of the presently claimed subject matter.

With respect to "Skepticism," the 1/20/15 Decision discusses (at pages 22-23) the Mirtsching Declaration and the Samadpour 2011 Declaration. Patent Owner maintains the

Declarations strongly support the underlying link/nexus of the commercial success of Patent Owner's methods to the elements of the presently claimed subject matter.

In the 1/20/15 Decision "Discussion" (beginning at page 21), the Decision states that Patent Owner did not provide an adequate explanation of the second "classical" product to understand the differences between the two and understand the reason for success. The Decision stated, "for instance, was the success solely attributable to the post-enriching step e2 or to another step in the prior art?"

Patent Owner points out that the Patent Owner's patent describes the "classical product" in detail in the '584 patent (see, e.g., Col. 2, line 46, through Col. 3, line 40; and see working Example 1). Additionally, the record of this *inter partes* re-examination and Appeal contains a detailed comparative description of the classical method relative to Patent Owner's new method. For example, Exhibit A and Exhibit B of Patent Owner's Appeal Brief show the classical assay method, and Patent Owner's new method, respectively:

Exhibit A: Figure 1 attached to and labeled as "Exhibit A" in the Response after non-final action filed via EFS-Web on July 26, 2010;

Exhibit B: Figure 2 attached to and labeled as "Exhibit B" in the Response after non-final action filed via EFS-Web on July 26, 2010;

As well established in the record, the classical approach did not simultaneous assay multiple operationally-linked production lots, but rather assayed a single production lot, which led to destruction loss of a large amount of product. Patent Owner's new method, despite increased sampling and assay costs, results in substantial overall financial savings directly because of the modular compositing approach (at least steps (c) through (e)) for simultaneously assaying multiple independent, operationally-linked lots in one application of the method, and whereby less product is diverted to waste and/or lower value products. The commercial success is clearly attributed to at least steps (c) though (e) that are not in the art, and are not motivated by the art for the reasons discussed herein. Working Example 1 of the '584 patent clearly shows why this is true:

> "Specifically, the individual single-unit production lot samples comprising the MWCS [modular composite sample] were analyzed separately following each positive MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a positive result out of the cumulative total of

> 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a positive result. If only the 391 individual single-unit production lots yielding a positive sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce."

Beginning at page 24 of the 1/20/15 Decision, the Decision states that "[a]ll of the data appears to involve testing of beef, for contamination by E. coli. It is not clear whether other bacterial contaminants are tested, or whether other food products had the same commercial success."

Patent Owner (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) has, in addition to beef, successfully applied the presently claimed method (and in the context of using the assay as outlined for beef, and **without the extra step of testing individual enriched samples** if the modular composite sample tests negative), to a variety of food products tested, including but not limited to: meats (e.g., beef, pork, poultry, fresh and cured sausages, and the like), fresh agricultural commodities (e.g., leafy greens, vegetables, fruit, herbs, and the like), agricultural seeds, dried foods (e.g., spices, powders, flour, bakery mixes, and the like), pet foods, baked goods, processed meats, fermented foods, dairy products, nuts (both ground and tree), nut butters, trail mixes, compost, organic fertilizers, seafood, energy bars, cereals, sponge, and swap samples taken from food and food production environments, and including assaying for various pathogens (e.g., pathogenic *E. coli*, Salmonella, Listeria, Campylobacter, Vibrio, etc.) to obtain comparable commercial success to that corroborated in the record for beef and *E. coli*, and for the same reasons (i.e., destruction of less product with a production run), and due to the modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)). Moreover, as appreciated in the art, fabrication of meats such as pork sheep, bison, poultry, and the like, is analogous to beef fabrication in terms of art-recognized production runs and lots, and thus derives comparable commercial benefits from the same modular compositing of multiple independent operationally-linked production lots within a production run (i.e., at least steps (c)-(e)).

Patent Owner, to provide for commensurate *nexus* with commercial success, amended claim 1 to recite "test lots of beef" in place of "test lots." Claim 17 was amended to recite "test lots of meat and poultry" in place of "test lots."

The Amendments serve to narrow the scope of the claims to address the concern of the 1/20/15 Decision with respect to the scope of the foods covered and the sufficiency of the secondary factor data.

Beginning at the bottom of page 24 of the 1/20/15 Decision, the Decision states that "[a]rguments were also made that lot sizes are smaller in the claimed method than in the prior art and "classical" method. Samadpour 2011 Decl. ¶¶ 8, 30, and 36. See also Oral Hearing Transcript 16:8-11; 17:1-5. However, the claims are not limited to a lot of a particular size. Thus, if this is a basis for patentability, the feature is not recited in the claim."

Patent Owner, to further clarify this aspect has amended claims 1 and 17 to recite "operationally-linked test lots of beef" and "operationally-linked single-unit production lots of meat or poultry," respectively. As argued in above in detail, however, there is no need to specify any particular lot size as "large" or "small", and the nexus is fully supported by the present claim limitations, including the formation of a modular composite sample, and that the test lots are operationally linked.

Patent Owner points out, as discussed above, that prior to the present invention, and including for at least the last forty years, there has been no such motivation because the food industry assumed that contamination was uniform, for purposes of production lot designation, throughout a production run, which justified use of very large lot sizes (i.e., the entire production run as a lot) to avoid the burdensome costs of sample collection and assaying. Hence, prior to Patent Owner's invention, it has always been deemed sufficient to test one large lot (i.e., an entire production run), and thus there was no motivation to even form and define multiple separate operationally-linked production lots within a production run, and thus no motivation to simultaneously/jointly test multiple separate operationally-linked production lots within a production run. As discussed during Oral Hearing, Patent Owner hypothesized that the long-standing art assumption of contamination uniformity for purposes of lot designation was incorrect, and that contamination was in fact non-uniform, and that by performing the presently claimed modular composite assay on multiple operationally-linked production lots within a

production run (e.g., as was done in working Example 1 of Patent Owner's patent), some of the operationally-linked production lots within the production run would not be contaminated, while others would be.

Beginning at page 25 of the 1/20/15 Decision, the Decision states that "Dr. Samadpour testified that to convince FSIS to accept the method, he had to modify the protocol by testing each individual enrichment component separately, even when the modular composite sample was negative. Samadpour 2011 Decl. ¶ 34. If the method responsible for the market share and increased revenue assays each test lot separately whether negative or positive, then it has not been established that the modular composite testing as claimed is responsible for the success. The commercial success must be due to a claimed feature."

Patent Owner points out (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)) that the FSIS requirement for the extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applies to a small fraction of instances (at most 10-15% of the data used in the record to support commercial success) when the separate individual lots used to build the modular composite sample are sold to different entities. In 85-90% of the instances, when all the separate individual lots used to build the modular composite sample are sold to the same entity, there is no such requirement for assaying each individual enrichment component separately, even when the modular composite sample was negative.

Patent Owner's commercial success data of record, therefore, clearly supports the nexus between commercial success and Patent Owner's claim elements, because the alleged extra step of assaying each individual enrichment component separately, even when the modular composite sample was negative only applied to a small fraction of instances (at most 10-15%) is not only not in the claims, but was also not required as recognized by the consumer's purchasing the claimed testing methods.

If anything, the requirement for an additional step for 10-15% of cases, would be a disincentive, and despite that disincentive consumers have overwhelming adopted Patent Owner's methods. The commercial success nexus is thus even stronger, because of this aspect.

Furthermore, the initial FSIS skepticism outlined in the record applied to the assay, whether with or without the aspect of assaying each individual enrichment component

separately, even when the modular composite sample was negative (see Declaration of Dr. Mansour Samadpour (EXHIBIT Z)).

In summary, Patent Owner contends that in view of the present claim amendments, there is a clear and sufficient *nexus* between Patent Owner's claim elements and the skepticism of the art, and the commercial success described in the record of this proceeding.

B. Grounds 2-4 (REJECTIONS 2-4)

The 1/20/15 Decision (at page 26) states that "Patent Owner made the same patentability arguments for dependent claims 5, 6, 21, 23, 24, 28-30, 32, and 33 cited in Rejections 2-4 (numbered 10, 11, 13, and 14 in the Appeal Brief) as they did for Rejection 1 (numbered 1 and 2 in the Appeal Brief). As we did not consider these arguments persuasive, we affirm the rejections for the reason set forth by the Examiner."

Patent Owner, based on the rebuttal arguments and amendments herein, contends that the rejections of the Examiner and Appeal Board have been overcome, including those for dependent claims 5, 6, 21, 23, 24, 28-30, 32, and 33 cited in Rejections 2-4 of the 1/20/15 Decision (numbered 10, 11, 13, and 14 in the Appeal Brief).

Declarations

In addition to the current Declaration (Exhibit Z), Appellant's six (6) Declarations (Exhibits E-J), and comments regarding same in the Appeal Brief, are incorporated herein by reference, and should be carefully considered by the Examiner and the Board in support of the current Response.

Response to Declarations

Patent Owner incorporates by reference herein Patent Owner's comments in the Appeal Brief relating to various incorrect statements made in the RAN/ACP Section entitled "Response to Declarations."

EVIDENCE APPENDIX

Evidence required under 37 C.F.R. § 41.67(c)(1)(ix). Patent Owner relies upon evidence submitted and of record in the *inter partes* reexamination case, Control No. 95/001,294.

Evidence (Exhibits A-Y) used in the Appeal Brief, filed 07 May 2012, is incorporated by reference herein.

RELATED PROCEEDINGS APPENDIX

There are no decisions by a court or the BPAI pursuant the 37 C.F.R. § 41.67(c)(1)(x) that are submitted herein.

CERTIFICATE OF SERVICE

Timely service to the third party requester, bioMerieux, via their attorney E. Anthony Figg, at Rothwell, Figg, Ernst & Manbeck, P.C., 607 14th Street N.W., Suite 800, Washington, D.C. 20005 is being affected by first class mail sent on 20 August 2015.

CONCLUSION

For the reasons provided herein, Patent Owner submits the rejections of the claims are overcome by the present Response, and that the claims are allowable as presently presented.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Patentee
Registration No. 47,309

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In *Inter Partes* Reexamination of	:	Examiner: Sharon Turner
Mansour SAMADPOUR	:	Group Art Unit: 3991
Patent No.: 7,534,584 B2	:	**Control No.: 95/001,294**
Issued: May 19, 2009	:	

Reexam Request Filed: April 5, 2010

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THIRD-PARTY REQUESTER COMMENTS ON THE PATENT OWNER'S RESPONSE TO INTER PARTES REEXAMINATION UNDER 37 C.F.R. § 41.77(D)

These Comments are submitted in response to the Patent Owner's Response to Inter Partes Reexamination Determination filed and served August 20, 2015. Pursuant to 41.77(e), Third Party Requester has one month to submit these Comments; however, September 20, 2015 is a Sunday. Accordingly, these Comments are timely filed if submitted on or before Monday, September 21, 2015. Entry and consideration of these Comments is therefore respectfully requested. It is not believed that any fees are necessary in conjunction with the filing of these Comments; however, to the extent that any fees are deemed necessary, the Commissioner is authorized to charge any required fees to Counsel's Deposit Account Number 02-2135.

National Beef Ex. 1007
Page 1755

The Patent Owner's Claim Amendments Do Not Overcome the Rejection

Following the Patent and Trial Appeal Board's ("PTAB") issuance of the Decision on Appeal ("DOA"), the Patent Owner was given an opportunity to amend its claims in an attempt to overcome the new ground of rejection entered by the PTAB. Patent Owner responded by amending independent claims 1 and 17. Patent Owner's amendments do not meaningfully limit the claim, or establish a nexus between any alleged secondary considerations and the claim limitations. Accordingly, Patent Owner's amendments have failed to overcome the PTAB's new ground of rejection.

The "Operationally-Linked" Amendment Fails to Limit the Claim

Patent Owner has amended claims 1 and 17 to include the limitation "operationally-linked" purportedly to "clarify that the test lots, while separate, are nonetheless operationally-linked during a production run." (PO Req.[1] at 9). However, the term "test lots" as defined in the '584 patent specification are already "operationally-linked:"

> The term "test 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 product 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 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.

('584 patent, 5:20-30) (emphasis added). The '584 patent also repeatedly refers to test lots as being "operationally-linked." (*See, e.g.*, '584 patent, 7:28-31, 8:53-58, 9:9-11). Because "test lots" are specifically defined in the patent as operationally-linked, the specific inclusion of the words "operationally-linked" does not serve meaningfully to limit the claim.

---

[1] Patent Owner Request to Reopen Prosecution, filed February 20, 2015.

Moreover, the amendment does nothing to distinguish Patent Owner's claim from the prior art of record. The PTAB set forth the definition of "test lot" in the DOA, including the operationally-linked language that Patent Owner now adds to the claims. (DOA at 13). The PTAB correctly explains that FSIS and Midura both teach taking samples from a plurality of separate test lots as the term "test lot" is defined in the specification. (DOA at 13-14). The Examiner also found that FSIS and Midura specifically teach collecting samples from operationally-linked production lots, which means test lots that are linked in a manner that preserves the linkage, for example, through a proximity, time, or process step. (Ex. Determination[2] at 5, 7). For example, the Examiner explains that FSIS discloses sampling procedures during an operationally-linked production run that are based on time or space. (Ex. Determination at 7). The Examiner further explains that Midura discloses the considerations for operationally-linked test lots, particularly the variables of proximity, time and process step, while developing representative sampling plans. (*Id.*). Accordingly, even if addition of the term "operationally-linked" were a new limitation to the claim, it is taught by the prior art of record.

Patent Owner also implied that the addition of the term "operationally-linked" was to clarify that the invention involved smaller lot sizes. (PO Req. at 22; Ex. Determination at 5). The Patent Owner's argument was apparently made in response to the PTAB's finding that the Patent Owner's argument relating to the use of smaller size test lots in the claimed method when compared to the "classical method" (*See e.g.,* Hearing Transcript at 16:17-17:19) is ineffective because the claims do not specify a particular size. With this understanding of the Patent Owner's position, the Examiner thoroughly reviewed the specification of the '584 patent and concluded that the "the limitation does not serve to limit the samples, portions, specimens or lots

---

[2] Examiner's Determination under 41.77(d), issued July 20, 2015

National Beef Ex. 1007
Page 1757

with respect to any particular number or size." (Ex. Determination at 5). As a consequence, Patent Owner has now reversed course, and states "Patent Owner has not argued that the claims is specifically limited to "large" or "small" test lots," and that the "patentability of Patent Owner's claims do not depend on any particular lot size..." (PO Resp.[3] at 21 (emphasis in original)). Accordingly, the addition of the term operationally-linked does nothing to alter the PTAB's finding that test lot size is not a basis for patentability.

The Patent Owner has failed to explain why the prior art does not teach testing "operationally-linked" test lots. In fact, the Patent Owner admits that the concept of testing multiple separate lots was well recognized in the art. (PO Resp. at 12). Patent Owner further admits that Midura "taught distinguishing separate lots by lot number, date, place and time..." (*Id.*). The considerations Patent Owner admits were taught in Midura are the considerations for operationally-linked test lots. (*See* Ex. Determination at 7). Accordingly, the Patent Owner has admitted that the testing of "operationally-linked test lots" was known in the art. Thus, Patent Owner's "operationally-linked" amendment fails to overcome the rejection.

The "Of Beef" And/Or "Meat or Poultry" Amendments Fail to Overcome the PTAB's Rejection

The Patent Owner has amended claim 1 to specify "test lots of beef" purportedly to "clarify that the test lots are separate test lots of beef." (PO Req. at 9). The amendment appears to be in response to the PTAB's pointing out that all of the alleged evidence of commercial success and skepticism that was put forth by the Patent Owner is limited to beef, but the claims are not limited to beef products. (DOA at 24-25). Although the amendment may now limit claim 1 to beef, it fails to establish a nexus between the claimed method and the alleged secondary considerations. For example, the amendment does not serve to link the alleged

---

[3] Patent Owner Response to the Examiner's Determination, filed August 20, 2015

success of the method to a particular step that is not found in the prior art. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) ("If the feature that creates the commercial success was known in the prior art, the success is not pertinent.") (citing *Ormco Corp. v. Align Tech., Inc.* 463 F.3d 1299, 1311-12 (Fed. Cir. 2006)). It also does not clarify how the claimed method is different from the "classical" method, which is also used on test lots of beef.

Similarly, the Patent Owner has amended claim 17 to specify "test lots of meat or poultry" purportedly to "clarify that the test lots are separate test lots of meat or poultry." (PO Req. at 9). The purpose of the amendment again seems to be an attempt to correlate evidence of commercial success to a particular type of food product. However, this amendment also fails to provide an adequate nexus to the claims for the same reasons discussed with respect to "beef."[4] Interestingly, Patent Owner appears to have defined beef as a subset of meat, which means that the Patent Owner has still not introduced evidence commensurate with the scope of the claims. (PO Resp. at 27).

The PTAB explained that Patent Owner's assertions that the revenue derived from the claimed method was greater than that derived from the "classical method" were not persuasive, because the Patent Owner did not explain that the difference was attributable to a step that was not found in the prior art. (DOA at 23-24). In response, the Patent Owner now seems to argue that the distinction between the two methods is that "the classical approach did not simultaneous [sic] assay multiple operationally-linked production lots, but rather assayed a single production lot," whereas the claimed method uses a "modular compositing approach (at least steps (c)

---

[4] There is even less evidence to support Patent Owner's claims that "meat or poultry" is commercially successful than there is for test lots of beef. The only support for the alleged commercial success is a conclusory paragraph in the Samadpour declaration that cites to no evidence to support its claims. Such evidence should be accorded little or no weight. *See* MPEP 716.01(c).

through (e)) for simultaneously assaying multiple independent, operationally-linked lots in one application of the method..." (PO Resp. at 26-27). But that argument overlooks that the prior art taught these steps.

As explained by both the PTAB and the Examiner, the Midura and FSIS references taught that statistically significant samples from multiple test lots should be collected. (DOA at 12 – 15; Determination at 7-8). The Examiner also pointed out that FSIS is directly on point for taking samples from operationally-linked test lots of beef. (Ex. Determination at 7). The Jarvis and Price references taught that the collected samples can be composited, such that a single analysis takes the place of multiple analyses to reduce the workload on the laboratory. (DOA at 15-16; Ex. Determination at 12). The claims also do not exclude a pre-enrichment step (DOA at 17; Determination at 9-11), and, regardless, the Jarvis and Price references teach the testing of pooled enrichment samples. (DOA at 18; Determination at 11-12). In addition, these references teach compositing in two stages (DOA at 18; Ex. Determination at 12), and the Patent Owner apparently agrees that Jarvis Method 3 teaches a two-tiered compositing step. (PO Resp. at 17). Finally, the validation steps recited in step (e) do not limit the claim because they recite a mental step. (DOA at 19; Determination at 14-16). Moreover, just as in the rejected claims, the Price and Jarvis references both teach retaining stored samples for the purpose of retesting in the event of a positive test results. (DOA at 19-20; Ex. Determination at 14). Accordingly, the Patent Owner's claimed method is simply an aggregate of steps that were known in the prior art. Jarvis and Price provide a motivation, namely reducing laboratory workload, for compositing the statistically valid samples of multiple test lots, as taught by FSIS and Midura, testing the composite and retaining samples from each test lot for individual testing in the event that the composite sample tests positive for contamination. Thus, the Patent Owner cannot show that any

commercial success was due to a particular feature of the claimed method that was not taught in the art.

Patent Owner's attempt to link alleged evidence of commercial success to the claims by amending those claims to specify a type of product must fail. Amendments specifying the type of test lot tested do not create a nexus to the claims because Patent Owner has failed to show that any such evidence is due to a feature of the claims that was not known in the art. Moreover, even if such a nexus did exist, evidence of commercial success may not overcome a strong prima facie case of obviousness, such as the one presented here. *Asyst Tech., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008).

The Claimed Method is Obvious in View of the Prior Art of Record

The DOA numbered the various limitations of the '584 patent claims. The Patent Owner adopted the notation used by the DOA, and so did the Examiner. Accordingly, Requester will also use this notation.

Step A1 Would Have Been Obvious in View of the Cited Prior Art

The PTAB found that step A1 pertains to collecting samples from a plurality of separate test lots, and that this step was disclosed in the prior art. (DOA at 12-13). The Examiner agrees, and has also found that the limitations of step A1 are met by the cited prior art. (Ex. Determination at 6-7). In particular, the Examiner noted that the Patent Owner has acknowledged that step A1 is found in the prior art because the Samadpour declaration admits that the cited art "pertains to sampling of a single lot of food or serial applications of the respective methods to additional single lots..." (Ex. Determination at 6). Indeed, as discussed above, the Patent Owner has again acknowledged that the testing of multiple separate test lots was known in the prior art, and that Midura "taught distinguishing separate lots by lot number,

date, place and time...," which are considerations for operationally-linked tests lots. (PO Resp. at 12). Accordingly, there can be no real dispute that step A1 is obvious in view of the cited prior art.

Step A2 Would Have Been Obvious in View of the Cited Prior Art

The PTAB found that Jarvis, Midura, the '584 patent, and the FSIS reference all render the use of statistical sampling plans on test lots obvious. (DOA at 14-15). The Examiner has confirmed that statistical sampling plans are taught by the cited reference, including the use of such plans for beef production lots. (Ex. Determination at 7-8). The Patent Owner does not appear to dispute that the use of statistical sampling plans was known, but contends such plans have not been applied to the formation of the modular composite sample claimed in step d1. However, if statistical sampling plans have been applied to each separate test lot, then they will necessarily have been applied to the modular composite sample, because it is composed of samples from each of the separate test lots. Accordingly, there can again be no real dispute that step A2, which requires only that test lots be sampled according to a statistical-based sampling plan, is obvious in view of the cited prior art.

Step B1 Would Have Been Obvious in View of the Cited Prior Art

The PTAB found that step B1 requires the portions collected in step 1 to be composited to form a separate test lot sample, and that Jarvis and Price both teach that step. (DOA at 15-16). The PTAB notes that "it was an art-recognized goal to make food testing more efficient by reducing the number of samples test [sic] to be tested," and this goal was accomplished by pooling. (*Id.*). The Examiner also has applied the PTAB's reasoning. (Ex. Determination at 8). The Patent Owner also now "agrees that mere compositing (combining multiple samples taken

from a single test lot to form a test lot sample) was known in the art."[5] (PO Resp. at 13). According, there can be no real dispute that step B1, which requires only compositing samples from a test lot, is obvious in view of the cited prior art.

Step C1 Would Have Been Obvious in View of the Cited Prior Art

The PTAB interpreted step C1 to be an enrichment step, and found that Price and Gabis teach direct enrichment of samples. (DOA at 17). However, the PTAB also found that a pre-enrichment step is not excluded by the claims.[6] (*Id.*). The Examiner agreed with the PTAB on both points, and thus found that step C1 is taught by the prior art. (Ex. Determination at 9-11).

The Examiner also addressed Patent Owner's contention that the Gabis and Price references teach away from using direct enrichment. (Ex. Determination at 10 – 11). With respect to Gabis, the Examiner properly concluded that the variable sample testing methods disclosed by Gabis, including the use of optional pre-enrichment and/or direct enrichment of samples, would have been recognized by a person of ordinary skill in the art. (Ex. Determination at 10). For example, Gabis teaches that direct enrichment of composited samples permits the detection of contamination, albeit at a lower rate. (Gabis at 668). However, as the Examiner found, Gabis also teaches that the inclusion of a pre-enrichment step increases the number of samples testing positive, which is an improvement of the direct enrichment procedure. (*Id.*). In

---

[5] Despite the acknowledgement that step B1 is obvious, Patent Owner again argues that formation of the "modular composite sample" of step D1 is not obvious. (PO Resp. at 13-14). Again, the Patent Owner's argument with respect to step D1 is misplaced in the discussion of step B1.

[6] Pre-enrichment was a way of multiplying or resuscitating microorganisms when conventional culturing techniques were used for identifying contaminating bacteria. A person skilled in the field would readily appreciate that with modern and sensitive techniques, such a PCR, pre-enrichment is not necessary. (Entis at 94) (explaining that although a preliminary enrichment step is common in PCR detection protocols, "direct detection, i.e., without the need for a lengthy enrichment step, is possible.").

this case of pre-enrichment, the Examiner properly found that because the pre-enrichment cultures in Gabis are subsequently transferred into an enrichment culture the claim limitations are met. (*Id.*).

The Examiner likewise found that the Price reference teaches pooling pre-enrichment cultures into enrichment broths, and that this results in obtaining higher numbers of positive results as opposed to pooling the samples themselves. (Ex. Determination at 11). The Examiner also concluded that Price further teaches that retaining small amounts of pre-enrichment culture allows samples to be retested in the case of a positive result. (*Id.*). Finally, the Examiner found that Price teaches that direct selective enrichment, two selective enrichments, or reduced incubation in pre-enrichment broth are also suitable alternatives well within the skill of the artisan. (*Id.*).

In response, the Patent Owner first asserts that "the prior art only teaches combining portions of pre-enrichment samples, and not enriched samples."[7] (Response at 16). However, the Patent Owner is incorrect that the prior art does not teach combining portions of enriched samples. For example, Price clearly teaches the combining of pre-enrichment cultures. (Price at Fig. 1) But, 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.

---

[7] The Patent Owner's response to the Examiner's finding is largely a verbatim repeat of the arguments it made in response to the DOA. (*Compare* PO Resp. at 14 – 16 *with* PO Req. to DOA at 13-15). Requester has already addressed these arguments, and incorporates its prior Comments filed March 20, 2015, pages 11-15 by reference. In addition, the Examiner has considered those portions of the Patent Owner's response, and correctly found it to be unpersuasive. (Ex. Determination at 9-11).

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 at16). 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.

The Patent Owner also asserts that the Examiner is incorrect because she overlooks the requirement of step E3, which indicates that in the event of a positive test further testing on the individual test lots can be conducted without further enrichment. (Response at 16-17). But it is Patent Owner who overlooks that the claims permit the individual test lots to first be composited in pre-enrichment broth followed by inoculation into enrichment broth. The enrichment broth cultures may then be composited, and samples saved for subsequent testing as taught by Price and Jarvis. Accordingly, the requirements of step E3 are also satisfied, and step C1 is obvious.

Step D1 Would Have Been Obvious in View of the Cited Prior Art

The PTAB found that step D1 is obvious in view of the cited prior art. (DOA at 17-18). In particular, the PTAB found that Jarvis teaches methods of compositing pre-enrichment and enrichment samples that attain the "same degree of statistical significance." (DOA at 17) (citing Jarvis at 141). The PTAB further found that Jarvis discloses the compositing of samples reduces the workload on the laboratory, and that Price contains a similar teaching. (DOA at 17). Based on these disclosures, the PTAB correctly concluded that "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 "it would have been reasonably expected that pooling samples at two different steps... would have the requisite sensitivity in detecting positives for contamination." (DOA at 17-18). Finally, the PTAB determined that "compositing in two stages as described in Jarvis provides the motivation to have carried out the second compositing step recited in step d1." (DOA at 18-19). The Examiner agreed that the teachings referenced in the DOA render the second combining step of D1 obvious. (Ex. Determination at 11-12).

In response, Patent Owner asserts that the Examiner has erred by "equat[ing] mere compositing and pooling of pre-enrichment cultures (all corresponding to a single test lot), with Applicant's two-tiered testing which comprises compositing and pooling of enriched culture portions corresponding to different separate test lots..."[8] (Response at 20-21). But, Patent Owner ignores that the Examiner's determination is based on obviousness, not anticipation. Requester remains of the view that Jarvis and Price explicitly teach the testing of multiple test lots, but even if they are 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. Patent Owner's statement is nothing more than an unsupported assertion that the Examiner's conclusions, and those of the PTAB, are wrong. Notably, the Patent Owner does not include any substantive discussion – beyond what was already considered by the Examiner and the PTAB – as to why that is the case. Nonetheless, the Examiner did not err. Rather, the Examiner and the PTAB both recognized that the prior art, namely Price and Jarvis, teach two-tiered compositing at the pre-

[8] The Patent Owner's response is, again, largely a verbatim repeat of the arguments it previously made in response to the DOA. (*Compare* PO Resp. at 17 – 20 *with* PO Req. at 15 – 18). Requester has already addressed these arguments, and incorporates its prior Comments filed March 20, 2015, pages 15-17 by reference. In addition, the Examiner has considered those portions of the Patent Owner's response, and correctly found it to be unpersuasive. (Ex. Determination at 11-14).

enrichment and enrichment stages. In addition, the Examiner and the PTAB recognize that the prior art also taught the sampling from multiple, separate test lots as described in connection with step A1. Accordingly, step D1 is obvious in view of the cited prior art.

Patent Owner's statement is also belied by its admissions as to what was known in the prior art. Patent Owner has admitted that sampling multiple, separate test lots independently was known. (PO Resp. at 12). It would be well within the teachings of the prior art to incubate the composited, separate test lots so that the microorganisms reach detectable levels. Patent Owner has also admitted that combining portions of different samples was also known, albeit in the context of pre-enrichment cultures. (PO Resp. at 16). However, the PTAB and the Examiner found that the claims do not preclude pre-enrichment followed by enrichment, and Patent Owner has not rebutted this finding. Thus, when the Patent Owner's admissions are taken in combination, Patent Owner has effectively admitted it was known to pool samples from separate test lots, which would result in the formation of the modular composite sample of step D1.

The Patent Owner also disputes the Examiner's finding that the Patent Owner's prior argument that an increase in sampling and testing is counter-motivated by an increase in cost is simply an alternative motivation for selecting the suitable testing procedure. (PO Resp. at 21-22). Patent Owner asserts that although the art may have recognized the cost associated with destruction testing, "the art presumed that contamination was uniform, and thus had no conception or motivation that destruction costs could be minimized by simultaneously analyzing multiple separate operationally-linked test lots..." despite "substantial[ly] increased sampling costs." (PO Resp. at 22). But this is exactly the type of alternative motivation identified by the Examiner. (Ex. Determination at 13-14). The Examiner specifically notes that an "artisan most interested in preventing contamination would maximize the acceptance quality level in any

testing procedure." Such an artisan would naturally increase sampling and testing despite the increase in cost.

In addition, the Examiner also considered the "uniform contamination" argument advanced by Patent Owner and did not find it persuasive. (Ex. Determination at 12). In particular, the Examiner pointed to the Jarvis and Price references as acknowledging the art recognized advantages to compositing so that samples from individual test lots could be preserved for retesting. (*Id.* at 14). Patent Owner address this finding, but only repeats the earlier assertion that the art only recognized the cost of destructive testing, but had no conception that destruction costs could be minimized. (PO Resp. at 22). In doing so, the Patent Owner apparently overlooked the Examiner's additional finding that "[s]ubsequent testing was already known to save those lots that might be subsequently validated while controlling those lots which retest positive and should be subsequently destroyed." (Ex. Determination at 14). Accordingly, contrary to the Patent Owner's assertion, it was known that subsequent retesting could validate non-contaminated lots, and this would obviously minimize destruction costs. Thus, Patent Owner's arguments are without merit, and step D1 is obvious.

Steps E1 and E2 Would Have Been Obvious in View of the Cited Prior Art

The DOA found that step E1, which involves testing, is taught by Price and Jarvis. (DOA at 19). The Examiner also found that this step is taught in the prior art. (Determination at 14-15). Patent Owner does not appear to contest that testing was taught in the art.

The DOA found that step E2 involves obtaining a negative test result, and then validating the test lots for release into commerce. (DOA at 19). Although the DOA found that the "validation" limit is a mental step that does not limit the claim, the DOA also noted that the step

is also met by Jarvis and Price because they also obtain negatives. (*Id.*). The Examiner has agreed with PTAB on both points. (Ex. Determination at 14-15).

Patent Owner argues that the step is not mental because it involves a physical testing step. (PO Resp.at 22). However, Patent Owner misses the point that the validation for release into commerce based on the test result is necessarily a mental step. Regardless, Patent Owner has not rebutted the finding that the step is taught in the prior art regardless of whether it is or is not a mental step. Accordingly, steps E1 and E2 are obvious in view of the cited prior art.

Steps E3 and E4 Would Have Been Obvious in View of the Cited Prior Art

The DOA concluded that step E3 is taught by Jarvis and Price because both references teach the concept of saving samples prior to compositing and returning to those samples if the composited sample tests positive. (DOA at 19-20). The Examiner also agrees with the finding of obviousness as set forth in the DOA. (Ex. Determination at 15). In particular, the Examiner found that Jarvis and Price teach two-tiered compositing steps for the purpose of reducing the amount of testing, and permitting the retesting of individual samples in the event the pooled composite sample tests positive. (*Id.*). The Examiner also notes the teaching can be applied to multiple lots as in FSIS and Midura, and that based on the results the test lots can be released into commerce and/or destroyed. (*Id.*). The Examiner further notes that all lots for release are required to obtain a negative test for each lot to be released. (*Id.*).

The Patent Owner's response is that the stored sample in Jarvis is a pre-enrichment sample, and not an enrichment sample. (PO Resp.at 23). However, Patent Owner has overlooked that Price teaches that direct enrichment may be used. (Price at 682). In addition, the claims do not preclude pre-enrichment followed by inoculation of enrichment broth prior to formation of

National Beef Ex. 1007
Page 1769

the modular composite sample. Accordingly, as the PTAB and the Examiner have previously found, a person of ordinary skill in the art would have found such a step obvious.

Patent Owner also contends that each pre-enriched sample is not a statistical sample. (PO Resp.at 23). Patent Owner ignores that both the Jarvis reference and the Midura reference are devoted to statistical sampling methods. Thus, those references would have taught the taking of sufficient samples so that each separate test lot could be "validated." Accordingly, step ES would have been obvious in view of the cited prior art.

Patent Owner does not separately argue step E4. Accordingly, the Examiner's determination that step E4 is found in the prior art is unrebutted.

The Samadpour Declaration Fails to Overcome the Obviousness Rejection

The PTAB fully considered all of the alleged evidence of secondary considerations that Patent Owner submitted during this proceeding, and correctly found that it was lacking. (DOA at 23-25). In particular, the PTAB found that Patent Owner had failed to establish a nexus between the alleged evidence of commercial success, and overcoming skepticism in the field. (*Id.*). Patent Owner attempted to remedy this by submitting yet another Samadpour declaration. The Examiner considered this additional Samadpour declaration, but found it insufficient to overcome the PTAB's rejection. (Determination at 16-17).

In response, the Patent Owner asserts that there was a profound cost disincentive with respect to anything that would increase sampling and associated costs above what was required by the regulatory agencies. (PO Resp. at 24). However, the Examiner addressed this argument and found that it simply provides alternative motivation for selecting suitable testing procedures. (Ex. Determination at 13-14). Moreover, it is unclear how this relates to any secondary consideration. To the extent, Patent Owner alleges this is a factor for commercial success, Patent

Owner has still failed to demonstrate a nexus between any alleged commercial success and a claim limitation that is not found in the prior art. *See* Discussion of Claim Amendments, *infra*.

The Patent Owner also argues that the FSIS mandated modification of the testing procedure to test individual enrichment component samples separately, even when the claimed modular sample was negative, does not nullify the nexus between the claims and secondary considerations. (PO Resp. at 25). Patent Owner asserts that the extra step is only necessary in 10-15% of the data used to support commercial success. (*Id.*). However, Patent Owner has not submitted any corrected data to show sales data when the extra step was needed versus sales data when it was not needed. Moreover, even taking as true that the extra step is only needed in certain instances, the fact remains that the extra step is still needed. Accordingly, a nexus between the claimed method and any alleged secondary considerations has still not been established

Rejections 2 – 4 Should Be Affirmed

The PTAB affirmed Rejections 2 – 4 (covering dependent claims 5, 6, 21, 23, 24, 28 – 30, 32, and 33) because the Patent Owner made the same unpersuasive patentability arguments for these Rejections as it made for Rejection 1. (DOA at 26). The Examiner also noted that Rejections 2 – 4 have not been separately argued. (Ex. Determination at 17). In its Response, Patent Owner has again not argued these Rejections separately, and instead relies on the arguments it made in relation to Rejection 1. (PO Resp. at 30). Because those arguments fail to overcome Rejection 1, and Patent Owner has set forth no additional arguments, the rejections should be maintained.

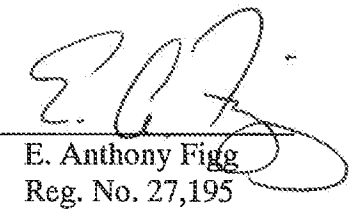
National Beef Ex. 1007
Page 1771

Conclusion

In view of the above comments, it is respectfully requested that the PTAB's Rejections 1 – 4 be affirmed.

Date: September 21, 2015

Respectfully submitted,



By: _____
E. Anthony Figg
Reg. No. 27,195

Rothwell, Figg, Ernst & Manbeck
1425 K. Street, N.W., #800
Washington, D.C. 2005
(202) 783-6040

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 12/23/2016

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
12/23/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMÉRIEUX, INC.
Requester and Respondent

v.

Patent of
INSTITUTE FOR ENVIRONMENTAL HEALTH INC.
Patent Owner and Appellant

Appeal 2017-001150
Reexamination Control 95/001,294
Patent 7,534,584 B2
Technology Center 3900

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION UNDER 37 C.F.R. § 41.77(f)

This Decision under 37 C.F.R. § 41.77(f) modifies the Decision on Appeal entered January 20, 2015 in Appeal 2014-007983 ("the 7983 Decision"). The 7983 Decision is a decision on the appeal to the Patent Trial and Appeal Board ("the Board") in an *inter partes* reexamination of United Stated Patent (US) 7,534,584 B2 ("the '584 patent"). The real party

in interest and assignee is Institute for Environmental Health Incorporated ("Patent Owner" or "IEH"). Appeal Br. 2 (dated May 7, 2012).

In the 7983 Decision, new grounds of rejection 1–4 were entered pursuant to 37 CF.R. § 41.77(b) because the rationale and cited prior art differed from how the rejections were stated in the Right of Appeal Notice. 7983 Dec. 3–4 (listing new grounds 1–4), 26.

In response to the new grounds of rejection, Patent Owner amended the claims and provided a fourth Declaration by Mansour Samadpour, Ph.D., the sole inventor of the '584 patent ("Samadpour 2015 Decl."). Patent Owner's Response Requesting Reopening of Prosecution (dated Feb. 20, 2015). Requester filed comments to Patent Owner's Response (dated Mar. 20, 2015). The Examiner subsequently entered the submissions by Patent Owner, and in a determination under 37 CF.R. § 41.77(d), maintained all four rejections. Patent Owner and Requester filed Comments subsequent to the Examiner's § 41.77(d) determination. As explained below, we reverse the Examiner's determination.

Claim 1 is representative and reads as follows (underlining and brackets indicate changes to the claim, relative to the original claim, made by Patent Owner during the reexamination proceeding; underlining and bold indicate changes made in the claim amendment after the PTAB 7983 Decision):

> 1. A method of sampling, testing and validating a plurality of **operationally-linked** test lots **of beef** for release into commerce [[microbial contamination]], 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[[, according to a statistical sampling plan]] 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 plurality of portions thereof]];

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 [[inter-lot]]composite sample; and

e) testing of the modular [[inter-lot]]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 lots [[samples]] are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots [[may nonetheless yet be]] are validated[[, according to the statistical sampling plan,]] for release into commerce, according to 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).

Claims

Claims 1–23 and 26–33 are pending. Claims 1 and 17 are independent claims; the remaining claims depend from them.

Independent claim 1 is directed to a method of sampling, testing, and validating a plurality of operationally-linked test lots of beef. The claim has five steps, numbered a) through e). The 7983 Decision, for further reference, numbered the additional limitations within each step of the claim. 7983 Decision 11–12. Patent Owner attached Exhibit B to the Appeal Brief, which contained Figure 2, illustrating an embodiment of the claim. The steps listed in Figure 2 are also referenced below.

In step a), portions from separate operationally-linked test lots are collected. As explained in the '584 patent and Patent Owner's briefs, a test lot can be a "combo bin." During typical beef processing, five combo bins are filled with meat. The combo bins represent the raw material upon which sampling and testing is carried out to determine whether the meat is accepted or rejected. '584 patent, col. 7, ll. 18–27.

In step b), the portions from each bin are collected into a "set" of separate test lot samples. This is shown as step 1 in Figure 2. For each bin, there is a separate test lot sample comprising all the portions taken from that bin.

In step c, each separate test lot sample is incubated to allow the microorganism to grow to detectable levels. This step, which the 7983 Decision characterized as the prior art "enrichment" step (7983 Decision 6–9), is shown in Figure 2 as step 2.

In other words, samples from every bin are collected and combined and then the combined samples from each bin are separately enriched in a culturing step.

Step d) comprises "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample." This step is illustrated in Figure 2 as step 4.

The final step of the method is step e) which comprises testing the samples.

Claim 17 has the same steps as claim 1, but the test lots are drawn to "meat or poultry."

Obviousness and Secondary Considerations

Patent Owner provided evidence of commercial success (7983 Dec. 20) and skepticism that the claimed invention would work (*id.* at 22). *See* Declarations of Mohammad Koohmaraie and Mansour Samadpour. The secondary considerations were not considered persuasive because the Board found that 1) it had not been established by Patent Owner that the stated success was due to the merits of the claimed method and because 2) the claims were not limited to beef and other meats, while the evidence, including both commercial success and skepticism, was directed to these embodiments. *Id.* at 23–24. In response to the 7983 Decision, Patent Owner amended the claims, restricting them to beef (claim 1) and meat or poultry (claim 17). Patent Owner's Response to Board Decision. As discussed above, Patent Owner also provided the new Samadpour 2015 Declaration. Upon reconsideration of the totality of the evidence, including the evidence

of obviousness based on the cited prior art rejections, we shall **reverse** all the rejections.

In the prior Decision, the Board questioned whether the testimony and reported data in the Declarations by Dr. Samadpour, Dr. Koohmaraie, and Mr. Mirtsching was due to the merits of the claimed invention, rather than a feature readily available in the prior art. The Declarations distinguished the claimed method from the "classical" product." The Board found that Patent Owner "did not provide an adequate explanation of the . . . 'classical' product to understand the differences between the two and understand the reason for the success. For instance, was the success solely attributable to the post-enriching step e2 or to another step which was readily available in the prior art?" 7983 Dec. 24.

Patent Owner explained in their Response to the Examiner's Determination under 37 C.F.R. § 41.77(d) ("41.77d Response") that the classical prior art method used in the meat industry to test for microbial contamination is outlined in Figure 1, attached as "**Exhibit A**" to the Response filed on July 26, 2010 to the Examiner's Non-Final Office Action. 41.77d Response 26. Figure 1 was also attached to the Appeal Brief. Patent Owner characterized the method illustrated in Figure 1 as the "Present Industry Art." Patent Owner indicates that the comparison for the purposes of the stated commercial success and skepticism is between this classical method and the claimed method as illustrated in Figure 2, attached to the Appeal Brief as Exhibit B. *Id.* The steps of the claimed method are shown in Figure 2.

The first 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. The second 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" (step d1 of the claimed method) and then tested for the presence of microorganisms. In other words, 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.

The rationale to have reversed these steps is based on the teachings in Jarvis and Price that statistically reliable results in testing for the presence and absence of microorganisms are obtained when samples are pooled together prior to the pre-enrichment and enrichment culture steps. 7983 Dec. 17. Based on these teachings, the Board determined that it would have been obvious to one of ordinary skill in the art to have pooled samples *after* the enrichment step to reduce the number of samples to be tested as expressly taught by Jarvis. *Id.* at 17-18. Thus, while pooling samples after the enrichment culture step had not been explicitly described in the cited prior art, samples had been pooled together and cultured to grow microorganisms for subsequent detection. *Id.* The Decision also pointed to disclosure in Jarvis of compositing samples at the pre-enrichment step, and

then compositing samples from the pre-enrichment stage and inoculating enrichment media with the composited samples. *Id.*; Jarvis 141 (method (3)).

Commercial Success

Declarants

In the 7983 Decision, testimony was cited by Dr. Mohammad Koohmaraie, CEO of the Meat Division of Institutes of Environmental Health (IEH) Laboratories and Consulting Group and formerly Director of the U.S. Meat Animal Research Center (US MARC) of the USDA-ARS. 7983 Dec. 20-21; Koohmaraie Decl. ¶¶ 3, 4. Dr. Koohmaraie testified that from "1992 to 2005" he was "the leader of all the post-harvest research conducted at USMARC" and has considerable and leading experience in food safety and control of *E. coli* in the red meat supply. *Id.* at ¶¶ 5–11. We find that, while Dr. Koohmaraie is employed by Patent Owner IEH, his experience as a former Director of the U.S. Meat Animal Research Center (US MARC) of the USDA-ARS and his extensive work in the control of *E. coli* in meat products, as set forth in his Declaration, makes Dr. Koohmaraie a qualified and credible Declarant.

Dr. Mansour Samadpour, who is the CEO of IEH, the assignee of the '584 patent, and the patent's sole inventor, also provided evidence of commercial success. Dr. Samadpour states in his curriculum vitae that "currently IEH conducts testing for about 1/3 of the U.S. market." Samadpour 2010 Decl. (Appendix A). In view of his education (Ph.D. in Food Science and Technology), publications, and extensive experience on

food safety as described in his curriculum vitae, we find him to be a qualified and credible Declarant.

Evidence

Dr. Koohmaraie testified that surprisingly, while "post-enrichment inter-lot pooling [(steps d1 and e2)], as disclosed and claimed in the current patent, requires increased sampling/testing expense (about 30% more than with the prior industry standard) it has been rapidly and widely adopted and solves a long standing problem in the art by providing for a more robust testing method with enhanced safety" for consumers. Koohmaraie Decl. ¶ 13. Further, Dr. Koohmaraie testified that "largely because of IEH's implementation of its modular inter-lot pooling methods [(step d1)], IEH provides laboratory testing for about 30% of the cattle processed in the United States and about 40% of the cattle processed in Canada." *Id.* ¶ 14.

Dr. Koohmaraie provided data "from an IEH conducted *E. coli* O157:H7 testing program in beef trim" using "inter-lot composite pooling method [(step d1)], as disclosed and claimed in the current patent." *Id.* ¶ 15. This data was said by Dr. Koohmaraie to have saved "a representative client of the company . . . 477 combo bins—each containing about 2000 lbs[.] of beef trim," avoiding unnecessarily discarding uncontaminated bins." *Id.* ¶¶ 15–16. Dr. Samadpour also testified about wide-spread acceptance of the claimed method and the cost-savings of using the method. Samadpour 2010 Decl. ¶ 7.

Dr. Koohmaraie concluded that "[w]et composite inter-lot pooling, as disclosed and claimed in the current patent, is the technology that

surprisingly makes single combo testing a viable option." Koohmaraie Decl. ¶ 18.

Dr. Samadpour also stated that it was surprising that the claimed method was widely adopted because of the costs and large number of samples utilized. Samadpour 2010 Decl. ¶¶ 4, 10.

Dr. Samadpour further testified that:

> IEH company sales figures for the last four years have increased at an average rate of 30% per year, based on client adoption of the methods claims in the present patent application comprising inter-lot pooling of enriched samples, and the ability to yet validate and release individual lots after obtaining a positive result for an inter-lot pool sample.

Samadpour 2010 Decl. ¶ 11.

Dr. Samadpour testified that "the increase in sales for the new inventive modular composite method was not the result of advertising effort." Samadpour 2011 Decl. ¶ 44. Appendix H of the same Declaration shows growing revenue for the modular compositing method, while revenue gradually decreased in the "classical" testing method that costs less and uses larger samples. *Id.* ¶ 38. In 2008, revenue from the classical testing method was over 12 million dollars, while the modular compositing revenue was less than 1 million. By 2010, revenue for the modular compositing method was over 10 million, while the classical testing method had declined to less than 2 million.

Skepticism

Declarants

In addition to the testimony by Dr. Samadpour, Declarations by Warren Mirtsching and James Byron were provided as evidence of skepticism in the industry that the claimed method would be suitable for meat testing.

Mr. Mirtsching is the Chief operating Officer in the Meat Division of IEH, and formerly was employed by Swift and Company in charge of food Safety. Mirtsching Decl. ¶¶ 3, 4. Mr. Mirtsching states that he was employed by Swift at the time the company decided to investigate whether Dr. Samadpour's wet composting method could be used for testing meat products. *Id.* ¶ 4.

Mr. Byron states that from 2005 until 2009 he was employed by a competitor of IEH. Byron Decl. ¶ 3. Mr. Byron states that he joined IEH in 2010. *Id.*

Evidence

Dr. Samadpour testified that he "was faced with a high degree of skepticism by experts in the field, and regulatory agencies (FSIS)." Samadpour 2011 Decl. ¶ 34.

> **It took years to overcome the skepticism of the experts in the field**. In my attempts to have USDA Food Safety Inspection Service (FSIS) accept the method and issue a letter of no objection, it became apparent that the agency was extremely apprehensive about the loss of sensitivity due to pooling, mainly masking a positive sample by a number of negative samples.

Id.

Dr. Samadpour described his efforts to gain acceptance of his method. *Id.* Dr. Samadpour testified that to get FSIS to accept the method, he had to modify the protocol as follows: "If the modular composite sample is negative, each individual enrichment component is tested individually before it is released into the chain of commerce." *Id.* Dr. Samadpour also described the skepticism of his clients. *Id.* ¶ 35.

Dr. Samadpour's testimony was corroborated by Mr. James Byron who had been a competitor of IEH, but has since joined the company. Byron Decl. ¶ 3. For example, Mr. Byron testified that the method was "scoffed" at by the manager for food safety at Mr. Byron's former company because it was believed that the method would result in false negative results. *Id.* ¶ 4. Mr. Byron also testified that he experienced the skepticism of customer's first hand. *Id.* ¶ 7.

Mr. Warren Mirtsching, Chief Operating Officer at IEH, testified that while he was employed by Swift and Company, a meat producer, he was concerned about the sensitivity of Patent Owner's method. Mirtsching Dec. ¶¶ 4–5. To address these concerns, Mr. Mirtsching stated that he carried out detailed testing using the method and found that "it was sensitive enough to meet the requirements prescribed by Swift." *Id.* ¶ 7. Mr. Mirtsching identified major customers of Swift, such as Tyson Company, that had "initially refused to accept product that was tested using Dr. Samadpour's methods," but were later convinced that Patent Owner's method worked. *Id.* ¶¶ 8–9.

Discussion

First, we begin with discussing the obviousness of the claimed method. As indicated above, step d) in which post-enrichment samples are pooled after the enrichment step is not disclosed in the cited prior art. Requester argues that such step would have been obvious to one of ordinary skill in the art because "two-tiered compositing" is described in Jarvis. Requester Comments on Patent Owner's Response after Examiner's § 41.77(d) Determination 6. The 7983 Decision also cited Jarvis for its teaching of compositing both pre-enrichment samples and enrichment samples (Jarvis 141, method 3), and Jarvis's statement that such method has "the same degree of statistical confidence as would be attained by testing the 10 samples separately." Jarvis 141; 7983 Dec. 18.

In Jarvis, the compositing is done prior to culturing; in the claimed method, however, the compositing is done after the culture step is done. Mr. Byron provided evidence of skepticism of the claimed method because diluting samples *after* culture could lead to false negative results. Byron Decl. ¶ 4:

> At the time, the 'idea' of wet modular composite pooling was not an obvious testing strategy, in fact it was scoffed [at] by Dr. Cloak [(Marketing Manager responsible for SDI Food Safety business)] when presented by IEH as she believed that detection limits would be compromised because of the small amount of enriched sample from a 'positive' sample when combined with 'negative' samples would lead to false negative results.

Thus, the skepticism is directed to a step that was not expressly disclosed in the prior art, but rather was said to be obvious based inferences from Jarvis.

With regard to the commercial success, Patent Owner did not challenge statements in the Decision that the commercial success evidence as summarized above related primarily to beef. 7983 Dec. 24. In Response to the Decision, Patent Owner amended claim 1 to require the test lots to be "operationally-linked test lots of beef." Consequently, the evidence of commercial success is now commensurate with the scope of claim 1.

In the previous Decision, the Board had found that Patent Owner did not persuasively demonstrate that the success of the claimed invention was a result of an inventive and claimed feature, rather than a step that was readily available in the cited prior art. *Id.* To address this concern, Patent Owner identified Figure 1 as the "industry art," inviting a comparison between Figure 1, the prior art of record, and the claimed invention as depicted in Figure 2.

We agree with Patent Owner that Figure 1 is representative of the cited prior art. Step 1 of Figure 1 shows compositing of samples, a step found in Price, Jarvis, and Gabis. 7983 Dec. 16. In the Decision, the Board acknowledged that these cited publications did not explicitly describe compositing samples from the same combo bin as required by step b1 and then enriching them separately as in step c1. *Id.* at 15–16. However, the Decision determined that 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 16. The Decision also acknowledged combining samples after enrichment, as required by step e1, was not described in the prior art.

Id. at 17. Thus, as discussed above, the steps described as responsible for the commercial success, namely steps b1, c1, and e1, 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. *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

In the 7983 Decision, the Board noted that Dr. Samadpour testified that to convince the USDA Food Safety and Inspection Service (FSIS) to accept the method, he had to modify the protocol by testing each individual enrichment component separately, even when the modular composite sample was negative. Samadpour 2011 Decl. ¶ 34. The Board stated that "[i]f the method responsible for the market share and increased revenue assays each test lot separately whether negative or positive, then it has not been established that the modular composite testing as claimed is responsible for the success." 7983 Dec. 25. Dr. Samadpour explained in his newly filed Declaration that in "85-90% of the instances, where all the separate individual lots used to build the modular composite sample are sold to the same entity, there is no such requirement for assaying each individual enrichment component separately, even when the modular composite sample was negative." Samadpour 2015 Decl. ¶ 14 (emphasis omitted). Dr. Samadpour also testified that "at most 10-15% of the data in the record used to support commercial success" was attributable to the extra step of assaying. *Id.* We have been given no reason to doubt the Declarant's credibility. Accordingly, since the majority of the sales do not require testing every combo bin in contrast to the method of claim 1, we conclude

that a preponderance of the evidence establishes that the claimed modular composite testing is responsible for the commercial success.

The skepticism described in the Mirtsching, Samadpour, and Byron Declarations was directed to the claimed method as it is used in the beef industry. Claim 1 has now been amended to limit its scope to beef. Consequently, a nexus between the stated skepticism and the claimed method has been established. For this reason, we withdraw the objection set forth in the 7983 Decision to the evidence of skepticism in the industry.

Independent claim 17 is not limited to beef, but was further amended to recite "meat or poultry." Dr. Samadpour testified that "fabrication of meats such as pork sheep, bison, poultry, seafood and the like, is analogous to beef fabrication in terms of art-recognized production runs and lots, and thus derives comparable commercial benefits from the same modular compositing of multiple independent operationally-linked production lots within a production run." Samadpour 2015 Decl. ¶ 12. We have not been directed to a persuasive deficit in this reasoning. Consequently, we conclude that evidence is commensurate with the scope of claim 17, as well.

SUMMARY

The evidence of secondary considerations when considered in light of the obviousness rejections, particularly the obviousness of steps d) and e), establishes the non-obviousness of claims 1, 17, and dependent claims 2–16, 18–23 and 26–33.

REVERSED

PATENT OWNER:

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, WA 98101-3045

THIRD PARTY REQUESTER:

ROTHWELL, FIGG, ERNST, & MANBECK, P.C.
607 14th Street, N.W.
Suite 800
Washington, DC 20005

Filed on behalf of bioMérieux, Inc.

By: Stanley E. Fisher
Registration No. 55,820
Williams & Connolly, LLP
725 12th St., NW
Washington, DC 20005
Telephone: 202-434-5000
Facsimile: 202-434-5029
Email: sfisher@wc.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMÉRIEUX, INC.
Requester and Respondent

v.

Patent of
INSTITUTE FOR ENVIRONMENTAL HEALTH INC.
Patent Owner and Appellant

Appeal 2017-001150
Reexamination Control 95/001,294
U.S. Patent No. 7,534,584 B2

PETITIONER'S REQUEST FOR REHEARING

Mail Stop: "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R § 41.77(b), bioMérieux, Inc. ("Requester") hereby requests rehearing of the Board's decision (December 23, 2016) ("Decision") to reverse the Examiner's rejection of Claims 1-4, 6-20, 22, 24-27, 31, and 32 of U.S. Patent No. 7,534,584 as obvious in view of Jarvis, Price, FSIS, and Madura (full citations in Decision).

In pertinent part, the patent claims at issue relate to and combine 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. As reflected by findings in two Examiner decisions and one Board decision prior to the Decision, the prior art disclosed that samples could be composited at multiple stages of the testing process, including before and after the pre-enrichment and enrichment steps. Indeed, multiple prior art references taught two-stage compositing. The purported improvement of the '584 patent is to composite samples within an individual lot before enrichment, and then after enrichment, perform a second compositing step to combine the enriched samples from individual lots into one sample for testing, *i.e.*, the patent adds a compositing step after enrichment.

The first time this patent came to the Board, the Board not surprisingly concluded on the basis of *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 413 (2007) that Requester had made a strong prima facie showing that the claimed method was

PAGE 5/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1792

obvious. *See* Decision of January 20, 2015 ("the 7983 Decision"). As 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." 7983 Decision at 17-18. And to the extent that the precise sequence of sample combination and enrichment claimed in the patent was not expressly taught, the Board reasoned that compositing within an individual lot was "commonsense," *id.* at 16, and that compositing before and after enrichment would have been obvious and predictable in light of the teaching in Jarvis that "pooling samples at two different steps" maintains "the requisite sensitivity in detecting positives for contamination." *Id.* at 18.

The Patent Owner challenged these conclusions in its Comments on Examiner's Determination after Board Decision (August 20, 2015) ("Patent Owner Comments"), but the Examiner reaffirmed that "[t]he art suitably motivates to testing multiple lots in a two-tier composite procedure," and "[t]he artisan aimed toward maximizing consumer protections and minimizing release of contaminated material over any concern for testing costs, would employ such suitable methods as was well within the skill of the art at the time of the invention." Examiner's Determination (July 20, 2015) at 16-17.

But in the Decision, the Board overturned the Examiner's rejection. The Decision did not contradict the Board's previous conclusion that the claimed

PAGE 6/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1793

subject matter was prima facie obvious, but instead turned on the Board's assessment of the Patent Owner's evidence regarding two secondary considerations of obviousness: commercial success and expert skepticism. For the reasons that follow, that decision was erroneous. Rehearing should be granted.

I. The Decision Misapprehended or Overlooked KSR and its Progeny In Concluding Secondary Considerations Rebutted the Prima Facie Case.

In the 7983 Decision, the Board cited common sense and common knowledge as reinforcing its conclusion that the steps of the claimed method were taught in the prior art. It is "commonsense," the Board pointed out, "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 16. That conclusion follows necessarily from the Supreme Court's recognition in *KSR* that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421.

In the Decision, however, the Board inexplicably abandoned reliance on the clear teachings of the prior art and common sense, finding that secondary considerations established the '584 patent's nonobviousness. That was error because, as set forth below, the Board's conclusions on commercial success and

PAGE 7/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1794

skepticism are legally and factually unsupported. Just as importantly, the Board disregarded the rule that such evidence "simply cannot overcome a strong prima facie case of obviousness" like the one found to exist in the 7983 Decision. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1242 (Fed. Cir. 2010).

In *KSR*, the Supreme Court upheld the district court's summary judgment of invalidity for obviousness despite evidence of commercial success. 550 U.S. at 413. That evidence, the Court explained, could not "dislodge the determination that claim 4 is obvious." *Id.* at 426. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), is similar. There, the Court held that the alleged secondary considerations did not "tip the scales of patentability" where the claimed invention "rest[ed] upon exceedingly small and quite non-technical mechanical differences in a device which was old in the art." *Id.* at 36.

The Board adhered to and applied this guidance in the 7983 decision when it affirmed the invalidity of the '584 patent; it should do so again on rehearing. If the Board fails to do so, it will be removing common knowledge from the public domain and ensure that numerous stakeholders in the food processing industry expend scarce resources to address a patent that is clearly invalid.

II. The Decision Misapprehended or Overlooked Several Points on Commercial Success.

1. In analyzing commercial success, the Board misapprehended the record evidence, and consequently gave too much weight to the Patent Owner's

PAGE 8/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1795

declarations. The Patent Owner has not pointed to any authority suggesting that the limited success purportedly achieved by its product—at most, a 30% market share in the United States—should be given dispositive weight in the face of strong evidence of obviousness, including the limited design choices available and the closeness of the prior art to what is claimed. Evidence regarding commercial success supports only a "chain of inferences" leading to a finding of non-obviousness. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). And that chain is broken if the Patent Owner cannot establish that the supposedly novel features of the invention that motivated those sales were not already available to the public. *Id.*

In the 7983 Decision, the Board correctly determined that the Patent Owner had failed to demonstrate the required nexus between the claimed invention and the evidence of commercial success. *See* 7983 Decision at 23-24. The Patent Owner since then has offered no new evidence to rebut that conclusion besides a new declaration from the patent's inventor, Dr. Samadpour, asserting that an example in the patent's specification "demonstrated the *nexus* between the invention as claimed and the related benefits which . . . have led to the current success of" the patent. Samadpour 2015 Decl. ¶ 11.

This is plainly inadequate. The Federal Circuit has repeatedly held that a patent owner cannot make a sufficient showing of commercial success simply by

PAGE 9/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1796

submitting a declaration that "merely repeats, in conclusory fashion, that there is a nexus between the success of [the commercial product] and the claimed invention." *In re Cree, Inc.*, 818 F.3d 694, 703 (Fed. Cir. 2016); *see also In re Mageli*, 470 F.2d 1380, 1384 (CCPA 1973) (finding that a submitted affidavit is the "kind of conclusionary, opinion, hearsay evidence [] entitled to little weight"). That rule is particularly apt where, as here, the evidence establishing commercial success consists solely of declarations from interested parties. "[S]elf-serving statements from researchers about their own work do not have the same reliability" as statements from independent sources. *Cree*, 818 F.3d at 702; *see also In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) ("[T]he inventor's opinion as to the purchaser's reason for buying the product . . . alone, is insufficient.").

But even crediting the Declaration, it was a mistake to conclude that the Patent Owner had addressed the lack of nexus by "inviting a comparison" between Figure 1 (the supposed "industry art"), the prior art of record, and the claimed invention as depicted in Figure 2. Decision at 14. Both Figure 1 and Figure 2 were included in the Patent Owner's Appeal Brief, and were before the Board for the 7983 Decision. The Decision does not explain why or how the information contained in those Figures alters its previous conclusion that the Patent Owner had failed to establish a nexus between commercial success and the claimed invention.

PAGE 10/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1797

In choosing to credit the Patent Owner's declarations, the Board also overlooked contrary testimony from Requester's declarant, Dr. Bailey. Dr. Bailey explained that, far from being surprising, the results obtained by the claimed method would have been "predictable" to a person of ordinary skill. In Dr. Bailey's view, the steps making up the claimed method would have been combined by anyone seeking "to improve efficiencies and reduce costs." Bailey Decl. ¶¶ 8a, 9f. It is exactly subject matter like this that *KSR* and its progeny directs is not patentable. Dr. Bailey's testimony thoroughly undermines the Patent Owner's evidence, but the Decision on Review does not even cite it, let alone explain why the Board concluded that the self-serving declarations of the patent inventor and his employees on commercial success should be considered more credible.

2. Despite the weakness of the Patent Owner's evidence of commercial success, the Board determined in the Decision that a nexus between the supposed inventive concept and commercial success existed because "the steps described as responsible for the commercial success, namely steps b1, c1, and e1, 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." Decision at 15 (internal citation omitted). That conclusion is a factual about-face from the 7983 Decision, which detailed at length the ways in which the improvements allegedly invented by the Patent Owner had already been disclosed in the prior art.

PAGE 11/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1798

Step b1, for example, was defined in the 7983 Decision as "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." As the Board pointed out in that earlier decision, both Jarvis and Price taught compositing samples to reduce the number of samples tested. 7983 Decision at 16.[1] The 7983 Decision similarly found that step e1 "involves testing which is taught by Jarvis and Price." *Id.* at 19. Step e1 was later amended from testing on an "inter-lot composite sample" to a "modular composite sample." Decision at 3. But that change does not affect the prior art teaching that testing could be performed on composited samples that had been enriched.

The 7983 Decision also addressed the Patent Owner's arguments for the nonobviousness of the "enrichment" limitation in step c1, defined as "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

[1] The Board's conclusion that step b1 was not known in the art is contrary to the admissions made by the Patent Owner in his Comments. There, the Patent Owner acknowledged that "mere compositing (combining multiple samples taken from a single test lot to form a test lot sample) was known in the art." Patent Owner Comments at 13.

PAGE 12/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1799

test lot samples to reach detectable levels." 7983 Decision at 11. The Patent Owner previously argued that the relevant references, Gabis and Price, taught away from using direct enrichment (*i.e.*, enrichment after compositing), because it was unreliable "due to effects related to dilution of the target organism and competition from non-target organisms." 7983 Decision at 16 (quoting Samadpour 2010 Decl. ¶ 8). But the Board "d[id] not find [those arguments] persuasive," observing that "[e]ven if direct enrichment is inferior, a teaching that a result would be inferior or less desirable is not a teaching away unless the use 'would render the result inoperable.'" *Id.* at 17. The Decision offers no explanation for why the Board is now persuaded by the exact arguments it previously rejected.

In any event, "just because better alternatives may exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1381 (Fed. Cir. 2015) (internal citation omitted). For example, *In re Cree, Inc.*, 818 F.3d 694 (Fed. Cir. 2016), endorsed the Board's finding that the prior art's discussion in negative terms of a pre-existing element of a claimed combination nonetheless disclosed the element and rendered the claimed subject matter obvious. *See id.* at 700 ("In saying that down-conversion was a discredited solution to the problem of generating white light from LEDs, Dr. Wetzel in effect acknowledged that down-conversion of LED light was at least known to those in the art."); *see also KSR*, 550 U.S. at 426 (prior art did not

PAGE 13/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1800

teach away where it was merely "inefficient as compared to [the] preferred embodiment"). The Board had it right the first time—where, as here, there are two options taught by the prior art, one purportedly superior to the other, picking the inferior option to optimize is no less obvious.

3. The Decision also misapprehended the evidence of commercial success applicable to Claim 17. The Patent Owner's declarant, Dr. Samadpour, acknowledged that his evidence, such as it was, was essentially limited to beef. Nevertheless, the Board credited his *ipse dixit* testimony—unsupported by any citation to corroborative industry guidance—that "fabrication of meats such as pork, sheep, bison, poultry, seafood, and the like, is analogous to beef fabrication," and went on to find the Patent Owner's amendment of Claim 17 to specify its application to "meat or poultry" was sufficient to make the claim commensurate with the evidence of commercial success. Decision at 16. But this again is an unexplained reversal from the Board's 7983 Decision, where it determined, correctly, that evidence regarding commercial success attributable to beef *could not* automatically be applied to other meats. 7983 Decision at 24. Dr. Samadpour's conclusory assertion to the contrary does not change this analysis.

III. The Board Misapprehended or Overlooked the Evidence Regarding Industry Skepticism.

The Board erred as well when it relied on the Patent Owner's evidence of experts' skepticism toward the claimed invention. Skepticism evidence cannot

PAGE 14/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1801

overcome a prima facie case of obviousness unless it establishes that the claimed invention "was not viewed as technically feasible" by persons of ordinary skill. *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 955, 958 (Fed. Cir. 1997) (crediting experts' fear of "violent explosions" when mixing the chemicals required to make the claimed invention). The Patent Owner's new evidence of skepticism—again consisting entirely of Dr. Samadpour's uncorroborated statements—did not and could not possibly satisfy that standard. To the contrary, as the 7983 Decision recognized, far from considering the method steps technically infeasible, everyone knew how to perform them.

In other words, the "skepticism" cited by the Patent Owner arose from the fact that the Patent Owner had not yet tested the method and the resulting uncertainty, including on implementation cost. But that is simply irrelevant because it does nothing to negate the fact the method was obvious to perform in light of the other advantages expected from combining the steps in the prior art, namely "improve[d] efficiencies and reduce[d] costs." Bailey Decl. ¶ 9f.

Even setting aside that fundamental flaw in the Patent Owner's evidence, the Decision failed to recognize and address the inherent "tension between [the Patent Owner's] argument about commercial success and its argument about widespread skepticism." *Kroy IP Holdings, LLC v. Safeway, Inc.*, 107 F. Supp. 3d 656, 676 (E.D. Tex. 2015) (Bryson, J., sitting by designation), *aff'd*, 639 F. App'x 637 (Fed.

PAGE 15/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1802

Cir. 2016). According to the Patent Owner's declarants, the claimed method's novelty meant that the industry did not recognize its benefits and, for that reason, refused to adopt it. But "[a]s a matter of simple logic, it seems unlikely that commercial success and lack of commercial success can both be indicative of non-obviousness in the same case." *Id.* Indeed, this was the Board's own reasoning in the 7983 decision when it rejected the Patent Owner's skepticism argument, pointing out that it had been "clearly established on the record that, *despite the skepticism*, the claimed method in its entire[t]y was adopted by the industry." 7983 Decision at 25 (emphasis added). Nothing in Dr. Samadpour's newly submitted declaration provides a basis for departing from that conclusion and elevating the Patent Owner's skepticism evidence above the clear evidence of obviousness.

IV. Independently, there is Good Cause for Rehearing Based on Recent Case Law on the Significance of Secondary Considerations.

Rehearing of the Decision is independently warranted under 37 C.F.R. § 41.79(b)(2) to consider the "radical[] changes [to] the law of obviousness,"[2] made by the Federal Circuit's recent *en banc* decision in *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034 (Fed. Cir. 2016), decided after submission of

[2] Hannemann et al., *Fed. Circ. Radically Changes the Law of Obviousness*, Law360 (Oct. 19, 2016).

PAGE 16/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1803

Requester's response to the Patent Owner's Comments last fall. *See* § 41.79(b)(2) (rehearing appropriate where good cause exists to "present a new argument based upon a recent relevant decision of either the Board or a Federal Court").

There is good cause to permit Requester to submit new argument because, as commentators and respected judges have pointed out, *Apple* "makes significant changes to the law of obviousness," *Apple*, 839 F.3d at 1075 (Dyk, J., dissenting), and, in particular, changes the extent to which secondary considerations of obviousness may be used to demonstrate the patentability of a claimed invention. For the first time, the Federal Circuit held in *Apple* that, in every case, "[a] determination of whether a patent claim is invalid as obvious . . . requires consideration of all four *Graham* factors," including the secondary considerations. *Id.* at 1048 (majority op.). It did so despite Chief Judge Prost's criticism of "the majority's elevation of secondary considerations beyond their historic role." *Id.* at 1063 (Prost, C.J., dissenting). The court further held that "the significance of secondary considerations [is] a factual question," rather than a legal determination. *Id.*, at 1076 (Dyk, J., dissenting). As a consequence, a party who challenges the validity of a patent on obviousness grounds must now prove that the patentee's evidence of secondary considerations is unpersuasive both legally *and* factually.

In connection with the Board's consideration of the *Apple* decision and the Federal Circuit's newfound requirement to evaluate secondary considerations as a

PAGE 17/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

National Beef Ex. 1007
Page 1804

factual matter, Requester files herewith two declarations addressed to the question of secondary considerations. Requester acknowledges the Board's interpretation of Section 41.79(b)(2) as not permitting the submission of new evidence on rehearing. Inasmuch as the Federal Circuit has thus far declined to address this issue, *see Lingamfelter v. Kappos*, 513 F. App'x 934, 938 & n.2 (Fed. Cir. 2012), Requester submits that the better reading of Section 41.79(b)(2) should permit a party seeking rehearing on the basis of new arguments to submit, where appropriate, evidence to support those arguments. In particular, such evidence should be permitted when rehearing is sought on the basis of a change in the law that requires the Board to address factual issues. *Apple* is such a decision.

As the accompanying declarations make clear, there are substantial reasons to question the Patent Owner's evidence regarding the secondary considerations of obviousness. For example, Dr. J. Stan Bailey, an expert with more than forty years of experience in the food testing industry, explains in his Declaration 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. *See* Bailey Decl. (2017) ¶¶ 9a-10d. In his opinion, the Patent Owner's increased sales were not due to compositing twice, a process that Dr. Bailey had previously explained was well-known in the prior art. And the Declaration of Nuno Reis, a sales and marketing executive with nearly two decades

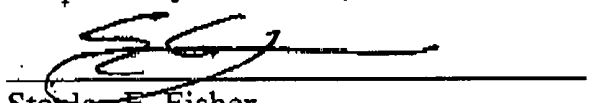
PAGE 18/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1805

of industry experience, explains that Requester's own sales increased significantly during the period in question, and that it was Patent Owner's marketing and business practices that were responsible for the Patent Owner's increase in revenue. This evidence convincingly contradicts what the Patent Owner has submitted on the issue of secondary considerations, and, in evaluating the impact of *Apple*, the Board should consider it.[3]

CONCLUSION

Rehearing of the Decision should be granted because it rested on erroneous legal conclusions that are inconsistent with the Board's prior decision in this matter. Rehearing should also be granted to permit the Board to reconsider its decision in light of the Federal Circuit's decision in *Apple* and Requester's evidence regarding Patent Owner's secondary considerations of obviousness.

Respectfully submitted,



Stanley E. Fisher
Attorney for bioMérieux, Inc.
Registration No. 55,820

DATE: January 23, 2017

[3] In the alternative, the Board should remand this matter to the Examiner for consideration of the declarations accompanying this Request.

PAGE 19/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1806

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Reexamination of the Patent of

Mansour SAMADPOUR

U.S. Patent No. 7,534,584

Issued: May 19, 2009 Docket No.: 2781-129

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

DECLARATION UNDER 37 C.F.R. §1.132

I, Nuno Reis, a citizen of the United States of America, hereby declare and state:

1a. I have over seventeen years of work experience in the area of sales and marketing of diagnostics for medical and industrial applications.

2a. I have a Bachelor of Science in Biology, which was conferred upon me by the State University of New York College at Cortland in Cortland, New York, in 1997.

2b. I have a Master in Business Administration (MBA), Marketing, which was conferred upon me by Iona College in New Rochelle, New York, in 2002.

3a. I have been employed by bioMérieux, Inc., the real party in interest under 37 C.F.R. §1.915(b)(8) in the *Inter Partes* Reexamination of the above-identified patent (hereinafter "the real party in interest"), since March 2004. I have held various roles, including Marketing Manager for Pathogen Detection Solutions Molecular Solutions, Asia Pacific Regional Business Manager for Food, and Account Manager in the bioFood Industry.

4a. I am familiar with the Institute for Environmental Health, Inc. (hereinafter "IEH") and its business practices through my experience in the field of *in vitro* diagnostics related to food for industrial applications.

PAGE 20/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

5a. I have read U.S. Patent 7,534,584 which issued to Mansour Samadpour on May 19, 2009 (referred to herein as the "584 patent").

5b. I have read the July 26, 2010 Declaration of Mohammed Koohmaraie, Ph.D., (hereinafter the "Koohmaraie declaration").

5c. I have read the July 26, 2010 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2010 declaration").

5d. I have read the January 31, 2011 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2011 declaration").

5e. I have read the February 20, 2015 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2015 declaration").

6a. From those documents, I am aware of IEH's assertion that the claimed modular composite testing is responsible for IEH's increased revenues during the time period in question (i.e., 2006-2010). It is my opinion that increased regulatory requirements, increased incidence of contamination, and IEH's business practices are the reason behind IEH's revenue growth.

6b. With respect to regulatory requirements, it is my opinion that the increasing regulatory environment has been a driving force behind increased testing of food products. The classification of *E. coli* as an adulterant in ground beef by the United States Department of Agriculture's Food Safety and Inspection Service (hereinafter the "FSIS") in 1994 led to increased testing of beef products. Similarly, the FSIS Federal Register Notice, published October 7, 2002, required all manufacturers of beef products to reconsider their sampling plans for *E. coli*. In many cases, it took several years for manufacturers to review their sampling plans, and the timing of the increased sales by IEH corresponds with increased interest in sampling plans more generally. It is my opinion that these increasing regulatory requirements or guidelines from the FSIS ultimately, after several years of back and forth with regulators after the Federal Register notice, led to an increased demand for testing services from beef manufacturers. This demand and resulting general increase in revenue is independent of the sampling strategy undertaken by the testing services.

6c. With respect to increased incidence of contamination, it is my opinion that the increased awareness of food recalls by consumers has led to an increase in testing volumes across all market segments (e.g., beef, produce, confectionary, processed foods, poultry). High profile incidents created consumer demand for more testing and caused concern among manufacturers regarding liability. These incidents included the FSIS recall of 354,200 pounds of ground beef manufactured at the ConAgra Beef

PAGE 21/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1808

Company Plant on June 30, 2002, which later expanded to 18.6 million pounds of ground beef, and the FSIS June 24, 2009 recall of 41,280 pounds of beef products from JBS Swift Been Company that may have been contaminated with *E. coli* O157/H7, which later expanded to 380,000 pounds of assorted pieces of beef.

6d. With respect to business practices, it is my opinion that IEH's offer to take all liability from manufacturer companies if there is a recall during the use of IEH services is a reason for the company's commercial success. Most of IEH's competitors do not make such offers, and in my opinion, explains why IEH's sales trended upward from 2006 to 2010. Two additional business practices of IEH further explain their increased revenue: (1) IEH is a service provider that performs sampling for their customers, which reduces the workload on the customer; and (2) IEH provides consultancy services to customers, which IEH then attempts to transition to testing services. Most of IEH's competitors do not offer those services.

7a. Moreover, it is my opinion that the beef and meat/poultry testing industries have had an increase in revenue over the time span covered by IEH's data that is not due to the claimed method but is instead due to external factors affecting the food testing industry in general. As discussed, it is my opinion that regulatory changes, public awareness, and IEH's business practices are the reason behind IEH's increased revenue, not the specific method claimed in the '584 patent.

7b. As evidence of increased revenue in general, Appendix A to his Declaration demonstrates that bioMérieux revenue from a product capable of testing for *E. coli* contamination of beef has increased year-over-year from 2009-2016 an average of 23% each year. This demonstrates that the increased revenue seen by IEH in that timeframe was not due to the invention per se, but by an overall trend in sales in the industry.

I hereby 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 so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code.

Date: 22 January 2017 Nuno Reis

Nuno Reis

PAGE 22/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

Appendix A

Annual Revenue and Percentage Increase from Previous Year for Vidas Up *E. coli* O157/H7 Product		
Year	Revenue ($)	Percentage Increase from Previous Year
2009	154,238	N/A
2010	289,160	87%
2011	421,302	46%
2012	404,717	-4%
2013	463,276	14%
2014	429,827	-7%
2015	466,277	8%
2016	552,952	19%
Average % Increase Year-over-year:		23%

PAGE 23/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Reexamination of the Patent of

Mansour SAMADPOUR

U.S. Patent No. 7,534,584

Issued: May 19, 2009 Docket No.: 2781-129

For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

DECLARATION UNDER 37 C.F.R. §1.132

I, Dr. J. Stan Bailey, a citizen of the United States of America, hereby declare and state:

1a. I have over forty years of work and research experience in the area of testing for microorganisms in food.

2a. I have a Bachelor of Science in Environmental Health Science, which was conferred upon me by the University of Georgia in Athens, Georgia, in 1974.

2b. I have a Master of Science in Food Science, which was conferred upon me by the University of Georgia in Athens, Georgia, in 1978.

2c. I have a Ph.D. in Poultry Science, which was conferred upon me by the University of Georgia in Athens, Georgia, in 1989.

3a. I have been employed by bioMérieux, Inc., the real party in interest under 37 C.F.R. §1.915(b)(8) in the *Inter Partes* Reexamination of the above-identified patent (hereinafter "the real party in interest"), since January 2008 as the Director of Scientific Affairs.

3b. Prior to my employment with bioMérieux, Inc., I spent thirty-four years as a research microbiologist employed by the United States Department of Agriculture ("USDA") within the Agricultural Research Service ("ARS") during which time I received seventeen USDA Certificates of Merit and was named "Outstanding Senior Research Scientist of the Year" in 2002.

PAGE 24/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

3c. I have taught as an Adjunct Professor in the Poultry Science Department at the University of Georgia and at the Department of Food Science at Kansas State University.

3d. I have been a Faculty Member at the "Rapid Methods and Automation in Microbiology Workshop" taught at Kansas State University where over one thousand scientists from fifty countries have received training in the area of microbiological testing.

4a. I have authored or coauthored over five hundred scientific publications in the area of food microbiology.

5a. I have read the July 26, 2010 Declaration of Mohammed Koohmaraie, Ph.D., (hereinafter the "Koohmaraie declaration").

5b. I have read the July 26, 2010 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2010 declaration").

5c. I have read the January 31, 2011 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2011 declaration").

5d. I have read the February 20, 2015 Declaration of Mansour Samadpour, Ph.D., (hereinafter the "Samadpour 2015 declaration").

6a. I have read U.S. Patent 7,534,584 which issued to Mansour Samadpour on May 19, 2009 (referred to herein as the "584 patent"). On January 13, 2010, I explained in a declaration submitted to the Patent Office why the claimed method in the '584 patent is well-known and obvious in view of the prior art of record. For the following five years, I understand that the Examiner and the Board agreed that the claims were obvious (See, the May 26, 2010 Non-Final Action; the December 17, 2010 Action Closing Prosecution; the February 8, 2012 Right of Appeal Notice; the July 17, 2013 Examiner's Answer to the Appeal Brief; the January 20, 2015 Patent Board Decision; and the July 20, 2015 Examiner's Determination on Patent Owner Response/Requester Comments after Board Decision.

6b. While I am not an attorney, I have been advised on certain relevant legal principles that I accept for the purposes of my opinion. In particular, I have been informed that under recent changes to the law of patentability, "[a] determination of whether a patent claim is invalid as obvious . . . requires consideration of all four *Graham* factors." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016). I have further been informed the *Graham* factors are: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) the so-called "secondary considerations" of obviousness, including evidence of commercial success and expert skepticism. As set forth below, applying this standard, it remains my opinion that it

PAGE 25/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1812

would have been obvious to a person of ordinary skill in August 2004 to have combined the steps in the '584 patent, as set forth in the claims, to improve efficiencies and reduce costs.

6b. I have read the December 23, 2016 Patent Board Decision reversing its prior decision. Based on my experience and knowledge, it is my opinion that the December 23, 2016 Patent Board Decision overlooked material facts from my prior declaration and made incorrect conclusions regarding the prior art. It is my opinion that each of the steps comprising the claimed method is present in the prior art and that the combination of steps, as defined by the claims yields predictable results. It remains my opinion that it would have been obvious to a person of ordinary skill in the art in August 2004 to have combined the steps, as set forth in the claims, to improve efficiencies and reduce costs. The commercial success of IEH's product and skepticism about the product, identified by IEH, does not change my opinion. Based on a totality of the circumstances, the claimed subject matter is plainly obvious.

7a. Regarding the prior art, in its latest decision, the Board accepts the Patent Owner's characterization of Figure 1 as the Present Industry Art and the characterization of Figure 2 as the Claimed Method. The Board then continues to believe that "In other words, 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." Page 7 of the December 23, 2016 Opinion. In my opinion, this distinction is not supported by disclosure in the prior art in view of the common sense inferences and ordinarily creative steps a person of ordinary skill in the art would employ.

7b. As I set forth in my January 13, 2010 Declaration, Jarvis teaches that "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." Page 141 of Jarvis. It remains my opinion that it is well within the knowledge of one of skill in the art in August 2004 to composite samples at various stages of the testing process including both before and after enrichment.

7c. As I discussed in my January 13, 2010, it is my opinion that the "pre-enrichment" in Jarvis would cause the target microorganism to grow. As I set forth in 2010, "In August of 2004, it was well known in the art that this type of enrichment would both resuscitate the target microorganism and cause it to grow to reach detectable levels and become substantially uniform within the liquid pre-enrichment culture." Paragraph 9d. Given that no diagnostic technique is required by the claims of the '584 patent, it remains my opinion that incubating a first composited sample in pre-enrichment media would allow levels of a target microbial agent or organism that is present in one or more separate test lot samples

PAGE 26/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

comprising the first composited sample to reach detectable levels and become uniform, or substantially uniform.

7d. It remains my opinion that, like the '584 patent, Jarvis teaches two stage compositing, an intermediate culturing step that increases the concentration of a microorganism in the first composite sample, and a diagnostic step that is performed on the second composite sample. Jarvis recognizes that if the second composite sample is determined to be positive, method 2 "permits the tests to be repeated on stored pre-enrichment cultures so that some indication of the proportion of contaminated samples can be obtained." See, page 141-142 of Jarvis. It is my opinion that if the pre-enrichment cultures did not increase the 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, which is the interpretation given by the Board, then this disclosure in Jarvis would have no meaning. One of skill in the art would understand that repeating tests on stored pre-enrichment cultures to gain some indication of the proportion of contaminated samples is only done if the pre-enrichment cultures increased the level of microorganisms in the pre-enrichment cultures to detectable, uniform levels. In other words, Jarvis describes what the '584 patent claims.

8a. I understand that the Board deviated from its prior decision that the claimed subject matter was obvious over the prior art based on evidence of commercial success and skepticism in the field. I have been instructed that the recent *Apple* case—which was not available when I submitted my prior declaration—requires that these factors be considered notwithstanding how obvious the IEH method appears to be. I have now considered all of the evidence previously submitted by IEH and disagree with many of the factual statements of its declarants. First, I do not believe that the evidence of commercial success is now commensurate with the scope of claim 1. It is my understanding that claim 1 is directed to all types of beef products (e.g., ground beef, beef trim, carcasses, tenderized beef product, blended beef products, etc.), is directed to all types of microorganisms (e.g., *E. coli, Salmonella, Listeria*, etc.), is directed to all sizes of lots and samples, and is directed to all type of "suitable detection assay[s]." In contrast, the evidence provided by the Patent Owner is directed to testing of beef trim for *E. coli* O157/H7 using an undisclosed diagnostic assay (see, paragraphs 15 and 16 and Appendix A of the Koohmaraie declaration), and a comparison between an "IEH Multiplex - Classical" and an "IEH Multiplex – Modular Compositing" offering by IEH in the Samadpour 2011 declaration. It is my opinion that evidence of sales for a single beef type, a single microorganism, and (presumably) a single

PAGE 27/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

diagnostic assay does not support evidence of commercial success across a huge range of testing protocols.

9a. In the December 23, 2016 Patent Board Decision, the Board stated that "Dr. Samadpour testified that 'fabrication of meats such as pork, sheep, bison, poultry, seafood and the like, is analogous to beef fabrication in terms of art-recognized production runs and lots, and thus derives comparable commercial benefits from the same modular compositing of multiple independent operationally-linked production lots within a production run.' Samadpour 2015 Decl. Paragraph 12. We have not been directed to a persuasive deficit in this reasoning." Page 16 of the December 23, 2016 Decision. I have been told that the recent change in the law requires the Board to consider statements such as that made by Samadpour notwithstanding the fact that the prior art plainly renders obvious the subject matter. To the extent the Board found Samadpour's statement on this and other subjects of interest, I believe it important to consider my differing perspective. It is my opinion that regulatory requirements have led to increasing revenue in *E. coli* testing and beef, and that it is inappropriate to extrapolate from evidence limited to testing of E. coli O157/H7 in beef trim to all "meat or poultry." In one example, *E. coli* O157/H7 has never been identified in U.S. poultry and therefore no testing for *E. coli* O157/H7 is required. As a result, there is no connection between evidence of commercial success for testing of beef trim for E. coli O157/H7 and testing across a wide variety of meat and poultry.

10a. It is my opinion that the claimed modular composite testing is not responsible for the commercial success of IEH during the 2006-2010 time period. Rather, the United States Department of Agriculture's Food Safety and Inspection Service (hereinafter the "FSIS") changed their regulations for *E. coli* O157:H7 in 1994 to make it a legal adulterant, which means that any product containing the microorganism cannot be sold into commerce. As a result, companies now test every lot before shipment and all of the commercial laboratories working with beef have increased their business significantly. It is my opinion that FSIS regulations and industry concerns about not having a product recall are the reason for IEH's increasing revenue.

10b. Attached as Appendix A is an FSIS Timeline of Events Related to E. coli O157/H7[1] (hereinafter the "FSIS Timeline"). It is my opinion that the FSIS Timeline discloses the reason behind IEH's increasing revenue, which is increasing FSIS regulations and guidelines as well as increasing awareness by the public of the risks of *E. coli* contamination and the response of manufacturers. As shown in the FSIS Timeline, in 1994 *E. coli* O157/H7 was determined to be an adulterant. In 1999, the FSIS published an article to explain the Agency's policy regarding inspection and enforcement of meat products that

PAGE 28/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

contain *E. coli* O157/H7. In 2002, the FSIS published a notice in the *Federal Register* that required all manufacturers of beef products to reassess their plans regarding *E. coli* O157/H7 contamination. In 2004, the FSIS released compliance guidelines for establishments on the FSIS microbiological testing program and other verification activities for E. coli O157/H7. In 2005, the FSIS required established that process mechanically tenderized beef products to account for E. coli O157/H7 in their next annual assessment. It is my opinion that these continuing changes in the regulatory environment are responsible for the increased revenue for testing of *E. coli* that has been experienced by commercial laboratories such as IEH. While many of these examples are prior to the revenue figures provided by IEH, the FSIS Timeline demonstrates that regulatory requirements dwarf any contribution made by a testing method that is well within the skill of one in the art.

10c. Attached as Appendix B is a study by Rangel et al., 2005[ii] (hereinafter "Rangel 2005"). It is my opinion that Rangel 2005 and the FSIS Timeline in conjunction illustrate a second reason why commercial laboratories that test for E. coli had increased revenue during the time period in question. Figure 1 of Rangel 2005 demonstrates the increasing number of *E. coli* O157 outbreaks by year between 1982-2002. In particular, Figure 1 illustrates that the number of outbreaks from 1997 to 1998 more than doubled. Figure 3 of Rangel 2005 illustrates that foodborne transmission of E. coli O157 also increased during the period under study. Again, Figure 3 discloses that the number of foodborne outbreaks more than doubled between 1997 and 1998.

10d. As shown in the FSIS Timeline and in Rangel 2005, the meat processing industry responded to the increasing regulatory environment and the public awareness engendered by the increasing incidence of *E. coli* O157 outbreaks by "Since 2002 . . . implementing robust microbiological testing schemes" (see, the FSIS Timeline) and conducting "increased *E. coli* O157 testing." (see, page 608, right col., of Rangel 2005). It is my opinion that the increasing revenue demonstrated by IEH for testing of beef trim for E. coli O157/H7 is due to the combination of increasing regulations and increasing concern by manufacturers relating to recalls, not a method which is a mere combination of known steps.

PAGE 29/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02
National Beef Ex. 1007
Page 1816

I hereby 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 so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code.

Date: 01/21/2017

J. Stan Bailey, Ph.D.

[i] Available at https://www.fsis.usda.gov/wps/wcm/connect/83a56429-6660-43d0-bf6d-96d510266cb4/Ecoli_O157_Timeline.pdf?MOD=AJPERES

[ii] Rangel, J. M., Sparling, P. H., Crowe, C., Griffin, P. M., & Swerdlow, D. L. (2005). Epidemiology of Escherichia coli O157:H7 Outbreaks, United States, 1982–2002. *Emerging Infectious Diseases, 11*(4), 603-609. https://dx.doi.org/10.3201/eid1104.040739.

PAGE 30/43 * RCVD AT 1/23/2017 2:06:53 PM [Eastern Standard Time] * SVR:W-PTOFAX-001/14 * DNIS:2739900 * CSID:202 434 5029 * DURATION (mm-ss):08-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Patentee:	Mansour Samadpour
Control No.:	95/001,294
Confirmation No.:	1914
Filed:	05 April 2010
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Examiner:	Sharon Turner
Art Unit:	3991
Confirmation No.:	1914
Docket No.:	0066090-008US2
Date:	23 February 2017

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

PATENT OWNER'S COMMENTS IN OPPOSITION TO THE REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.79(C)

These Comments in Opposition to the Request for Rehearing are timely filed on 23 February 2017. No fee is deemed due, but if additional fees are necessary, Commissioner is authorized to charge any deficiency (or credit any overpayments) to Deposit Account No. 04-0258.

Patent Owner opposes the Request for Rehearing ("Request"). The Request misconstrues *Apple*, which explicitly applied existing obviousness law and fails to support that the Board's Decision ("Decision") made factual or legal errors.

I. The Decision did not misapprehend or Overlook KSR and its Progeny in Concluding Secondary Considerations Rebutted the Prima Facie Case.

In considering the evidence for secondary factors of commercial success and skepticism, the Board in the 7983 Decision did not abandon common sense or misapprehend or overlook KSR, but merely concluded at that time that evidence based on testing lots of beef provided insufficient *nexus* with the claim scope. During subsequent continued re-examination, claim scope was limited to beef, meat or poultry, providing sufficient *nexus*, which the Board acknowledged in the Decision. Obviousness is a question of law based on underlying facts (*Kinetic Concepts, Inc. b. Smith & Nephew Inc.*, 688 F.3d 1342, 1356-57 (Fed Cir. 2012); cited in *Apple*).

II. The Decision did not Misapprehend or Overlook Points on Commercial Success.

1. Requester (citing *In re Cree, Inc.*, 818 F.3d 694 (Fed. Cir. 2016) ("*Cree*"), and *In re Mageli* 470 F.2d. 1380, 1384 (CCPA 1973) ("*Mageli*") alleges that the 2015 Dr. Samadpour Declaration merely repeats in conclusory fashion that

there is a nexus between commercial success and the claimed invention, and that the inventor's opinion as to the purchaser's reason for buying the product…alone is insufficient and should be given little weight. Both *Cree* and *Mageli* are factually distinguished, and thus don't apply. Cree alleged (*Cree*, 702) that the Board in *Cree* improperly: (i) discounted Industry praise as not directed to the inventor's work (*Id*); (ii) found no nexus to licensing (*Cree*, 703); and (iii) discounted sales evidence in the Dr. Brandes declaration as not having nexus with the claimed invention (*Cree*, 703, 704). In *Mageli*, the CCPA determined that the Board had improperly ignored Affidavit evidence of chemical sales in assessing commercial success (*Mageli*, 1382), but concluded that Affidavit sales figures were mere estimates and lacked *nexus* to the claim (*Id*).

None of these facts apply to Patent Owner's declaration evidence, which does not rely on praise, licensing, or sales numbers lacking nexus. Rather the sales evidence of the Samadpour Declarations directly relates to dramatic *differential* sales of "classical assay" (decreasing from 12 to 2 million $) versus the "new assay" (increasing from under 1 to 10 million $) in a highly cost-sensitive market that historically embraced the cheaper classical assay. Patent Owner's claims provide for *saving* of lots for release into commerce instead of *rendering* as in the prior art (discussed in the Dr. Koohmaraie Declaration and the Samadpour 2015 Declaration at 6; see also Example 1 and Table 1 of the '584 patent), and thus

directly relate to Patent Owner's capturing of a 30% U.S. market share in a commodity testing market despite initial expert skepticism in view of potential *false negatives* and the substantial disincentive of increased sampling and cost. Patent Owner's evidence thus has a direct nexus to the '584 patent claim steps, justifying the Board's reliance thereon. The 2015 Samadpour Declaration (at paragraph 14, page 8) further clarified that at most 10-15% of the data in the record used to support commercial success was attributable to assays that used the extra step required by FSIS. The 2015 Samadpour Declaration (at paragraph 14, page 8) confirmed that the claimed method and commercial benefits are broadly applicable in terms of both the type of test lots, and the target microbes tested.

The Decision states that "the evidence of secondary considerations when considered in light of the obviousness rejections, particularly the obviousness of steps d) and e), establishes the non-obviousness of claims 1, 17 and dependent claims 2-16, 18-23 and 26-33. Requester's own cited *Apple* opinion cautions against discounting even subtle aspects of the invention with the benefit of hindsight (*Apple*, 1052, 1053; citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1538-39 (Fed. Cir. 1983).

2. Request at 7 alleges (citing Decision at 15) that the Board did a factual "about-face" with respect to obviousness of steps b1, c1, e1.

Rather, the Decision (at 15) states that "the steps described as responsible for the commercial success, namely b1, c1 and e1, were not described in the cited publications and cannot [in view of the secondary considerations discussed a pages 8-12 of the Decision] be said to have been readily available" to one of ordinary skill in the art at the time of the invention." Testing step e1 necessarily requires formation of the modular composite sample in step d1. The Board concluded (Decision at 16) the "[t]he evidence of secondary considerations when considered in light of the obviousness rejections, particularly the obviousness of steps d) and e), establishes the non-obviousness of claims 1, 17, and dependent claims 2-16, 18-23 and 26-33." The Decision gave more weight to the secondary factor evidence in view of the amended claim scope. The Request comments at 9-10 relating to "teaching away" are irrelevant because the Decision does not rest on whether direct enrichment is obvious or not, but rather on the non-obviousness of steps d) and e) in view of the secondary consideration evidence.

3. Request at 10 cites Decision at 16, and alleges that the Board misapprehended the evidence of commercial success applicable to claim 17. Patent Owner disagrees. *First*, Patent Owner narrowed the scope of the claims, and the 2015 Samadpour Declaration confirmed (at paragraph 14, page 8) broad applicability of the claimed methods. The '584 patent also teaches (at col. 1, ll. 24-33) that the method is broadly applicable to different types of lots and microbes.

Second, contrary to Requester's comment about uncited industry guidance, the '584 patent *per se* describes such industry guidance on the applicability of art-recognized production runs and lots to foods generally (e.g., see '584 patent under "Background" at col. 1-3; and particularly at col. 1, line 65 through col. 2 line 5) describing corroborative industry guidance from USDA, FSIS, and ICMSF. *Third*, with respect to target microbes, the claims merely require tester to enrich the target microbe to detectable levels (merely requiring selection of appropriate media, incubation conditions), which is well within the knowledge of one of ordinary skill in the relevant art. Indeed, the knowledge of how to grow and detect all the microbes falling under regulatory and/or quality control is well known, and the regulatory agencies issue relevant guidelines pertaining to all of these target microbes and detection protocols. Likewise, nothing in the record, including the proffered extrinsic Dr. Bailey Declaration, indicates that the methods would not be applicable to essentially any lots of food materials produced using art-recognized production runs and lots, and thus would derive comparable commercial benefits from the claimed method. Enrichment and detection protocols are also available through reference books, literature, and test kit manufacturers.

III. The Board did not Misapprehend or Overlook the Evidence Regarding Industry Skepticism, and Rather Considered it Under the Proper Legal Standards.

Request at 10 urges that the Board also erred in relying on Patent Owner's evidence of skepticism toward the claimed invention, citing *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 955, 958 (Fed. Cir. 1997). *Arkie Lures*, has also been misconstrued by Requester, and rather supports the Board's reliance on skepticism evidence. *First*, *Arkie Lures* rather held that "[t]he evidence that the combination was not viewed as technically feasible must be considered [rather than being ignored], for conventional wisdom that a combination should not be made is evidence of unobviousness", as discussed in more detail below. However, even if *Arkie Lures* was construed as requiring proof of technical unfeasibility, the skepticism in the industry and by FSIS described in the 2011 and 2015 Dr. Samadpour Declarations supports that pooling to form the claimed modular composite pool was viewed as technically not feasible (something that should not be done) because of the belief that it would lead to *false negatives* (diluting out an otherwise detectable positive) that could result in plant closures and consumer death, and where microbe detection, particularly in low quantities, is an art-recognized technical area.

Second, *Arkie Lures* actually supports the Board's reliance on the evidence of skepticism. In *Arkie Lures*, Larew had presented evidence of commercial success (salt impregnated plastic fishing lures) in the form of testimony from Dr. Carver and Mr. Harville supporting skepticism. The *Arkie Lures* opinion states:

"[t]he question is not whether salt "could be used" as the district court concluded, but whether it was obvious to do so in light of all the relevant factors" (*Arke Lures*, 957); and "[t]he evidence that the combination was not viewed as technically feasible must be considered" (*Arke Lures*, 958). The *Arkie Lures* opinion states "[t]he district court's statement that "secondary considerations are just that—secondary," suggests a misperception of the role of these considerations in determination of the ultimate question", and "[o]n the correct standard, we look to the state of relevant knowledge at the time of Larew's activities, …including the widespread skepticism that Mr. Larew encountered among those of skill in the field" (*Id*).

Request at 11, cites *Kroy IP Holdings, LLC v. Safeway, Inc.*, 107 F. Supp. 3d 656, 676 (E.D. Tex. 2015) ("*Kroy*") and urges that it is unlikely that commercial success and lack of commercial success can both be indicative of non-obviousness in the same case. There is, however, no universal inconsistency or tension between "skepticism" and "commercial success", and no reason, including in view of *Kroy*, that skepticism may not exist at one point in time and then, at a later time, commercial success may exist, which is precisely what happened in this case.

IV. The Request for Rehearing Grossly Misconstrues *Apple*, and thus Fails to Provide Basis for Rehearing under 37 C.F.R. § 41.79(b)(2).

In the underlying district court case, Apple alleged infringement of three patents. The district court granted summary judgment on one patent, and after jury trial also found infringement of the other two patents. Samsung's subsequent JMOL with respect to these patents was denied and Samsung appealed to the Federal Circuit. A Federal Circuit panel opinion (authored by Judge Dyk) ruled that Apple failed to show infringement of one patent and that the other two were invalid as being obvious. Apple petitioned the Federal Circuit for *en banc* review, questioning the three-judge panel's decision to reverse nearly every jury finding of fact that favored Apple by relying on extra-record extrinsic evidence. The full Federal Circuit reversed the panel and reinstated the district court verdict.

Contrary to the Requester's mischaracterization of the majority opinion (by citing phrases from dissenting opinion), no changes in obviousness law, including that relating to secondary considerations, were made in *Apple*. Rather, *Apple* merely reaffirmed the boundaries of appellant jurisdiction by reaffirming that the Federal Circuit cannot consider extrinsic evidence [the same standard that applies to PTAB hearings] or engage in fact finding, and *explicitly* applied existing obviousness law to the facts:

> "We did not take this case *en banc* to decide important legal questions about the inner workings of the law of obviousness. We have applied existing obviousness law to the facts of this case. We took this

> case *en banc* to affirm our understanding of our appellate function, to apply the governing law and to maintain our fidelity to the Supreme Court's *Teva* decision."

(*Apple* majority opinion, 1039). This includes the existing law relating to secondary factors, where the majority opinion cites Graham v. John Deere Co., 383, U.S. 1, 17-18, 86 S. Ct. 684, 15L.Ed.2d 545 (1966), and KSR Int'l Co. v. Teleflex Inc. 550 U.S. 398, 406, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). Moreover, the *Apple* majority opinion statements that "a determination of whether a patent claim is invalid as obvious under 103 requires consideration of all four Graham factors" and that "[o]bjective indicia of nonobviousness must be considered when present" is based on established case law cited in the opinion (e.g., *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent litig.*, 676, F.3d 1063, 1075-76 (Fed. Cir. 2012) (citing *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997); and *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). In discussing secondary considerations, the *Apple* majority opinion cites established law (*Apple* majority opinion, 1052, 1053; citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1538-39 (Fed. Cir. 1983).

Requester's statement (based on Judge Dyk's dissenting opinion) that the *Apple* opinion held that "the significance of secondary considerations [is] a factual

question," rather than a legal determination is a *blatant* mischaracterization of *Apple*. *Apple* changes no established patent law in this respect, and rather states that "[o]bviousness is a question of law based on underlying facts (*Apple*, 1047; citing *Kinetic Concepts, Inc. b. Smith & Nephew Inc.*, 688 F.3d 1342, 1356-57 (Fed Cir. 2012). *Apple* does not change the law on secondary considerations.

The Board, in the 7983 Decision, at 20, based its treatment of secondary considerations on the same case law (e.g., *Graham*) as cited in *Apple*, which is the same law relied upon in Requester's cited *Arkie Lures*. *Apple* expressly disclaims changing the law of obviousness, and upholds the claims and the conclusions of the district court regarding the sufficiency of the secondary factor evidence. Moreover, even if *Apple* was construed to change the law of obviousness, that change would not justify use of Sec. 41.79(b)(2) under the present facts where Requester has already taken the position in the record that the secondary factors are not significant. Requester's desire to introduce extrinsic evidence to support the *same* argument is not a "new argument" justified under Sec. 41.79(b)(2).

V. Requester's Attempt to Introduce Extrinsic Evidence is Improper Under 37 C.F.R. §§ 41.79(b)(1) and (2), and Would Represent Clear Error if Granted by the Board.

Request at 14 makes attempts to introduce extrinsic evidence by implying that the Federal Circuit's failure, in *Lingamfelter v. Kappos,* 513 F. App'x 934, 938

& n.2 (Fed. Cir. 2012), to address Lingamfelter's assertion that declarations submitted by a third party Requester during an *inter partes* re-examination proceeding violated *due process* under 35 U.S.C 143(b)(2), somehow allows the Board to admit such extrinsic evidence in the context of a Request for Rehearing under 37 C.F.R. § 41.79(b)(2). Requester's attempt is flawed. *First*, the facts of *Lingamfelter*, where third party requester declarations were filed ***during*** an *inter partes* re-examination proceeding, don't apply to the present situation. *Second*, the *Lingamfelter* court stated (*Lingamfelter*, 938) that it need not address the merit of Lingamfelter's arguments because he waived the right to object at early stages of the *inter partes* proceedings. Requester's urging, that the "better reading" of Section 41. 79(b)(2) should permit a party seeking rehearing on the basis of new arguments to submit, where appropriate, evidence to support those arguments, misconstrues both fact and law. Requester invites the Board to erroneously admit extrinsic evidence, and under facts that aren't even applicable to *Lingamfelter*.

VI. Requester's Proffered Declarations are Extrinsic Evidence, and Contain Misleading Opinions.

Extrinsic Mr. Reis Declaration. The Reis opinion that "increased regulatory requirements" in 1994 and 2002 led to an increased demand for testing services from beef manufacturers that is independent of the sampling strategy is

flawed. *First*, IEH Laboratories was founded in mid-2001, and any testing volume increase after 1994 was already in place and *owned* by IEH's competitors. Moreover, consistent with the FSIS event timeline of the proffered new Dr. Bailey Declaration, all major beef companies were at 100% testing (all lots were tested) by the beginning of 2003, and by 2004 100% testing programs were entirely in place for beef trim. As such, Mr. Reis' opinions have no impact on Patent Owner's submitted Declaration evidence covering the 2008-2010 period, well after test volume increases related to any "increased regulatory requirements". *Second*, the testing data of the 2011 Samadpour Declaration is based on actual revenue data of differentially increased sales of the new assay (from about 1 million to over 10 million $), while over the same 2008-2010 period revenue decreased from 12 million to under 2 million $ for the "classical" testing method that costs less per pound of product, and used fewer and larger samples relative to the claimed invention. The Reis opinion ignores the fact that at **all** times in this industry there is an overwhelming pressure to minimize the number of tests performed, and the attendant costs, and not rush to embrace a more sample intensive, expensive assay with an initial *handicap* of expert skepticism. *Third*, Patent Owner's (2008-2010) revenue data was accompanied by a market penetration of 30% of U.S. beef testing market for new assay. This cannot be explained by Reis' opined "increased

regulatory requirements", nor the 23% average yearly sale increase data of the extrinsic data table of Appendix A of the Reis Declaration.

The Reis Declaration, with no basis, opines (at 6d) that "IEH's offer to take all liability from manufacturer companies if there is a recall during the use of IEH services is a reason for IEH's commercial success." This is a complete fabrication and no one, including Patent Owner, makes such indemnification offers. The Reis Declaration, with no basis, opines (at 6d) that two additional business practices of IEH further explain their increased revenue: (1) IEH performs sampling for its customers, which allegedly reduces workload on the customer; and (2) IEH provides consultancy services to its customers, which IEH then attempts to transition to testing services. Reis further opines that "[m]ost of IEH's competitors do not offer those services." In fact, most major testing laboratories offer consulting services, and most offer limited sampling. For about six months over the 2008-2010 period, IEH provided very limited sampling services, totaling about $10,000, for a single small client, which does not even begin to support Reis' business practices theory. The Reis' allegation is thus also meritless, and unsupportable on this basis.

Additionally, the extrinsic data of the table showing sales of Requester's Vidas UP *E. coli* O157:H7 cannot be accurate, based on information publicly available on Requester's website (see **APPENDIX A**) that shows that the assay got

AOAC approval in June of 2009, such that it could only have been used for beef testing for 6-months of 2009. Accordingly, a full-year projection of the 2009 sales numbers would give $308,476, placing the 2009-2010 sales change at **-6.3%**, and giving an overall 2011-2016 average of only about **+6%** per year. Moreover, the assay was validated for a host of other types of foods (e.g., 2011 Accreditation expanded to include cookie dough), so the data nexus to beef is questionable.

Extrinsic Dr. Bailey Declaration. Much of the Dr. Bailey Declaration simply disagrees with the Board Decision, and states "as set forth in my January 13, 2010 Declaration" (e.g., at 7b, 7c) or "it remains my opinion" (e.g., at 7d). The remainder of the Dr. Bailey Declaration comprises new arguments based on extrinsic evidence (e.g., FSIS time-line; and the Rangel 2005 publication). At 10b, an Appendix A (FSIS timeline) is introduced and discussed and argued as in the Reis Declaration. Dr. Bailey additionally mentions a 2005 requirement establishing that "process mechanically tenderized beef products to account for *E. coli* O157:H7 in their next annual assessment." However, the Dr. Bailey opinion should not be given any weight for the same reasons as discussed above in relation to the Declaration of Mr. Reis. Dr. Bailey discusses an extrinsic 2005 publication by Rangel et al., outlining outbreaks that occurred between 1982 and 2002, but the Rangel Figs. 1 and 2 data actually shows that the number and size of outbreaks was decreasing from 1996 to 2002. The trends supported by Rangel actually run

counter to the proposition that increased regulatory pressure was driving Patent Owner's commercial success during the relevant period of 2008-2010. Moreover, Patent Owner's '584 patent was filed on August 8, 2005 and Patent Owner was not marketing the assay until about 2007. Bailey at 9a questions the general applicability of the patented method across more than beef and *E. coli* O157:H7, based on the allegation that *E. coli* O157:H7 has never been identified in poultry.

Dr. Bailey is incorrect, however, as shown by the publications listed in attached **APPENDICES B-D**, showing detection of *E. coli* O157 and other Shiga-toxin producing *E. coli* (STEC) has been reported in scientific literature from U.S. poultry. Moreover, Patent Owner's test platform used in the beef industry is *multiplexed* to simultaneously detect *E. coli* O157, STEC, and *Salmonella* in poultry, and has been thus used. Finally, the Board is directed to Patent Owner's discussion herein above (under section **II (3.)**) supporting the broad applicability of the claimed methods, which is not repeated here for efficiency reasons.

CONCLUSION: Requester's Request for Rehearing should be denied.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

DATE: February 23, 2017

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Patentee
Registration No. 47,309

CERTIFICATE OF SERVICE

Timely service to the third party requester, bioMerieux, via their attorney Stanley E. Fisher, at Williams & Connolly, LLP, 725 12th St., NW, Washington, D.C. 20005 is being affected by first class mail sent on 23 February 2017.

APPENDIX A

(www.biomerieux-usa.com/sites/subsidiary_us/files/vidas_up_e._coli_o157_8.5x11_v5.pdf):

"AOAC Performance Tested Method: PTM#060903

In **June 2009**, the VIDAS ECPT Assay was granted Performance Tested Method SM (PTM) status by the AOAC Research Institute for the detection of E. coli O157 (including H7) in selected foods. The VIDAS ECPT method was validated according to AOAC Microbiology Guidelines (2002). Results of the validation study demonstrated the ability of the VIDAS ECPT method to: 1) detect 55 different E. coli O157 (including H7) strains; 2) correctly show negative results for 42 non-E. coli O157 strains; 3) support a shelf life of 12 months from date of manufacturing and quality of the test kit; 4) perform appropriately after varied protocol parameters including enriched sample boiling time (2, 5, 10 min), sample temperature after boiling (10, 25, 50°C) and sample volume analyzed by VIDAS (450, 500, 550µL); and 5) demonstrate no statistically significant differences when compared to a reference method for the following matrices: ground beef (25, 75, 375g), beef trim (25, 75, 375g) bagged lettuce (25g), fresh spinach (25g) and irrigation water (25 mL). Independent testing included a method comparison study for ground beef (25g). A matrix extension was approved in January 2011 adding frozen cookie dough (25g) to the existing PTM certification."

(emphasis by Patent Owner).

APPENDIX B

References for STEC in poultry and poultry products

Doyle, M.P., and Schoeni, J.L. 1987. Isolation of *Escherichia coli* O157:H7 from retail fresh meats and poultry. *Appl Environ Microbiol* 53:2394-2396

Batz, M.B., Hoffmann, S., Morris, J.G. Jr. 2012. Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. *J Food Prot* 75:1278-1291.

Doyle and Schoeni (1987) examined 263 samples of raw poultry for the presence of *Escherichia coli* O157:H7. Two hundred and seven refrigerated poultry samples were obtained from grocery stores in Madison- area from June 1985 to July 1986. Six frozen samples were obtained from grocery stores in Canada in June 1986. From the 263 samples, 1.5% (4/263) were positive to *Escherichia coli* O157:H7. The positive samples were isolated from chicken legs and turkey drumsticks.

Batz *et al.* (2012). Estimated the U.S. health burden of 14 major pathogens in 12 categories of food. In this study, the attribution of illnesses reported relied on outbreak data and expert elicitation. Based on foodborne outbreaks with known etiology and vehicle from 1999 to 2008, the 0.7% was attributed to poultry contaminated with *E. coli* O157:H7, and 6.7% to poultry with STEC non-O157. The analysis based on expert elicitation showed that 0.9% of illnesses were associated with the consumption of poultry contaminated with *E. coli* O157:H7.

APPENDIX C

APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Oct. 1987, p. 2394–2396
0099-2240/87/102394-03$02.00/0
Copyright © 1987, American Society for Microbiology
Vol. 53, No. 10

Isolation of *Escherichia coli* O157:H7 from Retail Fresh Meats and Poultry

MICHAEL P. DOYLE* AND JEAN L. SCHOENI

Food Research Institute, University of Wisconsin, Madison, Wisconsin 53706

Received 15 May 1987/Accepted 16 July 1987

A total of 896 samples of retail fresh meats and poultry was assayed for *Escherichia coli* serogroup O157:H7 by a hydrophobic grid membrane filter-immunoblot procedure developed specifically to isolate the organism from foods. The procedure involves several steps, including selective enrichment, filtration of enrichment culture through hydrophobic grid membrane filters, incubation of each filter on nitrocellulose paper on selective agar, preparation of an immunoblot (by using antiserum to *E. coli* O157:H7 culture filtrate) of each nitrocellulose paper, selection from the filters of colonies which corresponded to immunopositive sites on blots, screening of isolates by a Biken test for precipitin lines from metabolites and antiserum to *E. coli* O157:H7 culture filtrate, and confirmation of isolates as Vero cell cytotoxic *E. coli* O157:H7 by biochemical, serological, and Vero cell cytotoxicity tests. *E. coli* O157:H7 was isolated from 6 (3.7%) of 164 beef, 4 (1.5%) of 264 pork, 4 (1.5%) of 263 poultry, and 4 (2.0%) of 205 lamb samples. One of 14 pork samples and 5 of 17 beef samples contaminated with the organism were from Calgary, Alberta, Canada, grocery stores, whereas all other contaminated samples were from Madison, Wis., retail outlets. This is the first report of the isolation of *E. coli* O157:H7 from food other than ground beef, and results indicate that the organism is not a rare contaminant of fresh meats and poultry.

Several outbreaks and cases of hemorrhagic colitis and hemolytic uremic syndrome caused by *Escherichia coli* serogroup O157:H7 have been linked epidemiologically to consumption of ground beef (4, 6–9); however, the organism reportedly has been isolated only once from food. This isolation was made from a frozen ground-beef patty obtained from a meat processor that supplied beef patties to restaurants associated with an outbreak of *E. coli* O157:H7 hemorrhagic colitis (10). Dairy cattle recently have been identified as a reservoir of *E. coli* O157:H7, with the organism isolated on two occasions from the feces of young animals of herds associated with cases of hemolytic uremic syndrome in children following consumption of raw milk (2, 5). Studies by Beery et al. (1) revealed that *E. coli* O157:H7 can readily colonize the ceca of chickens and be excreted in the feces for several months, suggesting that chickens may also be a reservoir of the organism.

The purposes of this study were to develop a procedure that could specifically isolate *E. coli* O157:H7 from foods and to use this procedure to determine the prevalence of the organism in retail meats and poultry.

MATERIALS AND METHODS

Meat and poultry samples. A total of 147 ground-beef, 250 pork, 257 poultry, and 200 lamb retail samples was obtained from the refrigerated-meats sections of several Madison-area grocery stores from June 1985 to July 1986. All meat and poultry samples were fresh, uncooked, packaged, and on display for consumer selection. Usually, 20 to 25 samples were purchased on each day of testing. The samples were immediately (within 1 h) brought to the laboratory and assayed for *E. coli* O157:H7.

Additionally, a total of 17 ground-beef, 14 pork, 6 poultry, and 5 lamb retail samples was obtained from several grocery stores in the Calgary, Alberta, Canada, area during June 1985. These samples were frozen (−29°C) after purchase and sent on dry ice to the Food Research Institute. Once received, samples were held at −70°C and tested for *E. coli* O157:H7 within 3 weeks of receipt.

Enrichment. A 25-g portion of food specimen was aseptically removed from each meat or poultry sample and added to 225 ml of modified Trypticase soy broth (mTSB) in a 1-liter Erlenmeyer flask. The mTSB enrichment medium was composed of (per liter) Trypticase soy broth (TSB; 30 g; BBL Microbiology Systems, Cockeysville, Md.), bile salts 3 (1.5 g; Difco Laboratories, Detroit, Mich.), dipotassium phosphate (1.5 g), and novobiocin (20 mg; Sigma Chemical Co., St. Louis, Mo.). The enrichment medium without novobiocin was autoclaved and allowed to cool to room temperature before filter-sterilized novobiocin was added. The pH of the mTSB was 7.4. Food specimens were added to the mTSB soon after the addition of novobiocin. The enrichment cultures were then incubated with agitation (100 gyrations per min) at 37°C for 18 to 24 h.

Filtration. After incubation, the enrichment culture was diluted (for raw meats, usually 10^{-6} and 10^{-7}) in 0.01 M phosphate-buffered saline, pH 7.5, and 1 ml of each dilution in 10 ml of PBS was filtered individually through hydrophobic grid membrane filters (HGMF; ISO-GRID; QA Laboratories, Toronto, Ontario, Canada). The appropriate dilutions of enrichment culture were determined on the basis of colony development on HGMF, with 10 to 500 colonies per HGMF being an acceptable range. Each HGMF was placed over an equivalent-size (6- by 6-cm) wetted (sterile mTSB) nitrocellulose paper (0.45-μm pore size; Schleicher & Schuell, Keene, N.H.) on the surface of a plate of modified Trypticase soy agar (mTSA). mTSA is composed of the same ingredients as mTSB plus 1.5% agar. The plates were incubated at 37°C for 18 to 24 h.

Immunoblots. After incubation, the HGMF was removed from the nitrocellulose paper, placed on a fresh plate of mTSA, and refrigerated for later use. The nitrocellulose paper was then treated by using an immunoblot procedure to

* Corresponding author.

Downloaded from http://aem.asm.org/ on February 23, 2017 by guest

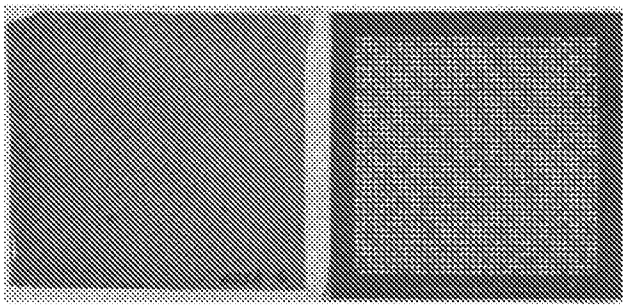


FIG. 1. HGMF (right) with bacterial colonies from a 10^{-6} dilution of enrichment culture of ground-beef specimen (25 g) inoculated with *E. coli* O157:H7 (1.5 CFU/g). Immunoblot (left) of nitrocellulose paper held in contact with HGMF during incubation on mTSA. Dark spots indicate areas that reacted with antiserum to O157CF.

detect Vero cell cytotoxin(s) produced by bacterial colonies developing on the HGMF. To inactivate any free microbial peroxidase, the nitrocellulose paper was treated with 0.02 M periodic acid (37°C, 15 min), washed twice in salts-PBS (S-PBS) solution (composed of 121 g of NaCl, 15.5 g of KCl, 12.7 g of $MgCl_2$, 10.2 g of $CaCl_2 \cdot 2H_2O$, 2.0 g of $NaH_2PO_4 \cdot H_2O$, and 3.9 g of $Na_2HPO_4 \cdot 7H_2O$ per liter, adjusted to pH 7.4), treated with 0.012 M sodium borohydride (30 min), and again washed three times in S-PBS. The nitrocellulose paper was treated with 1% bovine serum albumin (BSA) in S-PBS for 1 h with agitation (50 gyrations per min) at 37°C and suspended in rabbit antiserum to *E. coli* O157:H7 culture filtrate (O157CF; 1:5,000 dilution) in 1% BSA for 1 h with agitation at 37°C. The rabbit antiserum was prepared by intravenously inoculating (ear vein) New Zealand White rabbits with formalinized culture filtrate (treated with 0.5% Formalin for 2 weeks at 37°C) of *E. coli* 932 serogroup O157:H7 grown in TSB at 37°C for 18 h. A total of five inoculations was given (0.5, 1.0, 2.0, 4.0, and 4.0 ml), one each at 5-day intervals. The antiserum was heated at 56°C for 30 min and then was absorbed six times with ca. 10^{12} cells of heat-treated (121°C, 1 h) *E. coli* O157:H7 (1 ml of packed cells per 10 ml of antiserum) before use.

The nitrocellulose paper was washed twice in 1% BSA in S-PBS and then held for 10 min at 37°C in fresh 1% BSA in S-PBS. This procedure was repeated three times. The nitrocellulose paper was suspended in 1:1,000 goat anti-rabbit immunoglobulin G conjugated with horseradish peroxidase (ICN Immunobiologicals, Lisle, Ill.) for 1 h with agitation at 37°C and then washed three times and incubated in S-PBS (without BSA) by the procedure described above. The nitrocellulose paper was placed in 4-chloro-1-naphthol solution (0.25 g of 4-chloro-1-naphthol [Sigma] dissolved in 80 ml of methanol and added to 500 ml of Tris hydrochloride, pH 7.4, and 2.5 ml of 3% H_2O_2) at room temperature for about 5 min and washed in deionized, distilled water.

Selection of colonies. Each nitrocellulose paper with blue areas representing the possible presence of *E. coli* O157:H7 Vero cell cytotoxin(s) was aligned with its respective HGMF (Fig. 1), and colonies corresponding with each blue area were selected and grown on Trypticase soy agar (TSA) for further characterization.

Biken tests. Each isolate was assayed by a Biken test (3) to determine if the isolate was likely to be producing *E. coli* O157:H7 Vero cell cytotoxin(s). Biken plates with 8 to 10 ml of mTSA (0.75% agar instead of 1.5%) per petri dish (90 by 15 mm) were prepared by using the wide end of a sterile Pasteur pipette to punch a 6-mm well at each of the four quadrants of the plate. Three isolates and an *E. coli* O157:H7 culture (control) were spot inoculated in a square cluster approximately equidistant from each other and about 0.6 cm away from each well. Hence, 12 isolates were tested per Biken plate.

The plates were incubated for 18 to 24 h at 37°C to allow development of colonies, and then 1 drop (about 20 μl) of rabbit antiserum to O157CF, appropriately diluted based on precipitin line formation with control isolates of *E. coli* O157:H7, was added to each well. Plates were again incubated at 37°C for 18 to 24 h and observed for precipitin lines between the isolates and the central wells of antiserum. Isolates producing precipitin lines were selected for further characterization, whereas the other isolates were discarded.

Vero cell cytotoxicity testing. A continuous monkey kidney (Vero) cell line was maintained by weekly trypsinization of confluent monolayers grown in Medium 199 (GIBCO Laboratories, Grand Island, N.Y.) containing 5% fetal calf serum and 0.005% gentamicin. After trypsinization, 10^5 cells were suspended in 1 ml of growth medium in each well of a 24-well polystyrene, flat-bottom tissue culture plate (Becton Dickinson Labware, Oxnard, Calif.). The cells were allowed to grow for 2 days, at which time fresh growth medium (1 ml per well) was added. Culture filtrate (0.1 ml) of individual isolates selected from HGMF was added to duplicate wells with confluent monolayers. Culture filtrate was obtained by growing each isolate in TSB at 37°C for 18 to 24 h, removing the cells by centrifugation (5,000 × *g*, 15 min), and filtering the supernatant fluid through a 0.2-μm-pore-size Acrodisc membrane filter (Gelman Sciences, Inc., Ann Arbor, Mich.). A portion of culture filtrate (0.3 ml) was treated with rabbit antiserum (0.3 ml) to O157CF and incubated at 37°C with agitation (50 gyrations per min) for 30 min, and 0.1 ml was added to duplicate wells of Vero cells to determine if toxicity could be neutralized. After 48 h, detached Vero cells were removed by vigorous shaking and the remaining cells were washed three times with 0.01 M PBS, treated for 30 min with methanol, again washed three times with 0.01 M PBS, stained with 10% Giemsa, and rinsed with deionized, distilled water. Duplicate wells of each plate were treated with 0.1-ml portions of O157CF to be used as controls. Vero cells treated with O157CF were completely detached, and plates were visibly clear after staining. Culture filtrates of isolates producing an equivalent toxicity (no evidence of purple-stained Vero cells on plates) and neutralized by antiserum to O157CF were considered to contain Vero cell cytotoxin(s) like that of *E. coli* O157:H7.

Confirmation of isolates. Isolates determined to produce *E. coli* O157:H7-like Vero cell cytotoxin(s) were confirmed as enterohemorrhagic *E. coli* O157:H7 by identification based on the API 20E miniaturized diagnostic kit (Analytab Products, Plainview, N.Y.), by serology with O157 and H7 antisera (Difco; *E. coli* Reference Center, Pennsylvania State University, University Park), and by inability to produce acid from sorbitol (10) within 24 h at 37°C on MacConkey agar base (Difco) plus 1% sorbitol.

Inoculation and recovery tests. Four 100-g portions of ground beef (aerobic plate count, ca. 10^5 CFU/g) with no detectable *E. coli* O157:H7 were each inoculated with a different level (ca. 1.5, 2.5, 4.5, or 10 cells per g) of a nalidixic acid-resistant strain of *E. coli* O157:H7 (1). For each level of inoculum, a 25-g portion of meat was added to duplicate flasks of the enrichment medium described above. Enrichments and *E. coli* O157:H7 isolations were done by the procedure described above, and the number of *E. coli* O157:H7 in each culture after enrichment was determined by

Downloaded from http://aem.asm.org/ on February 23, 2017 by guest

plating dilutions of enrichment culture on MacConkey agar with 30 μg of nalidixic acid per ml. Isolates from plates inoculated with the highest dilution were randomly selected and confirmed as *E. coli* O157:H7 by the API 20E diagnostic kit and serology. This study was done in duplicate.

RESULTS AND DISCUSSION

Isolation of *E. coli* O157:H7 from inoculated samples. Inoculation studies revealed that, by using the HGMF-immunoblot procedure, *E. coli* O157:H7 could be isolated from ground beef that had been inoculated with as few as 1.5 *E. coli* O157:H7 cells per g and that had an aerobic plate count of 10^5 CFU/g. *E. coli* O157:H7 grew well in enrichment cultures held at 37°C for 18 h, with cell populations developing to 2×10^6 to 4×10^6 CFU/ml in cultures that had been inoculated with 1.5 to 10 *E. coli* O157:H7 cells per g of ground beef, respectively. Plate counts of enrichment cultures on TSA at 35°C for 48 h ranged from 2×10^9 to 5×10^9 CFU/ml; hence *E. coli* O157:H7 was present in considerably lower numbers than the predominant microflora of the enrichment cultures.

Although this procedure can effectively isolate Vero cell cytotoxic *E. coli* O157:H7 from raw meats inoculated with low numbers of the organism, the method is not amenable to routine testing because of its complexity and extensive need for personnel time. An additional drawback of the procedure was that many isolates selected from the HGMF for further testing were not the organism of concern because the antiserum used for the immunoblots was not strictly specific for *E. coli* O157:H7 Vero cell cytotoxins. More-specific antisera for these Vero cell cytotoxins have recently been produced in rabbits and will greatly improve the procedure by reducing the number of false-positive spots on immunoblots. However, a more-rapid procedure that can easily be used for routine testing of foods is definitely needed.

Isolation of *E. coli* O157:H7 from retail meats and poultry. A total of 164 ground-beef, 264 pork, 263 poultry, and 205 lamb samples was assayed for *E. coli* O157:H7. The organism was isolated from 6 beef (3.7%), 4 pork (1.5%), 4 poultry (1.5%), and 4 lamb (2.0%) samples, indicating that the bacterium is associated with foods of animal origin and not specifically with beef. The organism was isolated from a large percentage of Calgary meats, i.e., 5 (31%) of 17 beef and 1 (7.1%) of 14 pork samples, which correlates with the unusually high incidence of *E. coli* O157:H7 infections reported in the Calgary area (6). Perhaps the high prevalence of the organism in Calgary meats is responsible for the high incidence of infection in that location.

The types of meat and poultry specimens from which *E. coli* O157:H7 was isolated included ground beef, pork chop, pork loin, pork hock, ground pork, chicken leg, turkey drumstick, lamb riblet, lamb loin chop, lamb shoulder blade chop, and lamb leg. Additionally, we have isolated the organism from specimens of foods associated with outbreaks of hemorrhagic colitis or hemolytic uremic syndrome. These foods included unpasteurized milk from the bulk tank of a farm at which *E. coli* O157:H7 was isolated from the feces of a heifer (5), a frozen chicken nugget obtained from an opened box from which a sitter of children with *E. coli* O157:H7 infection periodically removed pieces for meals, and ground beef from a restaurant epidemiologically linked to an outbreak of hemorrhagic colitis. These results suggest that foods, particularly foods of animal origin, may be an important source of *E. coli* O157:H7 infections.

ACKNOWLEDGMENTS

This project was supported by the College of Agricultural and Life Sciences, University of Wisconsin, Madison, and by contributions to the Food Research Institute.

LITERATURE CITED

1. **Beery, J. T., M. P. Doyle, and J. L. Schoeni.** 1985. Colonization of chicken cecae by *Escherichia coli* associated with hemorrhagic colitis. Appl. Environ. Microbiol. **49**:310–315.
2. **Borczyk, A. A., M. A. Karmali, H. Lior, and L. M. C. Duncan.** 1987. Bovine reservoir for verotoxin-producing *Escherichia coli* O157:H7. Lancet **i**:98.
3. **Honda, T., R. I. Glass, Q. Akhtar, and A. K. M. Golam Kibriya.** 1981. A simple assay to detect *Escherichia coli* producing heat labile enterotoxin: results of a field study of the Biken test in Bangladesh. Lancet **ii**:609–610.
4. **Lamothe, F., C. Gaudreau, D. Bernard, and S. Gill.** 1983. Hemorrhagic colitis following the consumption of hamburgers—Quebec. Can. Dis. Weekly Rep. **9**:50–51.
5. **Martin, M. L., L. D. Shipman, M. E. Potter, I. K. Wachsmuth, J. G. Wells, K. Hedberg, R. V. Tauxe, J. P. Davis, J. Arnoldi, and J. Tilleli.** 1986. Isolation of *Escherichia coli* O157:H7 from dairy cattle associated with two cases of haemolytic uraemic syndrome. Lancet **ii**:1043.
6. **Pai, C. K., R. Gordon, H. V. Sims, and L. E. Bryan.** 1984. Sporadic cases of hemorrhagic colitis associated with *Escherichia coli* O157:H7. Ann. Intern. Med. **101**:738–742.
7. **Riley, L. W., R. S. Remis, S. D. Helgerson, H. B. McGee, J. G. Wells, B. R. Davis, R. J. Hebert, E. S. Olcott, L. M. Johnson, N. T. Hargrett, P. A. Blake, and M. L. Cohen.** 1983. Hemorrhagic colitis associated with a rare *Escherichia coli* serotype. N. Engl. J. Med. **308**:681–685.
8. **Ryan, C. A., R. V. Tauxe, G. W. Hosek, J. G. Wells, P. A. Stoesz, H. W. McFadden, Jr., P. W. Smith, G. F. Wright, and P. A. Blake.** 1986. *Escherichia coli* O157:H7 diarrhea in a nursing home: clinical, epidemiological, and pathological findings. J. Infect. Dis. **154**:631–638.
9. **Stewart, P. J., W. Desormeaux, and J. Chéné.** 1983. Hemorrhagic colitis in a home for the aged—Ontario. Can. Dis. Weekly Rep. **9**:29–32.
10. **Wells, J. G., B. R. Davis, I. K. Wachsmuth, L. W. Riley, R. S. Remis, R. Sokolow, and G. K. Morris.** 1983. Laboratory investigation of hemorrhagic colitis outbreaks associated with a rare *Escherichia coli* serotype. J. Clin. Microbiol. **18**:512–520.

Downloaded from http://aem.asm.org/ on February 23, 2017 by guest

APPENDIX D

Journal of Food Protection, Vol. 75, No. 7, 2012, Pages 1278–1291
doi:10.4315/0362-028X.JFP-11-418

Ranking the Disease Burden of 14 Pathogens in Food Sources in the United States Using Attribution Data from Outbreak Investigations and Expert Elicitation†

MICHAEL B. BATZ,[1]* SANDRA HOFFMANN,[2,3] AND J. GLENN MORRIS, JR.[1]

[1]*Emerging Pathogens Institute, University of Florida, P.O. Box 100009, Gainesville, Florida 32610-0009;* [2]*Resources for the Future, 1616 P Street N.W., Washington, DC 20036; and* [3]*U.S. Department of Agriculture, Economic Research Service, 1800 M Street N.W., Washington, DC 20036, USA*

MS 11-418: Received 17 September 2011/Accepted 24 January 2012

ABSTRACT

Understanding the relative public health impact of major microbiological hazards across the food supply is critical for a risk-based national food safety system. This study was conducted to estimate the U.S. health burden of 14 major pathogens in 12 broad categories of food and to then rank the resulting 168 pathogen-food combinations. These pathogens examined were *Campylobacter*, *Clostridium perfringens*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, norovirus, *Salmonella enterica*, *Toxoplasma gondii*, and all other FoodNet pathogens. The health burden associated with each pathogen was measured using new estimates of the cost of illness and loss of quality-adjusted life years (QALYs) from acute and chronic illness and mortality. A new method for attributing illness to foods was developed that relies on both outbreak data and expert elicitation. This method assumes that empirical data are generally preferable to expert judgment; thus, outbreak data were used for attribution except where evidence suggests that these data are considered not representative of food attribution. Based on evaluation of outbreak data, expert elicitation, and published scientific literature, outbreak-based attribution estimates for *Campylobacter*, *Toxoplasma*, *Cryptosporidium*, and *Yersinia* were determined not representative; therefore, expert-based attribution were included for these four pathogens. Sensitivity analyses were conducted to assess the effect of attribution data assumptions on rankings. Disease burden was concentrated among a relatively small number of pathogen-food combinations. The top 10 pairs were responsible for losses of over $8 billion and 36,000 QALYs, or more than 50% of the total across all pairs. Across all 14 pathogens, poultry, pork, produce, and complex foods were responsible for nearly 60% of the total cost of illness and loss of QALYs.

Risk-based food safety, as called for by the FDA Food Safety Modernization Act and national and international public health bodies, relies on systematic identification and quantification of the specific pathogens in specific foods that are responsible for the greatest burden of foodborne disease in the United States *(6, 13, 34, 35, 37, 50, 52–54)*. Such an approach requires use of integrated measures of the public health burden associated with these pathogens that allow for the comparison of diseases with very different incidence, symptoms, and severities *(29, 33)*. Food attribution estimates, i.e., measures of how illnesses associated with a given pathogen are distributed across food sources, are also needed *(2, 40)*.

Much like recent Centers for Disease Control and Prevention (CDC) national foodborne disease incidence estimates, this study was conducted to provide a systematic, national assessment of the relationship between the burden of disease from major foodborne pathogens and food consumption across the entire U.S. food supply. It builds on new cost of illness and quality-adjusted life year (QALY) loss estimates for 14 major foodborne pathogens in the United States *(20)*. These pathogens account for more than 95% of the illnesses, hospitalizations, and deaths due to identified foodborne pathogens, as estimated by Scallan et al. *(48)*.

A growing body of scientific research has been focused on methods for attributing foodborne illness to their source *(2, 40)*. Five basic approaches to source attribution have emerged: analysis of outbreak surveillance *(1, 10, 16, 39, 42, 45)*, case-control and other epidemiological studies *(14, 19, 25, 26, 56, 57)*, use of microbiological subtyping analysis to compare pathogen strains in food and in clinical cases *(17, 28, 32, 41, 43)*, comparative exposure assessments *(12, 51)*, and expert elicitation studies *(8, 9, 18, 21–23, 44, 55)*. These studies typically do not use the counterfactual approach common in epidemiological studies of causation *(46)* but rather focus on quantifying the portion of illness due to a particular pathogen that can be attributed directly to a food source. The present study is innovative in combining information from two distinct data sources to attribute illnesses from pathogens to foods: 10 years of outbreak data (1999 through 2008) taken from publicly available line listings published by the CDC *(4)* and a

* Author for correspondence. Tel: 352-273-7010; Fax: 352-273-6890; E-mail: mbatz@ufl.edu.

† The views expressed herein are those of the authors and do not necessarily reflect the views of the Economic Research Service or the U.S. Department of Agriculture.

compatible expert elicitation conducted for this project *(21–23)*. Although reported outbreak cases reflect a very small percentage of overall foodborne illness, these data nevertheless are the most comprehensive primary source of information to explicitly link human infections to food vehicles for a wide range of pathogens *(40)*. Attribution estimates based on case-control studies, serotyping, or comparative exposure assessment are available for only a small subset of these 14 major pathogens and are extremely difficult to integrate across a wide range of pathogens and foods due to differences in study designs *(2)*. Based on evidence from multiple sources, we found that for some pathogens outbreak data do not provide a reliable representation of food attribution. For these pathogens, we instead used attribution estimates from the expert elicitation study.

We estimated that the top 10 pathogen-food combinations, which reflect five pathogens (*Campylobacter*, *Listeria monocytogenes*, norovirus, *Salmonella*, and *Toxoplasma gondii*) in eight food categories (poultry, pork, deli meats, dairy, produce, beef, eggs, and complex foods), are responsible for losses of more than $8 billion and 36,000 QALYs, or more than 50% of the total health burden from all foods due to all 14 pathogens studied. Based on exposure to all 14 pathogens, poultry, pork, produce, and complex foods are the commodities responsible for the most disease burden.

MATERIALS AND METHODS

In the following sections we discuss methodological decisions made in this study: choice of public health burden measures, development of a food categorization scheme, estimation of attribution percentages based on outbreak data, estimation of attribution percentages based on expert elicitation, and analysis supporting choice of attribution data source for each pathogen. Additional tables and figures, including outbreak data tables, expert elicitation details, and the complete list of pathogen-food rankings, may be found in the online Appendix (http://foodrisk.org/pubs/riskranking).

Public health burden measures. The CDC has estimated 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths due to foodborne disease annually. Of these, 9.4 million cases, 56,000 hospitalizations, and 1,400 deaths are due to 31 identifiable pathogens *(47, 48)*. Although summary incidence estimates are valuable, they cannot be directly combined to compare the total burden of disease due to specific pathogens. Integrated measures of disease burden, such as cost of illness and QALYs lost, can be built on such incidence estimates to provide a common metric for comparing diseases with different symptoms and severities, including congenital impacts and chronic conditions not reflected in summary statistics *(27, 29, 33)*.

This study utilizes new estimates of the cost of illness and QALY loss from both acute and chronic illness due to 14 major foodborne pathogens as described in an accompanying article *(20)*. The pathogens discussed in this article will be referred to as indicated in parentheses: *Campylobacter* spp. (*Campylobacter*), *Clostridium perfringens* (*C. perfringens*), *Cryptosporidium parvum* (*Cryptosporidium*), *Cyclospora cayetanensis* (*Cyclospora*), *Escherichia coli* O157:H7 (*E. coli* O157), Shiga toxin–producing *E. coli* non-O157 (STEC non-O157), *Listeria monocytogenes* (*Listeria*), norovirus, nontyphoidal *Salmonella enterica* (*Salmonella*), *Shigella* spp. (*Shigella*), *Toxoplasma gondii* (*Toxoplasma*), *Vibrio vulnificus* (*V. vulnificus*), *Vibrio parahaemolyticus* and other noncholera *Vibrio* spp. (*Vibrio* other), and *Yersinia enterocolitica* (*Yersinia*). Cost of illness estimates reflect medical costs, productivity losses, and valuation of mortality, whereas QALY estimates capture loss of health-related quality of life using the EuroQol EQ5D instrument *(3, 49)*. These 14 foodborne pathogens are estimated to cause a total loss of $14.0 billion ($4.4 to $33.0 billion) and 61,000 (19,000 to 145,000) QALYs per year (Table 1), with roughly 90% of these impacts due to just five pathogens: *Salmonella*, *Campylobacter*, *Listeria*, *Toxoplasma*, and norovirus.

Food categories. No consensus exists on how to categorize foods for attribution *(1, 2, 16, 39, 45)*. Categorization schemes used for broad evaluation of risks across the entire food supply, as in the present study, are likely to be quite different from those useful for targeted risk management. Attribution approaches also differ in their points of attribution *(2)*. The "point of production" approaches focus on primary food production activities, such as animal reservoirs, as pathogen sources (e.g., *E. coli* O157 in cattle), whereas "point of consumption" approaches, such as the one used in the present study, focus on food vehicles that directly lead to exposure (e.g., *E. coli* O157 in hamburgers) *(40)*.

We estimated attribution to food as close to the time of consumption as practicable because this approach provides the most direct link between human disease surveillance and exposure to pathogens in foods. Upstream points of attribution, such as attribution to on-farm contamination sources, neglect the role of downstream contamination events, such as cross-contamination during preparation, in causing disease. Consumption-oriented categories better reflect the information provided in outbreak investigations. Estimates of disease burden focused at consumption also provide a basis for quantitative risk assessments focusing on the contribution of production, processing, and food preparation to final exposure of consumers. We therefore created a scheme with a dozen primary categories (Table 2) designed to span the U.S. food supply at the point of consumption and to be compatible for primary analysis of CDC outbreak data, useful to food safety practitioners, and congruent with established guidance on categorization for risk ranking *(30)*.

Categorization entails judgment. To better reflect foods at the point of consumption, our broad categories better reflect groupings found in grocery store aisles or restaurant menus than do ingredients of specific products (e.g., baked goods instead of grains, sugars, oils). In pretests, food safety experts also recommended that we treat deli meats (e.g., sliced turkey, ham, roast beef) as a separate category rather than categorizing them by food animal together with raw meat, principally for understanding risks due to *Listeria (51)*. The "complex foods" category is included for analysis of outbreak data to capture multi-ingredient dishes for which a specific contaminated ingredient was never identified; further explanation of this category is provided in the next section.

Estimating attribution percentages from outbreak data. As in other outbreak attribution studies *(1, 10, 16, 39, 42, 45)*, data from multiple years were averaged to address significant year-to-year variability in foodborne illness and to ensure sufficient data for analysis. We based our estimates on the most recent 10 years available (1999 through 2008) in the CDC's online repository of foodborne outbreaks with identified etiology *(4)*. Outbreaks with an unidentified etiology but suspected of being associated with enterohemorrhagic *E. coli* were treated as STEC non-O157.

Three methodological issues had to be addressed in developing attribution estimates from outbreak data: cleaning the data, coding each outbreak to a food category based on identified vehicle, and deciding whether to base attribution estimates on

National Beef Ex. 1007
Page 1841

TABLE 1. *Annual burden of disease caused by 14 foodborne pathogens*[a]

Pathogen	Cost of illness ($ million)	QALY loss	No. of illnesses	No. of hospitalizations	No. of deaths
Campylobacter	1,747 (841–4,152)	13,256 (7,993–26,021)	845,024 (337,031–1,611,083)	8,463 (4,300–15,227)	76 (0–332)
C. perfringens	309 (20–1,572)	876 (83–3,942)	965,958 (192,316–2,483,309)	438 (44–2,008)	26 (0–163)
C. parvum	47 (3–192)	341 (40–1,265)	57,616 (12,060–166,771)	210 (58–518)	4 (0–19)
C. cayetanensis	2 (0–8)	10 (0–33)	11,407 (137–37,673)	11 (0–109)	0
E. coli O157:H7	255 (25–1,102)	1,660 (131–7,872)	63,153 (17,587–149,631)	2,138 (549–4,614)	20 (0–113)
STEC non-O157	24 (1–77)	149 (10–268)	112,752 (11,467–287,321)	271 (0–971)	0
L. monocytogenes	2,577 (204–6,952)	9,375 (1,531–23,525)	1,591 (557–3,161)	1,455 (521–3,018)	255 (0–733)
Norovirus	2,002 (1,140–3,147)	5,027 (2,897–7,832)	5,461,731 (3,227,078–8,309,480)	14,663 (8,097–23,323)	149 (84–237)
S. enterica	3,309 (160–8,586)	16,782 (304–44,380)	1,027,561 (644,786–1,679,667)	19,336 (8,545–37,490)	378 (0–1,011)
Shigella	121 (8–639)	545 (14–3,372)	131,254 (24,511–374,789)	1,456 (287–3,695)	10 (0–67)
T. gondii	2,973 (1,763–4,437)	10,964 (6,026–16,771)	86,686 (64,861–111,912)	4,428 (2,634–6,674)	327 (200–482)
Vibrio other	103 (28–298)	210 (60–595)	52,228 (29,108–84,502)	183 (101–293)	12 (3–36)
V. vulnificus	291 (154–460)	557 (294–882)	96 (60–139)	93 (53–139)	36 (19–57)
Y. enterocolitica	252 (3–1,412)	1,415 (13–8,216)	97,656 (30,388–172,734)	533 (0–1,173)	29 (0–173)
Total	14,012 (4,352–33,034)	61,166 (19,397–144,974)	8,914,713 (4,591,947–15,472,172)	53,678 (25,189–99,252)	1,322 (306–3,423)

[a] Values are means with ranges or credible intervals in parentheses. Mean numbers of annual illnesses, hospitalizations, and deaths are followed by 90% credible intervals for acute disease reported by Scallan et al. *(48)* but do not include all cases of fetal and chronic disease included in estimates of cost of illness and quality-adjusted life year (QALY) loss. Ranges for cost of illness and QALY loss reflect estimates based on credible intervals reported by Scallan et al. and discussed in Hoffmann et al. *(20)*. *Vibrio* other refers to noncholera *Vibrio* spp. other than *V. vulnificus*.

counts of outbreak events or on cases of illness associated with these events.

For the 14 pathogens in this study, we compiled a data set of 5,830 outbreaks associated with 172,495 cases of illness. In 2,636 outbreaks (70,568 cases), the food vehicle was listed as "unknown." In an additional 606 outbreaks (22,485 cases), no single food was identified, so the investigation report listed multiple foods (e.g., steak, beets, and veggie-based pasta). We decided such information on food vehicle was too vague to support reliable food attribution. These multisource outbreaks were dropped from the analysis, although we explored this decision in sensitivity analyses. Thus, our outbreak data set included 2,588 attributable outbreaks with 79,442 associated cases.

Outbreak investigations do not use a standardized coding scheme for the responsible food vehicle but rather provide text descriptions that are often incomplete, colloquial, or otherwise vague. For example, an outbreak might be attributed in the data to "ethnic food." Thus, the first step in estimating outbreak-based attribution was to develop a coding scheme to categorize these descriptions of food vehicles.

In cases in which investigators identified the cause as a single food item (e.g., tomatoes) or a specific ingredient in a multi-ingredient dish (e.g., eggs in lemon meringue pie), we coded based on the identified food. In many outbreaks, however, the investigation report listed a multi-ingredient dish but did not specify a single ingredient (e.g., cheeseburger or seafood gumbo). Multi-ingredient dishes were classified in one of three ways: (i) those in which the vast majority of ingredients fell into a single category were lumped into that category (e.g., salsa as produce); (ii) because many foodborne pathogens are recognized as zoonoses with well-understood reservoirs in animal production, outbreaks in which beef, poultry, pork, seafood, or eggs were the primary ingredient were classified by species (e.g., beef stew as beef, chicken pot pie as poultry, quiche as egg); and (iii) all remaining dishes were classified as complex foods. For example, green salads were assumed to be composed solely of vegetables and were classified as produce unless the description also included nonproduce ingredients such as eggs or cheese, in which case these salads were classified as complex foods. Deli salads, such as macaroni salad, were assumed to be composed of foods from multiple categories and were therefore classified as complex foods rather than produce, eggs, or another category. Ultimately, 776 outbreaks reflecting 24,357 cases, or about a quarter of all outbreaks with identified vehicles, were categorized as complex foods. Our approach to multi-ingredient dishes might bias results toward meat and poultry because outbreaks due to foods such as cheeseburgers are classified as beef even though other ingredients, such as tomato, lettuce, or the bun, could have been the contaminated ingredient. An alternate approach to complex foods has been described by Painter et al. *(39)*, but this approach to disambiguation requires significant assumptions about which ingredients constitute each dish (recipes) and how risk of contamination is distributed across constituent ingredients. We examined the role of complex foods in the sensitivity analysis.

Outbreak-based attribution studies have based estimates either on the distribution of outbreak cases across foods *(1, 10, 39, 42)* or on the distribution of outbreak events across foods *(16, 45)*. These attribution percentages are calculated by dividing the number of outbreaks (or outbreak cases) associated with a specific pathogen-food combination by the number of outbreaks (or outbreak cases) associated with that pathogen.

Attribution based on outbreak counts are likely more representative of sporadic cases than those based on case counts. For each outbreak case in our data set, more than 1,000 cases of

National Beef Ex. 1007
Page 1842

TABLE 2. *Food categories used in food attribution*

Food	Food subcategories[a]
Beef	Ground beef, other beef (intact), beef dishes
Pork	Ham, other pork (intact), pork dishes
Poultry	Chicken, turkey, other poultry (intact), poultry dishes
Deli and other meats	Deli meats, other meats, other meat dishes
Game	Game
Eggs	Eggs, egg dishes
Dairy	Milk, cheese, ice cream, other dairy dishes
Seafood	Finfish, shellfish, other seafood, seafood dishes
Produce	Fruits, vegetables, produce dishes
Beverages	Juices, other beverages (not including water)
Baked goods	Breads, bakery goods, cereals
Complex foods	Nonmeat multi-ingredient dishes: salads (e.g., deli), sandwiches, rice, beans, hot pasta, sauces, dressings, oils, etc.

[a] Subcategories were used for coding outbreaks and were provided to participants in the expert elicitation reported by Hoffmann et al. *(21)* to provide a clearer understanding of the foods included in each category. The food subcategories were not used to categorize food in the present analysis.

sporadic disease are estimated, i.e., our data include 79,442 attributable outbreak cases over 10 years compared with nearly 9 million annual cases of illness estimated by Scallan et al. *(48)* for these same pathogens. This difference suggests that most of these 9 million foodborne illnesses occur in small, isolated events that are arguably better reflected by smaller outbreaks than large outbreaks. The larger an outbreak, the more likely it is to represent a major and unusual failure in food safety systems, the more likely it is to have been noticed and fully investigated, and the more likely it is that the vehicle will be identified. As a result, large events are likely overrepresented in the outbreak data. Outbreak size is heavily skewed to the right; the average outbreak size is about 28 cases, but the median is 12 and the mode is 2. To the extent that outbreak size varies by food category, attribution percentages based on number of cases become effectively skewed towards those foods more likely to cause large events. We found that produce outbreaks had an average of 51 cases, dairy outbreaks had 36 cases, and complex foods outbreaks had 31 cases, whereas beef, pork, and seafood outbreaks averaged 23, 24, and 15 cases, respectively. Thus, outbreak attribution estimates based on case counts attribute a greater portion of disease to produce, dairy, and complex foods than do estimates based on outbreak events. Attribution percentages based on outbreak counts are presented in Table 3. Attribution based on case counts was examined in the sensitivity analysis.

Attribution percentages from expert elicitation. Expert elicitation is a set of formal research methods used to characterize uncertainty about existing scientific knowledge and to provide alternative parameter estimates when there are meaningful gaps in available data *(7, 31, 38)*. Several studies have included expert elicitation to gain greater insight into attribution to food sources and other transmission pathways *(9, 18, 44, 55)*. As part of our larger research effort, Hoffmann et al. *(21–23)* conducted an expert elicitation for attribution estimates on 12 of the 14 pathogens included in this study.

The elicitation was designed to characterize uncertainty about food attribution estimates for these diseases and to provide alternative attribution estimates. Forty-five leading food safety scientific experts were identified by iterative peer nomination as having relevant, nationally recognized expertise *(22)*. For each pathogen, experts provided their best estimate and a 90% credible interval for the percentage of foodborne illnesses associated with consumption of food in various categories. Following Clemen and Winkler *(5)*, the percentage attributable to each pathogen-food combination was estimated as the unweighted mean of the best estimates of all the experts. The results are shown in Table 4.

The categories used in the 2003 elicitation were the same as those used to assign outbreak data to food categories, with two exceptions. First, the complex foods category necessary for evaluating outbreaks was removed after focus groups and pretesting indicated that experts could confidently attribute to single food categories, but overlaps between these categories and complex foods created ambiguity in categorization and increased uncertainty about attribution percentage estimates. Second, the elicitation included "other foods" as a residual category to ensure that attribution estimates would sum to 100%. Because focus group results showed that experts were thinking in terms of simple rather than complex foods, this category cannot be interpreted as complex foods. In analysis, the "other food" category was dropped, and remaining attribution estimates were normalized across the remaining food categories. We examined this treatment of "complex foods" through sensitivity analysis.

Choice of attribution source. Although outbreak data have been used as a primary empirical source for attribution of foodborne illness in the United States, case-control studies suggest that these data may not provide an equally accurate representation of the association between illness and food sources for all pathogens *(14, 24)*. We conducted a series of analyses to assess when outbreak data may and may not provide good representations of food attribution. In developing our baseline estimates, we started with the presumption that outbreak-based attribution would be used, but where the totality of evidence from these analyses suggested that these data were not representative, expert-based estimates were used instead.

First, for some pathogens there are simply too few outbreaks with identified food vehicles to estimate attribution (Table 5). From 1999 through 2008, *Toxoplasma*, *Yersinia*, and *Cryptosporidium* food vehicles were identified in zero, five, and four reported outbreaks caused by each of these pathogens, respectively. However, in this same period, 1,125 norovirus-associated outbreaks, 621 *Salmonella*-associated outbreaks, and 362 *C. perfringens*–associated outbreaks with identified food vehicles were reported.

Second, we looked at the ratio of the CDC's estimated annual number of illnesses reported by Scallan et al. *(48)* to the average annual number of reported outbreak cases for that pathogen from 1999 through 2008 (Table 5). The ratio represents the number of illnesses one would expect in the population for each reported outbreak case. A high ratio suggests that source attribution from outbreak data may not be representative of total foodborne illness caused by a particular pathogen. This ratio is particularly high for *Yersinia* (11,909:1), *Campylobacter* (1,712:1), and *Cryptosporidium* (1,152:1); it is lowest for *Listeria* (55:1), *Cyclospora* (87:1), and *E. coli* O157 (132:1).

Third, we analyzed the differences between outbreak-based attribution estimates and those from experts (Tables 3 and 4). Because experts draw on a range of scientific evidence, not just outbreak information, large differences may point to pathogens for which outbreak data may not be representative of food attribution. In this analysis, for each pathogen across noncomplex foods we

National Beef Ex. 1007
Page 1843

TABLE 3. *Attribution percentages for 12 pathogens based on foodborne outbreaks with known etiology and vehicle, 1999 through 2008*[a]

Food	*Campylobacter* spp.	*Clostridium perfringens*	*Cryptosporidium parvum*	*Cyclospora cayetanensis*	*E. coli* O157:H7	STEC non-O157	*Listeria monocytogenes*	Norovirus	*Salmonella* (nontyhpoidal)	*Shigella* spp.	*Vibrio* spp.	*Yersinia enterocolitica*
Beef	5.8	32.6	0.0	0.0	55.2	40.0	0.0	4.2	6.9	14.6	0.0	0.0
Beverages	0.0	0.0	50.0	0.0	2.1	13.3	0.0	2.0	1.1	0.0	0.0	0.0
Baked goods	0.0	0.0	0.0	0.0	0.7	0.0	0.0	7.9	2.6	0.0	0.0	0.0
Dairy	50.8	0.6	0.0	0.0	5.6	20.0	30.0	2.1	5.6	2.4	0.0	0.0
Eggs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	11.8	0.0	0.0	0.0
Game	1.7	0.3	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Deli and other meats	1.7	2.8	0.0	0.0	3.5	0.0	35.0	2.1	2.9	4.9	0.0	0.0
Complex foods	10.8	24.0	50.0	21.4	13.3	6.7	15.0	45.5	18.7	48.8	0.0	0.0
Pork	2.5	8.3	0.0	0.0	0.0	0.0	5.0	2.8	6.6	0.0	0.0	100.0
Poultry	18.3	27.3	0.0	0.0	0.7	6.7	5.0	7.7	20.9	9.8	0.0	0.0
Produce	5.8	3.0	0.0	78.6	18.2	13.3	5.0	15.6	17.6	12.2	0.0	0.0
Seafood	2.5	1.1	0.0	0.0	0.7	0.0	5.0	9.2	5.3	7.3	100.0	0.0
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Used in baseline ranking		■		■	■	■	■	■	■	■	■	

[a] No *T. gondii* outbreaks with known vehicles were identified from 1999 through 2008. These fractions were estimated by counting the number of outbreaks due to each pathogen-food combination and dividing by the total number of food attributable outbreaks for that pathogen. Food attributable outbreaks are those with known etiology and an identified food vehicle that could be placed into one of these categories. Attributions based on *Vibrio* spp. are applied to both *V. vulnificus* and *Vibrio* other.

TABLE 4. *Attribution percentages for 11 pathogens based on expert elicitation*[a]

Food	*Campylobacter* spp.	*Cryptosporidium parvum*	*Cyclospora cayetanensis*	*E. coli* O157:H7	*Listeria monocytogenes*	Norovirus	*Salmonella* (nontyhpoidal)	*Shigella* spp.	*Toxoplasma gondii*	*Vibrio* spp.	*Yersinia enterocolitica*
Beef	4.4	7.4	0.0	67.9	1.6	1.4	10.9	3.1	23.2	0.2	2.2
Beverages	0.0	9.0	1.5	3.2	0.2	4.5	1.7	4.7	0.0	0.8	1.1
Baked goods	0.0	0.3	0.3	0.0	0.2	5.8	0.3	1.9	0.0	0.0	0.0
Dairy	7.8	5.8	0.4	4.0	23.6	2.9	7.3	3.4	2.4	0.0	12.2
Eggs	2.6	0.3	0.0	0.0	0.3	1.1	21.8	0.9	0.0	0.0	0.1
Game	2.0	5.4	1.3	3.2	0.3	0.6	1.6	0.8	20.4	0.0	2.0
Deli and other meats	0.9	1.4	0.1	1.8	54.0	9.4	1.9	9.4	1.7	0.2	1.8
Complex foods	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pork	4.4	2.0	0.0	0.6	1.3	1.4	5.7	3.1	41.0	0.2	71.6
Poultry	72.0	1.2	0.0	0.9	2.7	1.5	35.1	4.9	3.7	0.2	1.2
Produce	5.2	59.5	96.1	18.4	8.7	37.3	11.7	60.0	7.0	1.4	3.2
Seafood	0.8	7.7	0.4	0.1	7.2	34.1	2.0	7.8	0.5	97.1	4.7
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Used in baseline ranking	■	■							■		■

[a] The expert elicitation did not include *C. perfringens* or STEC non-O157. Attributions based on *Vibrio* spp. are applied to both *V. vulnificus* and *Vibrio* other.

National Beef Ex. 1007
Page 1844

TABLE 5. *Factors influencing choice of attribution approach, by pathogen*

Pathogen	Data decision	Total no. of attributable outbreaks (1999–2008)[a]	Total no. of outbreak cases (1999–2008)[b]	Ratio of overall incidence to outbreak cases[c]	Sum of mean difference squared[d]	Mean SD of expert estimates[e]
Campylobacter	Expert	120	4,936	1,712	3,307	0.91
C. perfringens	Outbreak	362	19,523	495		
C. parvum	Expert	4	500	1,152	3,622	1.64
C. cayetanensis	Outbreak	14	1,306	87	62	0.42
E. coli O157:H7	Outbreak	143	4,768	132	20	0.76
STEC non-O157	Outbreak	15	1,514	745		
L. monocytogenes	Outbreak	20	290	55	827	0.96
Norovirus	Outbreak	1,125	98,384	555	701	1.77
S. enterica	Outbreak	621	34,717	296	218	1.02
Shigella	Outbreak	41	5,133	256	1,198	1.68
T. gondii	Expert	0	0		2,706	2.02
Vibrio spp.	Outbreak	59	671	780	9	0.25
Y. enterocolitica	Expert	5	82	11,909	562	1.38

[a] Number of foodborne outbreaks between 1999 and 2008 with identified etiology and food vehicle.
[b] Number of foodborne outbreak cases between 1999 and 2008 with identified etiology.
[c] Number of estimated annual cases from Scallan et al. *(48)* divided by the average annual number of foodborne outbreak cases between 1999 and 2008.
[d] Sum across foods of the mean difference squared between experts' food attribution percentages and outbreak attribution percentages based on data from 1993 through 2002 (to utilize data concurrent with the expert elicitation conducted in 2003).
[e] Mean across foods of the standard deviation among experts' food attribution percentages.

calculated the sum of the mean of the squared difference between experts' estimates and outbreak attribution estimates (Table 5). Outbreak attribution estimates used for this analysis were based on data from 1993 through 2002 (a 10-year window concurrent with the expert elicitation time frame). The sum of mean differences squared was highest for *Cryptosporidium* (3,622), *Campylobacter* (3,307), *Toxoplasma* (2,706), and *Shigella* (1,198) and lowest for *Vibrio* spp. (9), *E. coli* O157 (20), and *Cyclospora* (62) (Table 5). To provide a more intuitive feel for this measure of difference, outbreak estimates attributed 51% of *Campylobacter* cases to dairy and 18% to poultry, whereas experts attributed 72% to poultry and 8% to dairy on average (Tables 3 and 4). The discrepancy for dairy is likely due to the fact that many of the *Campylobacter* dairy outbreaks were associated with unpasteurized milk, a high-risk niche food consumed by a small percentage of the U.S. population. Likewise, expert judgment attributed 60% of *Shigella* infection cases to produce, whereas outbreak estimates attributed 12% of these cases to produce and 49% to complex foods.

We also looked at the mean standard deviation across experts' individual attribution estimates as an indicator of scientific agreement on food attribution relationships for a particular pathogen. This measure varies significantly across pathogens from 0.25 for *Vibrio* to 2.02 for *Toxoplasma* (Table 5). Hoffmann et al. *(21)* found that viewing information on multiple measures of uncertainty from expert elicitation can enhance understanding of the likely state of scientific understanding. For example, although expert and outbreak attributions for *Campylobacter* differ markedly, the low mean standard deviation among experts (0.91) suggests strong agreement about attribution. The mean standard deviation across experts is much higher for *Toxoplasma* (2.02), which points to greater uncertainty about attributing cases of toxoplasmosis.

Existing case-control studies have not included categories that are entirely congruent with our food categories, but this information can provide indications of the representativeness of outbreak attribution estimates. A FoodNet case-control study on *Campylobacter* revealed that the top three foodborne hazards were chicken prepared by a restaurant, nonpoultry meat prepared by a restaurant, and turkey prepared by a restaurant *(14)*. These results align strongly with expert judgment but not with outbreak attribution. In contrast, a recent case-control study on toxoplasmosis *(24)* revealed some important differences between outbreak and expert attribution. Although the present study did not include attributable fractions, published odds ratios point to much more important roles for lamb and shellfish than suggested by the percentages estimated by experts.

Together, these five pieces of evidence point to four pathogens for which outbreak attribution may not be representative (Table 5). The case for using expert elicitation is strongest for *Campylobacter*, which has a high ratio of estimated incidence to reported outbreak cases, large differences between expert and outbreak attribution, high agreement among experts, and case-control studies that support expert estimates. *Cryptosporidium* has sparse outbreak data and a high ratio of incidence to outbreak cases, although experts are not in close agreement, suggesting uncertainty in their attribution estimates. Outbreak data are nonexistent for *Toxoplasma* and plainly insufficient for *Yersinia*, although opinions about these pathogens also differ significantly among experts. Conversely, the case for using outbreak data is strongest for *Vibrio*, *Cyclospora*, and *E. coli* O157. Based on the totality of evidence, we substituted expert attribution estimates for outbreak estimates only for *Campylobacter*, *Cryptosporidium*, *Toxoplasma*, and *Yersinia* in our baseline scenario. This decision was examined through sensitivity analysis.

RESULTS AND DISCUSSION

Pathogen-food rankings. We developed rankings of pathogen-food combinations by cost of illness and QALY loss separately. Following recommendations of the National Academy of Sciences *(36)*, we treated these metrics as

National Beef Ex. 1007
Page 1845

TABLE 6. *Estimated annual disease burden for top 50 pathogen-food combinations, by combined QALY and cost of illness ranking*[a]

Rank	Pathogen-food combination	Cost of illness ($million)	QALY loss	No. of illnesses	No. of hospitalizations	No. of deaths
1	*Campylobacter*-poultry	1,257 (606–2,988)	9,541 (5,753–18,730)	608,231 (242,588–1,159,624)	6,091 (3,095–10,960)	55 (0–239)
2	*T. gondii*–pork	1,219 (723–1,819)	4,495 (2,471–6,875)	35,537 (26,590–45,879)	1,815 (1,080–2,736)	134 (82–198)
3	*L. monocytogenes*–deli meats	902 (71–2,433)	3,281 (536–8,234)	557 (195–1,106)	509 (182–1,056)	89 (0–257)
4	*S. enterica*–poultry	693 (33–1,797)	3,513 (64–9,290)	215,109 (134,979–351,621)	4,048 (1,789–7,848)	79 (0–212)
5	*L. monocytogenes*–dairy	773 (61–2,086)	2,812 (459–7,058)	477 (167–948)	437 (156–905)	77 (0–220)
5	Norovirus–complex foods	911 (519–1,432)	2,288 (1,319–3,565)	2,485,694 (1,468,679–3,781,737)	6,673 (3,685–10,615)	68 (38–108)
7	*S. enterica*–complex foods	618 (30–1,604)	3,135 (57–8,290)	191,944 (120,443–313,754)	3,612 (1,596–7,003)	71 (0–189)
8	*S. enterica*–produce	581 (28–1,507)	2,946 (53–7,790)	180,361 (113,175–294,821)	3,394 (1,500–6,580)	66 (0–177)
8	*T. gondii*–beef	689 (409–1,028)	2,541 (1,396–3,886)	20,086 (15,029–25,931)	1,026 (610–1,546)	76 (46–112)
10	*S. enterica*–eggs	389 (19–1,009)	1,973 (36–5,217)	120,792 (75,796–197,449)	2,273 (1,004–4,407)	44 (0–119)
11	*L. monocytogenes*–complex foods	387 (31–1,043)	1,406 (230–3,529)	239 (84–474)	218 (78–453)	38 (0–110)
12	*S. enterica*–beef	229 (11–595)	1,162 (21–3,073)	71,152 (44,647–116,305)	1,339 (592–2,596)	26 (0–70)
13	*S. enterica*–pork	218 (11–567)	1,108 (20–2,930)	67,842 (42,570–110,896)	1,277 (564–2,475)	25 (0–67)
14	Norovirus-produce	313 (178–492)	786 (453–1,225)	854,457 (504,858–1,299,972)	2,294 (1,267–3,649)	23 (13–37)
15	*S. enterica*–dairy	187 (9–484)	946 (17–2,501)	57,914 (36,341–94,667)	1,090 (482–2,113)	21 (0–57)
16	*Y. enterocolitica*–pork	180 (3–1,010)	1,013 (9–5,880)	69,889 (21,748–123,620)	381 (0–839)	21 (0–124)
17	*T. gondii*–produce	209 (124–312)	772 (424–1,181)	6,104 (4,567–7,880)	312 (185–470)	23 (14–34)
18	*V. vulnificus*–seafood	291 (154–460)	557 (294–882)	96 (60–139)	93 (53–139)	36 (19–57)
19	*Campylobacter*-dairy	136 (66–324)	1,034 (623–2,029)	65,886 (26,278–125,615)	660 (335–1,187)	6 (0–26)
19	*S. enterica*–seafood	176 (8–456)	892 (16–2,358)	54,605 (34,264–89,258)	1,028 (454–1,992)	20 (0–54)
21	*E. coli* O157:H7–beef	141 (14–609)	917 (72–4,349)	34,889 (9,716–82,663)	1,181 (303–2,549)	11 (0–62)
22	Norovirus-seafood	183 (104–288)	460 (265–717)	500,052 (295,457–760,779)	1,342 (741–2,135)	14 (8–22)
23	*L. monocytogenes*–pork	129 (10–348)	469 (77–1,176)	80 (28–158)	73 (26–151)	13 (0–37)
23	*L. monocytogenes*–poultry	129 (10–348)	469 (77–1,176)	80 (28–158)	73 (26–151)	13 (0–37)
23	*L. monocytogenes*–produce	129 (10–348)	469 (77–1,176)	80 (28–158)	73 (26–151)	13 (0–37)
23	*L. monocytogenes*–seafood	129 (10–348)	469 (77–1,176)	80 (28–158)	73 (26–151)	13 (0–37)
27	*Campylobacter*-produce	91 (44–217)	693 (418–1,360)	44,178 (17,620–84,228)	442 (225–796)	4 (0–17)
27	Norovirus-bakery	158 (90–249)	398 (229–620)	432,084 (255,298–657,372)	1,160 (641–1,845)	12 (7–19)
29	Norovirus-poultry	155 (88–243)	389 (224–606)	422,374 (249,561–642,600)	1,134 (626–1,804)	12 (6–18)
30	*S. enterica*–deli meats	96 (5–249)	486 (9–1,286)	29,784 (18,689–48,686)	560 (248–1,087)	11 (0–29)
31	*Campylobacter*-pork	77 (37–183)	584 (352–1,146)	37,215 (14,843–70,952)	373 (189–671)	3 (0–15)
32	*Campylobacter*-beef	76 (37–182)	580 (350–1,138)	36,952 (14,738–70,451)	370 (188–666)	3 (0–15)
32	*T. gondii*–poultry	111 (66–166)	410 (225–627)	3,242 (2,426–4,185)	166 (99–250)	12 (7–18)
34	*S. enterica*–bakery	85 (4–221)	432 (8–1,143)	26,475 (16,613–43,276)	498 (220–966)	10 (0–26)
35	*C. perfringens*–beef	101 (6–512)	285 (27–1,285)	314,870 (62,689–809,476)	143 (14–655)	8 (0–53)
36	*Vibrio* other–seafood	103 (28–298)	210 (60–595)	52,228 (29,108–84,502)	183 (101–293)	12 (3–36)
37	*C. perfringens*–poultry	85 (5–430)	240 (23–1,078)	264,171 (52,595–679,137)	120 (12–549)	7 (0–45)
38	Norovirus-beef	84 (48–131)	210 (121–327)	228,179 (134,820–347,152)	613 (338–974)	6 (4–10)
38	*Shigella*–complex foods	59 (4–312)	266 (7–1,645)	64,026 (11,957–182,824)	710 (140–1,802)	5 (0–33)
38	*T. gondii*–dairy	71 (42–106)	261 (143–399)	2,062 (1,543–2,662)	105 (63–159)	8 (5–11)
41	*Campylobacter*-eggs	45 (22–107)	341 (206–670)	21,749 (8,675–41,467)	218 (111–392)	2 (0–9)
41	*E. coli* O157:H7–produce	46 (5–200)	302 (24–1,431)	11,482 (3,198–27,206)	389 (100–839)	4 (0–21)

National Beef Ex. 1007
Page 1846

TABLE 6. *Continued*

Rank	Pathogen-food combination	Cost of illness ($million)	QALY loss	No. of illnesses	No. of hospitalizations	No. of deaths
43	*C. perfringens*–complex foods	74 (5–378)	210 (20–947)	232,150 (46,220–596,817)	105 (11–483)	6 (0–39)
44	*T. gondii*–deli meats	51 (30–76)	188 (104–288)	1,490 (1,115–1,923)	76 (45–115)	6 (3–8)
45	*E. coli* O157:H7–complex foods	34 (3–146)	221 (17–1,046)	8,391 (2,337–19,881)	284 (73–613)	3 (0–15)
45	Norovirus-pork	57 (32–90)	143 (82–223)	155,356 (91,792–236,359)	417 (230–663)	4 (2–7)
47	*S. enterica*–beverages	37 (2–97)	189 (3–500)	11,583 (7,268–18,933)	218 (96–423)	4 (0–11)
48	*C. parvum*–produce	28 (2–114)	203 (24–753)	34,286 (7,177–99,242)	125 (35–308)	2 (0–11)
48	Norovirus-dairy	43 (24–67)	107 (62–167)	116,517 (68,844–177,269)	313 (173–498)	3 (2–5)
48	Norovirus–deli meats	43 (24–67)	107 (62–167)	116,517 (68,844–177,269)	313 (173–498)	3 (2–5)
Top 10 subtotal		8,032 (2,498–17,704)	36,524 (12,144–78,934)	3,858,789 (2,197,641–6,172,870)	29,878 (14,698–53,657)	759 (167–1,829)
% of total		57%	60%	43%	56%	57%
Top 20 subtotal		10,359 (3,092–23,447)	46,200 (14,252–104,522)	5,106,973 (2,913,058–8,141,697)	38,570 (18,708–69,571)	998 (213–2,464)
% of total		74%	76%	57%	72%	76%
Top 50 subtotal		13,008 (3,905–30,576)	56,907 (17,695–133,741)	8,309,592 (4,406,310–14,109,640)	50,419 (24,007–92,205)	1,225 (262–3,171)
% of total		93%	93%	93%	94%	93%
Total (all combinations)		14,012 (4,352–33,034)	61,166 (19,397–144,974)	8,914,713 (4,591,947–15,472,172)	53,678 (25,189–99,252)	1,322 (306–3,423)

[a] Values are mean (ranges) and reflect baseline assumptions for attributing the disease burden from 14 major foodborne pathogens to 12 food categories for a total of 104 pathogen-food combinations with nonzero estimated disease burden. Combined QALY and cost of illness rank is the average of the QALY loss ranking and cost of illness ranking. Upper and lower bounds reflect estimates based on 90% credible intervals for incidence estimated by Scallan et al. *(48)*. Number of annual illnesses, hospitalizations, and deaths include only those reported by Scallan et al. that were due to acute infection and do not include all cases of congenital illness or chronic sequelae. Illnesses caused by pathogens in game animals were not included. *Vibrio* other refers to noncholera *Vibrio* spp. other than *V. vulnificus*.

National Beef Ex. 1007
Page 1847

TABLE 7. *Rank correlations for pathogen-food combinations, by disease burden and incidence measure*[a]

Comparison		Avg rank	Cost of illness rank	QALY rank	Death rank	Hospitalization rank	Illness rank
Pathogen-food pairs							
All	Avg rank	1.00					
	Cost of illness rank	1.00	1.00				
	QALY rank	1.00	0.99	1.00			
	Death rank	0.98	0.99	0.98	1.00		
	Hospitalization rank	0.96	0.96	0.96	0.93	1.00	
	Illness rank	0.81	0.81	0.80	0.75	0.89	1.00
Top 50	Avg rank	1.00					
	Cost of illness rank	0.97	1.00				
	QALY rank	0.97	0.89	1.00			
	Death rank	0.91	0.96	0.94	1.00		
	Hospitalization rank	0.87	0.86	0.87	0.80	1.00	
	Illness rank	0.01	0.03	−0.01	−0.09	0.67	1.00
Top 10	Avg rank	1.00					
	Cost of illness rank	0.89	1.00				
	QALY rank	0.89	0.59	1.00			
	Death rank	0.44	0.37	0.42	1.00		
	Hospitalization rank	0.09	0.00	0.16	−0.47	1.00	
	Illness rank	−0.04	−0.10	0.03	−0.58	0.98	1.00
			Cost of illness	QALY loss	Deaths	Hospitalizations	Illnesses
Burden measure for all pathogen-food pairs	Cost of illness		1.00				
	QALY loss		0.93	1.00			
	Deaths		0.95	0.82	1.00		
	Hospitalizations		0.36	0.80	0.69	1.00	
	Illnesses		0.48	0.36	0.36	0.75	1.00

[a] Values reflect baseline assumptions for attributing the disease burden from 14 major foodborne pathogens to 12 food categories for a total of 104 pathogen-food combinations with nonzero estimated disease burden. Combined QALY and cost of illness rank is the average of the QALY loss ranking and cost of illness ranking. Number of annual illnesses, hospitalizations, and deaths include only those reported by Scallan et al. *(48)* that were due to acute infection and do not include all cases of congenital illness or chronic sequelae. Illnesses caused by pathogens in game animals were not included.

distinct measures of disease burden and did not monetize QALY loss. Because the Academy's recommendation was based in part on incomparability of the cardinal properties of these two metrics, we compute a unified ranking across these metrics based on ordinal rather than cardinal properties. The combined rank of each pathogen-food combination is the rank order of the average of that pair's cost of illness and QALY loss rankings.

Table 6 presents estimates of public health burden for the top 50 pathogen-food combinations based on baseline attribution assumptions and combined rank. These pathogen-food combinations account for 93% of cost of illness and QALY loss from the 14 pathogens included in this study.

Several conclusions can be drawn from these results. First, variability is high in both cost of illness and QALY loss across pathogen-food combinations; within the top 50 combinations, cost of illness ranges from $1.3 billion ($0.6 to $3.0 billion) for *Campylobacter* in poultry to $28 million ($2 to $114 million) for *Cryptosporidium* in produce. Second, the public health burden of foodborne illness is concentrated in the highest ranking pathogen-food combinations. The top 10 combinations caused nearly 60% of the total cost of illness and QALY loss due to these 14 pathogens in all foods, and the next 10 combinations were responsible for another 15%. Third, a few pathogens dominated the rankings; all top 10 combinations and 39 of the top 50 pairs involved just five pathogens. Fourth, the set of top 10 combinations were the same regardless of whether they were ranked by QALY loss or cost of illness, although ranks of individual combinations differed slightly.

Although *Campylobacter* ranked fifth in cost of illness and second in QALY loss (Table 1), more than 70% of illnesses caused by this pathogen were attributed to poultry (Table 4), making *Campylobacter*-poultry the highest ranked combination. By comparison, although *Salmonella* dominated pathogen rankings (Table 1), this burden was spread across several food categories (Table 3). *Salmonella* appears eight times among the top 20 ranked pathogen-food combinations, most notably associated with poultry, produce, eggs, and complex foods. *Toxoplasma* ranked highly in our estimates because it is the second leading cause of death from foodborne illness according to the CDC *(48)*. However, attribution of these illnesses to foods is uncertain because no outbreaks have been reported and considerable disagreement was found among experts.

National Beef Ex. 1007
Page 1848

TABLE 8. *Estimated annual disease burden for food categories, by combined QALY and cost of illness ranking*[a]

Rank	Food	QALY loss	Cost of illness ($million)	No. of illnesses	No. of hospitalizations	No. of deaths
1	Poultry	14,657 (6,369–32,025)	2,449 (810–6,067)	1,535,859 (685,972–2,898,212)	11,815 (5,679–22,040)	179 (14–578)
2	Complex foods	7,538 (1,650–19,047)	2,085 (591–4,922)	2,992,405 (1,650,512–4,922,715)	11,623 (5,583–21,056)	190 (38–494)
2	Pork	7,891 (3,019–18,582)	1,907 (817–4,150)	447,109 (213,747–796,957)	4,376 (2,095–7,712)	202 (84–460)
4	Produce	6,336 (1,479–15,770)	1,435 (393–3,378)	1,203,397 (662,055–2,008,054)	7,281 (3,374–13,557)	138 (27–353)
5	Beef	5,890 (1,997–14,931)	1,356 (526–3,226)	776,841 (291,370–1,637,898)	5,020 (2,092–9,979)	133 (50–337)
6	Dairy products	5,493 (1,319–13,827)	1,266 (205–3,351)	292,729 (142,517–520,589)	2,893 (1,250–5,589)	120 (7–350)
7	Deli and other meats	4,318 (788–10,914)	1,135 (140–3,003)	193,550 (99,616–340,533)	1,703 (721–3,313)	112 (5–317)
8	Seafood	2,906 (815–6,855)	941 (323–2,060)	644,021 (368,352–1,025,185)	2,977 (1,454–5,288)	100 (31–227)
9	Game	2,551 (1,392–4,186)	651 (377–1,033)	46,968 (24,546–81,356)	1,106 (632–1,739)	69 (41–110)
10	Eggs	2,347 (260–5,944)	447 (48–1,137)	176,766 (104,606–291,254)	2,583 (1,166–4,946)	47 (1–129)
11	Breads and bakery	843 (238–1,822)	246 (94–479)	459,188 (272,073–702,238)	1,674 (865–2,845)	22 (7–46)
12	Beverages	397 (73–1,071)	95 (27–229)	145,880 (76,581–247,180)	625 (280–1,187)	9 (2–22)
Total		61,166 (19,397–144,974)	14,012 (4,352–33,034)	8,914,713 (4,591,947–15,472,172)	53,678 (25,189–99,252)	1,322 (306–3,423)

[a] Values are mean (ranges) and reflect baseline assumptions for attributing the disease burden from 14 major foodborne pathogens to 12 food categories for a total of 104 pathogen-food combinations with nonzero estimated disease burden. Combined QALY and cost of illness rank is the average of the QALY loss ranking and cost of illness ranking. Upper and lower bounds reflect estimates based on 90% credible intervals for incidence estimated by Scallan et al. *(48)*. Number of annual illnesses, hospitalizations, and deaths include only those reported by Scallan et al. that were due to acute infection and do not include all cases of congenital illness or chronic sequelae that were included in cost and QALY estimates.

Although *Listeria* in deli meats ranks third, the number of outbreaks due to this combination has declined since the mid-2000s. Recent studies suggest that the highest risks in this category are due to retail-sliced products *(11, 15)*. *Listeria* in dairy ranks high because of a large number of recorded outbreaks due to soft unaged cheeses such as Mexican-style *queso fresco*.

Correlation analysis provides perspective on the stability of rankings and the relative contribution of different measures of disease burden (Table 7). In the bottom set of correlations, cost of illness estimates and QALY loss estimates were highly correlated (0.93) across all pathogen-food combinations. Cost of illness and QALY loss were both highly correlated with number of annual deaths (0.95 and 0.82), although only QALY loss was highly correlated with hospitalizations (0.80). In the top set of results, correlations among pathogen-food rankings were lower for smaller subsets of all pathogen-food combinations, as expected. Average rank was highly correlated with both cost of illness rank and QALY rank (1.00 for all pairs, 0.89 for the top 10), which suggests general similarities between the two integrated measures. However, for the top 10 pairs the correlation between cost of illness rank and QALY rank dropped to 0.59. This finding suggests that from a ranking perspective the difference between QALY and cost of illness estimates matters most when assessing the relative importance of the highest ranking pathogen-food combinations.

Food rankings. Table 8 presents rankings of foods, with public health impacts summed across pathogens, using baseline attribution assumptions. Poultry was ranked in first place because of the significant disease burden caused by both *Salmonella* and *Campylobacter*. Although complex foods were associated with twice as many illnesses as was poultry, 83% of these illnesses were caused by norovirus and were relatively mild. Pork ranked third, although this ranking was largely driven by highly uncertain attribution for *Toxoplasma*. Produce ranked quite highly in part because it is a major vehicle for norovirus and *Salmonella* infection outbreaks but also because it is associated with so many pathogens; the attributable percentage for produce, averaged across all pathogens, was higher than that for any other single food category. Because outbreak-based attribution identifies foods at exposure, some portion of these produce-associated illnesses likely were caused by cross-contamination during preparation with pathogens that entered the kitchen in meat, poultry, eggs, or other animal products. Overall, food categories associated with numerous pathogens (e.g., poultry, pork, and produce) ranked much higher than those associated with few pathogens (e.g., eggs and seafood). Eggs are noteworthy because although *Salmonella* in eggs ranks within the top 10 pathogen-food combinations, eggs are one of the lowest ranking food categories overall.

The second-place ranking of complex foods is important from a food safety management perspective. The nature of outbreaks associated with complex foods suggests an important role for contamination, cross-contamination, and other mistakes during handling, preparation, and cooking. In our analysis of outbreaks associated

National Beef Ex. 1007
Page 1849

TABLE 9. *Top 20 pathogen-food combinations under alternative attribution scenarios*[a]

Scenario[b]	**Baseline**	**1**	**2**	**3**	**4**	**5**	**6**
Attribution method	Out+Exp	Out+Exp	*Outbreak*	*Outbreak*	*Expert*	Out+Exp	Out+Exp
Outbreak approach	Events	*Cases*	Events	*Cases*	N/A	Events	Events
complex foods	Include	Include	Include	Include	Include	Include	*Drop*
Multi-source	Drop	Drop	Drop	Drop	Drop	*Include*	Drop
Pathogen-food combination							
Campylobacter-poultry	1	1	9	27	1	1	1
T. gondii–pork	2	2	----	----	4	2	2
L. monocytogenes–deli meats	3	4	3	3	2	4	3
S. enterica–poultry	4	9	4	8	3	6	4
L. monocytogenes–dairy	5	6	6	7	8	8	5
Norovirus-complex	6	5	5	5	----	4	----
S. enterica–complex	7	7	6	5	—	7	—
S. enterica–produce	8	8	8	9	9	9	6
T. gondii–beef	9	10	----	----	6	8	7
S. enterica–eggs	10	11	9	10	5	10	8
L. monocytogenes–complex	11	5	11	6	—	10	—
S. enterica–beef	12	18	14	17	11	12	10
S. enterica–pork	13	17	15	15	14	14	11
Norovirus-produce	14	12	15	11	7	17	9
S. enterica–dairy	15	13	17	13	12	18	13
Y. enterocolitica–pork	16	15	12	11	17	13	18
T. gondii–produce	17	15	----	----	17	15	19
V. vulnificus–seafood	18	19	18	16	20	19	19
S. enterica–seafood	19	29	19	26	29	20	14
Campylobacter-dairy	19	16	7	2	19	16	21
E. coli O157:H7–beef	21	20	20	20	16	20	17
Norovirus-seafood	22	27	21	25	10	27	12
L. monocytogenes–produce	23	39	22	36	14	22	22
Norovirus-bakery	27	20	28	19	27	33	15
Norovirus-poultry	29	26	29	24	45	34	16
Campylobacter-beef	32	30	26	18	26	29	33
Campylobacter-seafood	56	56	35	14	49	54	54
T. gondii–unknown	—	—	1	1	—	—	—
Campylobacter-complex	----	----	13	32	----	----	----
C. perfringens–unknown	----	----	----	----	13	----	----
Rank correlations with baseline[c]							
All pathogen-food combinations		0.98	0.82	0.81	0.78	1.00	0.91
Top 90 pathogen-food combinations		0.94	0.77	0.70	0.64	0.99	0.75
Top 10 pathogen-food combinations		0.65	-0.03	-0.16	0.16	0.85	0.18

[a] Table includes only pathogen-food combinations that rank in the top 20 in at least one of the scenarios. Shading indicates whether pairs were ranked 1 to 10, 11 to 20, or 20 and higher. Dashes indicate that a particular pathogen-food combination was not included in that scenario; for example, we did not have outbreak-based attribution percentages for *T. gondii*, so all illnesses are attributed to the "unknown" category in scenarios 2 and 3, with dashes for pork, beef, and produce.

[b] Italicized assumptions indicate variation from assumptions used in the baseline scenario. "Out + Exp" refers to attribution based on both outbreak and expert attribution estimates.

[c] Spearman rank correlations between baseline and alternative scenario rankings quantify the impact of changes in assumptions on rankings.

with complex food between 1998 and 2008, more than 70% of salmonellosis outbreaks and 80% of outbreaks of norovirus infection were associated with foods prepared in professional kitchens.

Sensitivity analyses. We conducted sensitivity analyses to assess the impact of key modeling assumptions. Table 9 shows pathogen-food combinations ranked within the top 20 by one of six alternate attribution scenarios as compared with baseline rankings. Shading is used to identify pairs ranked 1 through 10 for each scenario, 11 through 20, and 20 and above. Spearman rank correlations between the baseline and alternative scenario rankings quantify the impact of changes in assumptions on rankings.

The first four scenarios (1 through 4) explored the impacts of basing outbreak attribution on the number of outbreaks and of combining outbreak and expert attribution. Basing outbreak attribution on outbreak cases rather than outbreak events (scenario 1) had little impact on whether pathogen-food combinations were ranked in the top 10 or top 20 compared with the baseline, although it did change rankings within the top 10 and the next grouping of 10. Not using expert attribution estimates (scenarios 2 and 3) had a greater effect on rankings relative to the baseline when outbreak attribution was based on numbers of cases (scenario 3) than when it was based on numbers of outbreaks (scenario 2), although both rankings differed markedly from baseline estimates. The rank correlations confirm that these patterns carry through for rankings over a larger set of or all pathogen-food combinations. These differences reflect the fact that *Toxoplasma* was not represented at all in outbreak data, that expert judgment differed markedly from outbreak analysis for *Campylobacter*, and that outbreak sizes differ by food. Using expert attribution exclusively (scenario 4) resulted in some noticeable changes to rankings, primarily because the expert elicitation did not include a complex foods category. Thus, as those combinations dropped out of the analysis, others moved up. *Listeria* in deli meats rose to rank 2 from rank 4, and dairy dropped to rank 8 from rank 5, reflecting differences between experts and outbreak estimates, aside from the complex foods category.

The remaining two scenarios (5 and 6) further explored the role of the complex and multisource foods category. Including multisource outbreaks and categorizing them as complex foods (scenario 5) resulted in marginally higher attribution percentages for complex foods. Rank correlations indicated that this change had little overall impact on rankings. In contrast, dropping complex foods (scenario 6) resulted not only in removal of this category but in redistribution of outbreak attribution across remaining categories. Thus, changes from baseline were much more significant. The similarities in results for scenarios 4 and 6 reinforced that most of the differences from the baseline that resulted from relying solely on expert attribution were due to the lack of a complex foods category.

Together these sensitivity analyses suggest that our risk ranking model was most sensitive to two assumptions: the use of expert-based attribution for four pathogens and the decision to use a complex foods category in the outbreak attribution. Basing outbreak attribution on number of events rather than number of cases had a lesser but still noticeable impact on rankings, whereas the impacts of excluding multisource outbreaks and complex foods in the expert elicitation were negligible.

Both methodological and substantive lessons can be drawn from this study. Methodologically, we found that properly structured expert elicitation can be used to characterize uncertainty about and supplement, not substitute for, attribution estimates based on empirical outbreak data. It is not necessarily more accurate to rely on a single methodology for estimating attribution percentages, but the methods must be consistent and compatible. Substantively, results from this study support risk-based prioritization by identifying which pathogens in which types of foods cause the greatest burden for public health. These estimates say nothing, however, about the relative effectiveness of public or private management efforts. This study also highlights the fact that further research is needed on the relationship between attribution foodborne illness and food sources, particularly for *Toxoplasma*, *Campylobacter*, and *Salmonella*.

ACKNOWLEDGMENTS

This research was supported by competitive grants from the Robert Wood Johnson Foundation, the Cooperative State Research, Education, and Extension Service of the U.S. Department of Agriculture (now the National Institute of Food and Agriculture), and the Milbank Memorial Fund. We thank our collaborators on the research efforts extended by this study, in particular Alan J. Krupnick, Paul S. Fischbeck, Heather Green, Michael McWilliams, and Michael R. Taylor.

REFERENCES

1. Adak, G. K., S. M. Meakins, H. Yip, B. A. Lopman, and S. J. O'Brien. 2005. Disease risks from foods, England and Wales, 1996–2000. *Emerg. Infect. Dis.* 11:365–372.
2. Batz, M. B., M. P. Doyle, J. G. Morris, Jr., J. Painter, R. Singh, R. V. Tauxe, M. R. Taylor, D. M. Lo Fo Wong, and the Food Attribution Working Group. 2005. Attributing illness to food. *Emerg. Infect. Dis.* 11:993–999.
3. Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2011. Ranking the risks: the 10 pathogen-food combinations with the greatest burden on public health. University of Florida, Gainesville.
4. Centers for Disease Control and Prevention. 2011. Foodborne outbreak online database (FOOD). Available at: http://wwwn.cdc.gov/foodborneoutbreaks/. Accessed 2 September 2011.
5. Clemen, R. T., and R. L. Winkler. 1999. Combining probability distributions in risk analysis. *Risk Anal.* 19:187–203.
6. Codex Alimentarius Commission. 2007. Working principles for risk analysis for food safety for application by governments. GL-62/2007. Codex Alimentarius, Rome.
7. Cooke, R. M. 1991. Experts in uncertainty: opinion and subjective probability in science. Oxford University Press, New York.
8. Cooke, R. M., M. Nauta, A. H. Havelaar, and H. J. van der Fels. 2006. Probabilistic inversion for chicken processing lines. *Reliabil. Eng. Syst. Saf.* 91:1364–1372.
9. Davidson, V. J., A. Ravel, T. N. Nguyen, A. Fazil, and J. M. Ruzante. 2011. Food-specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey. *Foodborne Pathog. Dis.* 8:983–995.
10. Dewaal, C. S., G. Hicks, K. Barlow, L. Alderton, and L. Vegosen. 2006. Foods associated with foodborne illness outbreaks from 1990 through 2003. *Food Prot. Trends* 26:466–473.
11. Endrikat, S., D. Gallagher, R. Pouillot, H. Hicks Quesenberry, D. LaBarre, C. M. Schroeder, and J. Kause. 2010. A comparative risk

National Beef Ex. 1007
Page 1851

assessment for *Listeria monocytogenes* in prepackaged versus retail-sliced deli meat. *J. Food Prot.* 73:612–619.
12. Evers, E. G., H. J. Van Der Fels-Klerx, M. J. Nauta, J. F. Schijven, and A. H. Havelaar. 2007. *Campylobacter* source attribution by exposure assessment. *Int. J. Risk Assess. Manag.* 8:174–190.
13. FDA Food Safety Modernization Act. 2011. 21 USC §2201. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf. Accessed 2 September 2011.
14. Friedman, C. R., R. M. Hoekstra, M. Samuel, R. Marcus, J. Bender, B. Shiferaw, S. Reddy, S. D. Ahuja, D. L. Helfrick, F. Hardnett, M. Carter, B. Anderson, R. V. Tauxe, and the Emerging Infections Program FoodNet Working Group. 2004. Risk factors for sporadic *Campylobacter* infection in the United States: a case-control study in FoodNet sites. *Clin. Infect. Dis.* 38(Suppl. 3):S285–S296.
15. Gombas, D. E., Y. Chen, R. S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Prot.* 66:559–569.
16. Greig, J. D., and A. Ravel. 2009. Analysis of foodborne outbreak data reported internationally for source attribution. *Int. J. Food Microbiol.* 130:77–87.
17. Guo, C., R. M. Hoekstra, C. M. Schroeder, S. M. Pires, K. L. Ong, E. Hartnett, A. Naugle, J. Harman, P. Bennett, P. Cieslak, E. Scallan, B. Rose, K. G. Holt, B. Kissler, E. Mbandi, R. Roodsari, F. J. Angulo, and D. Cole. 2011. Application of Bayesian techniques to model the burden of human salmonellosis attributable to U.S. food commodities at the point of processing: adaptation of a Danish model. *Foodborne Pathog. Dis.* 8:509–516.
18. Havelaar, A. H., A. V. Galindo, D. Kurowicka, and R. M. Cooke. 2008. Attribution of foodborne pathogens using structured expert elicitation. *Foodborne Pathog. Dis.* 5:649–659.
19. Hennessy, T. W., L. H. Cheng, H. Kassenborg, S. D. Ahuja, J. Mohle-Boetani, R. Marcus, B. Shiferaw, F. J. Angulo, and the Emerging Infections Program FoodNet Working Group. 2004. Egg consumption is the principal risk factor for sporadic *Salmonella* serotype Heidelberg infections: a case-control study in FoodNet sites. *Clin. Infect. Dis.* 38(Suppl. 3):S237–S243.
20. Hoffmann, S., M. B. Batz, and J. G. Morris, Jr. 2012. Annual cost of illness and quality-adjusted life year losses in the United States due to 14 foodborne pathogens. *J. Food Prot.* 75:1292–1302.
21. Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Elicitation from large, heterogeneous expert panels: using multiple uncertainty measures to characterize information quality for decision analysis. *Dec. Anal.* 4:91–109.
22. Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Using expert elicitation to link foodborne illnesses in the United States to foods. *J. Food Prot.* 70(5):1220–1229.
23. Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2008. Informing risk-mitigation priorities using uncertainty measures derived from heterogeneous expert panels: a demonstration using foodborne pathogens. *Reliabil. Eng. Syst. Saf.* 93:687–698.
24. Jones, J. L., V. Dargelas, J. Roberts, C. Press, J. S. Remington, and J. G. Montoya. 2009. Risk factors for *Toxoplasma gondii* infection in the United States. *Clin. Infect. Dis.* 49:878–884.
25. Kassenborg, H. D., C. W. Hedberg, M. Hoekstra, M. C. Evans, A. E. Chin, R. Marcus, D. J. Vugia, K. Smith, S. D. Ahuja, L. Slutsker, P. M. Griffin, and the Emerging Infections Program FoodNet Working Group. 2004. Farm visits and undercooked hamburgers as major risk factors for sporadic *Escherichia coli* O157:H7 infection: data from a case-control study in 5 FoodNet sites. *Clin. Infect. Dis.* 38(Suppl. 3):S271–S278
26. Kimura, A. C., V. Reddy, R. Marcus, P. R. Cieslak, J. C. Mohle-Boetani, H. D. Kassenborg, S. D. Segler, F. P. Hardnett, T. Barrett, D. L. Swerdlow, and the Emerging Infections Program FoodNet Working Group. 2004. Chicken consumption is a newly identified risk factor for sporadic *Salmonella enterica* serotype Enteritidis infections in the United States: a case-control study in FoodNet sites. *Clin. Infect. Dis.* 38(Suppl. 3):S244–S252.
27. Lake, R. J., P. J. Cressey, D. M. Campbell, and E. Oakley. 2010. Risk ranking for foodborne microbial hazards in New Zealand: burden of disease estimates. *Risk Anal.* 30:743–752.
28. Little, C. L., S. M. Pires, I. A. Gillespie, K. Grant, and G. L. Nichols. 2010. Attribution of human *Listeria monocytogenes* infections in England and Wales to ready-to-eat food sources placed on the market: adaptation of the Hald *Salmonella* source attribution model. *Foodborne Pathog. Dis.* 7:749–756.
29. Mangen, M. J. M. B. Batz, A. Kasbohrer, T. Hald, J. G. Morris, Jr., M. Taylor, and A. H. Havelaar. 2009. Integrated approaches for the public health prioritization of foodborne and zoonotic pathogens. *Risk Anal.* 30:782–797.
30. Morgan, M. G., H. K. Florig, M. L. DeKay, and P. Fischbeck. 2000. Categorizing risks for risk ranking. *Risk Anal.* 20:49–58.
31. Morgan, M. G., and M. Henrion. 1990. Uncertainty: a guide to dealing with uncertainty in quantitative risk and policy analysis. Cambridge University Press, Cambridge.
32. Mullner, P., G. Jones, A. Noble, S. E. F. Spencer, S. Hathaway, and N. P. French. 2009. Source attribution of food-borne zoonoses in New Zealand: a modified Hald model. *Risk Anal.* 29:970–984.
33. Murray, C. J. L., and A. D. Lopez (ed.). 1996. The global burden of disease: a comprehensive assessment of mortality and disability from diseases. Harvard University Press, Cambridge, MA.
34. National Academy of Sciences. 1998. Ensuring safe food: from production to consumption. Institute of Medicine and National Research Council. National Academies Press, Washington, DC.
35. National Academy of Sciences. 2003. Scientific criteria to ensure safe food. Institute of Medicine and National Research Council. National Academies Press, Washington, DC.
36. National Academy of Sciences. 2006. Valuing health for cost-effectiveness analysis. Institute of Medicine. National Academies Press, Washington, DC.
37. National Academy of Sciences. 2010. Enhancing food safety: the role of the Food and Drug Administration. Institute of Medicine and National Research Council. National Academies Press, Washington, DC.
38. National Research Council. 2002. Estimating the public health benefits of proposed air pollution regulations. National Academies Press, Washington, DC.
39. Painter, J. A., T. Ayers, R. Woodruff, E. Blanton, N. Perez, R. M. Hoekstra, P. M. Griffin, and C. Braden. 2009. Recipes for foodborne outbreaks: a scheme for categorizing and grouping implicated foods. *Foodborne Pathog. Dis.* 6:1259–1264.
40. Pires, S. M., E. G. Evers, W. van Pelt, T. Ayers, E. Scallan, F. J. Angulo, A. Havelaar, T. Hald, and the Med-Vet-Net Workpackage 28 Working Group. 2009. Attributing the human disease burden of foodborne infections to specific sources. *Foodborne Pathog. Dis.* 6:417–424.
41. Pires, S. M., and T. Hald. 2010. Assessing the differences in public health impact of *Salmonella* subtypes using a Bayesian microbial subtyping approach for source attribution. *Foodborne Pathog. Dis.* 7:143–151.
42. Pires, S. M., A. R. Vieira, E. Perez, D. Lo Fo Wong, and T. Hald. 2012. Attributing human foodborne illness to food sources and water in Latin America and the Caribbean using data from outbreak investigations. *Int. J. Food Microbiol.* 152:129–138.
43. Ranta, J., D. Matjushin, T. Virtanen, M. Kuusi, H. Viljugrein, M. Hofshagen, and M. Hakkinen. 2011. Bayesian temporal source attribution of foodborne zoonoses: *Campylobacter* in Finland and Norway. *Risk Anal.* 31:1156–1171.
44. Ravel, A., V. J. Davidson, J. M. Ruzante, and A. Fazil. 2010. Foodborne proportion of gastrointestinal illness: estimates from a Canadian expert elicitation survey. *Foodborne Pathog. Dis.* 7:1463–1472.
45. Ravel, A., J. Greig, C. Tinga, E. Todd, G. Campbell, M. Cassidy, B. Marshall, and F. Pollari. 2009. Exploring historical Canadian foodborne outbreak data sets for human illness attribution. *J. Food Prot.* 72:1963–1976.
46. Rothman, K. J., and S. Greenland. 2005. Causation and causal inference in epidemiology. *Am. J. Public Health* 95(Suppl. 1):S144–S150.
47. Scallan, E., P. M. Griffin, F. J. Angulo, R. V. Tauxe, and R. M. Hoekstra. 2011. Foodborne illness acquired in the United States—unspecified agents. *Emerg. Infect. Dis.* 17:16–22.
48. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis.* 17:7–15.

49. Shaw, J. W., J. A. Johnson, and S. J. Coons. 2005. U.S. valuation of the EQ-5D health states: development and testing of the D1 valuation model. *Med. Care* 43:203–230.
50. U.S. Food and Drug Administration. 2011. Food Safety Modernization Act. 21 USC § 2201. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf. Accessed 5 September 2011.
51. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; and U.S. Department of Agriculture, Food Safety and Inspection Service. 2003. Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm. Accessed 11 August 2011
52. U.S. General Accounting Office. 1992. Food safety and quality: uniform, risk-based inspection system needed to ensure safe food supply. Report RCED-92-152. U.S. General Accounting Office, Washington, DC.
53. U.S. General Accounting Office. 2001. Food safety and security—fundamental changes needed to ensure safe food. GAO-02-47T. U.S. General Accounting Office, Washington, DC.
54. U.S. Government Accountability Office. 2011. Federal food safety oversight: food safety working group is a positive first step but government-wide planning is needed to address fragmentation. GAO-11-289 March 18. Available at: http://www.gao.gov/products/GAO-11-289. Accessed 10 August 2011.
55. Van der Fels-Klerx, H. J., R. M. Cooke, M. N. Nauta, L. H. Goossens, and A.H. Havelaar. 2005. A structured expert judgment study for a model of *Campylobacter* transmission during broiler-chicken processing. *Risk Anal.* 25:109–124.
56. Varma, J. K., M. C. Samuel, R. Marcus, R. M. Hoekstra, C. Medus, S. Segler, B. J. Anderson, T. F. Jones, B. Shiferaw, N. Haubert, M. Megginson, P. V. McCarthy, L. Graves, T. van Gilder, and F. J. Angulo. 2007. *Listeria monocytogenes* infection from foods prepared in a commercial establishment: a case-control study of potential sources of sporadic illness in the United States. *Clin. Infect. Dis.* 44: 521–528.
57. Voetsch, A. C., M. H. Kennedy, W. E. Keene, K. E. Smith, T. Rabatsky-Ehr, S. Zansky, S. M. Thomas, J. Mohle-Boetani, P. H. Sparling, M. B. McGavern, and P. Mead. 2007. Risk factors for sporadic Shiga toxin–producing *Escherichia coli* O157 infections in FoodNet sites, 1999–2000. *Epidemiol. Infect.* 135:993–1000.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 04/18/2018

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
04/18/2018	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMÉRIEUX, INC.
Requester and Respondent

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH INC.
Patent Owner and Appellant

Appeal 2017-001150
Reexamination Control 95/001,294
Patent 7,534,584 B2
Technology Center 3900

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

This is a Decision on a Request for Rehearing under 37 C.F.R. § 41.77(b) ("Req. Reh'g") by the Requester of the final Decision entered Jan. 23, 2017 ("41.77f Dec.").[1] The 41.77f Decision reversed new grounds

---

[1] Requester submitted two new declaration in the Request for Rehearing. However, as recognized by Requester, new evidence is not permitted under

of rejection 1–4 based on Patent Owner's narrowing of the independent claims and reconsideration of the relied-upon evidence as a whole, including entered new evidence and evidence of secondary considerations.

Requester contends that the 41.77f Decision misapprehended or overlooked the evidence of secondary considerations and that the Board erred in reversing all rejections, particularly in reversing its conclusion in the original Decision on Appeal that the claims are unpatentable under 35 U.S.C. § 103(a). Req. Reh'g 1–3.

We have considered Requester's arguments, but decline to modify the 41.77f Decision.

Claim 1 is directed to a method of sampling, testing, and validating a plurality of operationally-linked test lots of beef for release into commerce. See 41.77f Dec. 2–4. Claim 17 is the same, but recited meat or poultry instead of being limited to only beef. *Id.* at 5. The samples are tested for microbial agents or microorganism.

In the original Decision on Appeal ("7983 Decision" or "7983 Dec."), we found that in presenting the evidence of secondary considerations, Patent Owner had not provided an adequate explanation of the classical industry method to which the claimed method had been compared. 7983 Dec. 24. For this and other reasons, the 7983 Decision concluded that a nexus had not

---

37 C.F.R. § 41.79(b)(1) unless the conditions of (b)(2) or (b)(3) are met. Requester attempts to establish under (b)(2) that a new Federal Circuit decision warrants consideration of the new evidence, but such new evidence relates to "secondary considerations" which have been at issue throughout the appeal and thus do not constitute "a showing of good cause" as required by 37 C.F.R § 41.79(b)(2). Accordingly, the new evidence has not been entered into the record or considered.

been established between the claims and the evidence of secondary considerations. As it turns out, Patent Owner's original Appeal Brief had contained two Exhibits, A and B (labeled Figs. 1 and 2, respectively) that illustrated the differences between the claimed method and the industry method, but we had overlooked these exhibits in reaching the decision in the Decision on Appeal. In the subsequent 4177f Decision, we recognized that Figs. 1 and 2 contained the information we had believed to be deficient in the record. 41.77f Dec. 4, 6. This evidence, while being part of the original record, provided additional clarity as to the differences between the prior art and the claimed subject matter, and led, along with other evidence in the record and the accompanying narrowing of the claims, to conclude that a "nexus" had been established between the claims and the secondary considerations. 41.77f Dec. 15, 16. Requester now objects:

> Both Figure 1 and Figure 2 were included in the Patent Owner's Appeal Brief, and were before the Board for the 7983 Decision. The Decision does not explain why or how the information contained in those Figures alters its previous conclusion that the Patent Owner had failed to establish a nexus between commercial success and the claimed invention.

Req. Reh'g 6.

The simple fact is that this information had been overlooked, and when Patent Owner drew attention to Figs. 1 and 2 (PO Response under 41.77b at 20), it prompted reconsideration of the evidence in the record, as we are required to do. *Cf. In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a

preponderance of evidence with due consideration to persuasiveness of argument.").

The claimed invention

Claim 1 is reproduced in the 41.77f Decision at 2–3. In steps a and b, the claim requires collecting portions from separate test lots and combining the portions to produce separate test lot samples for each test lot. The samples are incubated and enriched in step c "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." Portions are removed from the enriched samples and *combined* in step d to form a modular inter-lot sample and then are tested in step e. Fig. 2 illustrates the claimed method (step 1 corresponds to steps a and b of the claim; step 2 corresponds to claimed step c; step 3 to claimed step d; step 4 to claimed step e). Fig. 1 illustrates the "industry art," which we found to be representative of the cited prior art. As explained in the 41.77 Dec. with references to Figs. 1 and 2:

> The first 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. The second 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" (step d1 of the claimed method) and then tested for the presence of microorganisms. In other

> words, 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.

41.77f Dec. 7. Thus, the testing for microorganisms is performed at different times in the claimed invention and in the prior art industry method.

The Request for Rehearing contends that the original 7983 Decision was correct in finding that there was a strong evidence of obviousness:

> It is "commonsense," the Board pointed out, "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.* [7983 Decision] at 16.

Req. Reh'g 3.

While we made such a statement in the 7983 Decision, upon reconsideration, we determined in the 41.77f Decision that the obviousness rejections had been overcome in light of considering the evidence anew, including the newly presented evidence. In the 7983 Decision, it was stated that it would have been obvious to have composited samples *after enrichment* to reduce the number of test necessary to perform. 7983 Dec. 18. We found a reason to composite after enrichment because "Jarvis describes compositing both pre-enrichment samples and enrichment samples (141, method 3)." 7983 Dec. 18.

The statement from Jarvis we relied upon is as follows: "5 samp1es are composited at pre-enrichment stage and aliquots of the duplicate pre-enrichment media are composited at the stage of inoculating the enrichment medium." Jarvis 141. In other words, the duplicative pre-enrichment

samples that are subsequently enriched are obtained from different containers—as shown in step 1 of attached Figure 1. The claims, however, combine samples from the same container, perform enrichment on them, and then composite samples from different containers and test for bacteria. The original reasoning that we found the claimed step d to have been obvious was based on the obviousness of reducing sample number. However, Jarvis was combining pre-enrichment samples and provides no sufficient reason for deviating from its method to reduce sample number by compositing *after enrichment* has been performed. The difference between Jarvis and the claimed method is not insignificant because steps d and e of claim 1 involve diluting the enrichment samples and then testing for microbial contamination, while Jarvis tests *directly* on undiluted enriched samples. As discussed in the 41.77f Decision, there was skepticism that a sample after enrichment was as reliable as an undiluted one. 41.77f Dec. 5–6. Consequently, we do not agree that the reason for arriving at the claimed order of steps is as compelling and "strong" as Requester asserts and as we had previously (and erroneously) believed. Req. Reh'g 5. We do not agree that it would have been obvious to a person of ordinary skill in the art to reverse the order in which the steps are performed because reversing the order as claimed would have resulted in testing diluted samples for the presence of microorganisms, rather than an undiluted sample.

Requester contends that we have upended the 7983 Decision because it had been stated that even if direct enrichment was "inferior," an inferior step would still have been obvious. Req. Reh'g 9. However, Requester has misconstrued this statement in the 7983 Decision. The Decision was

referring to the obviousness of performing "direct enrichment" without a pre-enrichment step. 7983 Dec. 16–17. We have not changed our stance on this analysis. Nonetheless, it is not pertinent to the obviousness determination because pre-enrichment is not required by the claim and does not serve as the nexus to commercial success.

Secondary considerations

Commercial Success

To determine whether the claimed product has achieved commercial success, it must first be determined whether a product that embodies the claimed invention has been sold in the marketplace. In the 7983 Decision, the Board did not challenge Patent Owner's contention that the claimed process was embodied in the marketed process. However, the 7983 Decision found it had not been established that the success was a result of the order of the enrichment and testing steps and that the alleged success for beef would be representative of other food products. 7983 Dec. 23–24. In other words, we found a nexus had not been established between the evidence and the claimed subject matter. A nexus is established when the secondary consideration is attributed to a feature of the claimed invention. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12 (Fed. Cir. 2006).

Patent Owner responded by limiting claim 1 to beef and claim 17 to meat or poultry. Patent Owner also made clear to us that 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. 41.77f Dec. 6–7. This step was not performed in the prior art,

and the articulated reason for a person of ordinary skill in the art to do so was based strictly on reducing sample number, a step which was already carried out by the Jarvis, Price, and industry methods. But upon reconsideration, it is our opinion that such steps (particularly steps d and e of claim 1) were not readily available in the prior art and appropriately constituted a "nexus" between the sales data and the claims. For these reasons, we do not agree with Requester that the conclusion that a nexus has been established is not supported by the evidence in the record. Req. Reh'g 5.

Requester characterizes the 41.77f Decision as a "factual about-face from the 7983 Decision" (Req. Reh'g 7). We find this irrelevant. The 7983 Decision was not a final decision, but rather afforded the Patent Owner to address the concerns and Requester with the opportunity to respond. The fact that the rule states that "Board . . . shall reconsider the matter and issue a new decision" necessarily implies that the Board is authorized, *and required*, to modify its earlier rulings in any respect based on such reconsideration, if warranted.

Requester contends that "Patent Owner has not pointed to any authority suggesting that the limited success purportedly achieved by its product-at most, a 30% market share in the United States-should be given dispositive weight in the face of strong evidence of obviousness" and that the evidence of commercial success "supports only a 'chain of inferences' leading to a finding of nonobviousness," which is broken if "Patent Owner cannot establish that the supposedly novel features of the invention that

motivated those sales were not already available to the public." Req. Reh'g 5.

First, the sales of 30% in the US and 40% in Canada of the market cannot be ignored as evidence that the process was commercially successful. Indeed, in *Classco, Inc. v. Apple*, 838 F.3d 1214, 1219 (Fed. Cir. 2016), the Federal Circuit found error in the Board dismissing evidence of commercial success when the marketed product, as here, embodied all the features of the claimed invention. Requester appears to be arguing that the features were readily available in the prior art, but as already stated, there is inadequate evidence in this record that the recited enrichment and testing steps had been performed in the prior art, and we have not been pointed to a persuasive reason to have composited and tested samples for microorganisms after the enriching step had been performed. For completeness, we address this once again.

> In their comments dated March 20, 2015, Requester stated:
>
> > Patent Owner did not address the DOA's finding that Price also teaches testing pooled enrichment samples. (DOA at 18). Figure 1 of Price clearly teaches compositing samples at the enrichment stage, and subsequently testing them. (Price at Fig. 1). Accordingly, the Price reference further buttresses the conclusion that step (d)(1) was obvious.
>
> Requester's 41.77c Comments 16.

We do not agree. Figure 1 of Price is reproduced below:

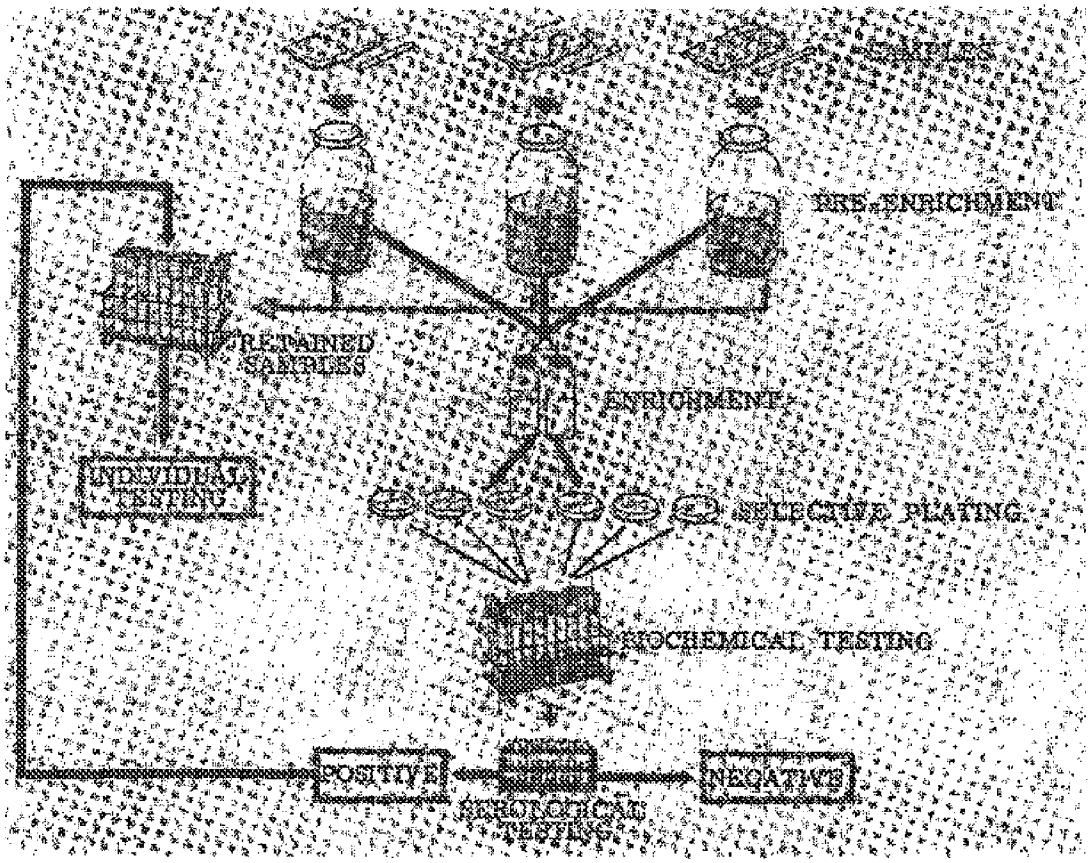


Fig. 1. Salmonella testing of pooled pre-enrichment broths.

Fig. 1 of Price shows the pre-enrichment samples as being composited, but not the enrichment samples. The enrichment samples are tested directly by plating on selective media and then testing. Requester's statement that Price describes compositing enrichment samples in Figure 1 is not supported by the figure drawing.

The Examiner stated that "two-tiered compositing were well understood and practiced by the artisan at the time of the invention, particularly for the noted advantages of reducing workload, increasing testing capacity and preserving portions from different sample lots for repeat testing." Examiner's 41.77d Determination 12. However, the so-called two tier testing of Price refers to pooling samples in the pre-enrichment and

enrichment steps, not enriching samples separately from the same container and then pooling for the purpose of testing as required by the claims.

Despite Requester's objections to the data, we have not been pointed to an error in determining that the 30% market share is strong evidence of commercial success.[2] While Requester characterized the data as "weak," the only apparent identified weakness was an alleged lack of nexus. However, because Patent Owner's process embodies all the claimed features, and recited steps d and e were not readily available to one of ordinary skill in the art, we do not find this argument to be persuasive.

With regard to Requester's complaint that there was no explained reason that the data from beef is extrapolatable to poultry and other meats as recited in claim 17, the 41.77f Decision relied upon testimony by Dr. Samadpour and we had not been "directed to a persuasive deficit in this reasoning." 41.77f Dec. 16.

Skepticism

In the 41.77f Decision, we found the evidence of skepticism compelling because it was tied to features of the commercial process embodying the claimed invention. 41.77f Dec. beginning on page 11. Requester contends that the reliance on skepticism was an error:

> Skepticism evidence cannot overcome a prima facie case of obviousness unless it establishes that the claimed invention

[2] "Denso argues that this [sales] evidence is insufficient because Tec Air failed to provide market share data. Although sales figures coupled with market data provide stronger evidence of commercial success, sales figures alone are also evidence of commercial success." *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1361-62 (Fed. Cir. 1999).

> "was not viewed as technically feasible" by persons of ordinary skill. *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.,* 119 F.3d 953, 955, 958 (Fed. Cir. 1997) (crediting experts' fear of "violent explosions" when mixing the chemicals required to make the claimed invention). The Patent Owner's new evidence of skepticism – again consisting entirely of Dr. Samadpour's uncorroborated statements – did not and could not possibly satisfy that standard. To the contrary, as the 7983 Decision recognized, far from considering the method steps technically infeasible, everyone knew how to perform them.

Req Reh'g 10-11.

To being with, *Arkie Lures* did not equate skepticism with the requirement for technical feasibility. As held in *Arkie Lures*:

> It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements. Indeed, the years of use of salty bait and of plastic lures without combining their properties, weighs on the side of unobviousness of the combination. Mr. Larew persisted against the accepted wisdom, and succeeded. The evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of unobviousness.

Arkie Lures, 119 F.3d at 957–58.

In *Arkie Lures*, there was evidence of skepticism that a salty bait could be combined with a plastic lure. *Id.* at 957. The court did not make it a rule that skepticism required technical feasibility to be considered evidence of nonobviousness. As discussed in MPEP § 716.05 "'Expressions of disbelief by experts constitute strong evidence of nonobviousness.'" Here, the skepticism evidence indicated that persons skilled in the art would have expected diluting samples after culture would lead to false negatives but testing of the invention proved the contrary. 41.77f Decision 12–13.

Requester attempted to disparage the evidence of skepticism by only citing to Dr. Samadpour's declarations. However, the 41.77f Decision cited corroborating declarations by Warren Mirtsching and James Byron as evidence of skepticism by experts, in addition to Dr. Samadpour's testimony. 41.77f Dec. 11. Although the 7983 Decision may have stated that the method was adopted over skepticism in the industry (Req. Reh'g 12), Mr. Warren Mirtsching explained that he had to carry out detailed testing to be convinced that the method had the requisite sensitivity to be used for meat testing. 41.77f Dec. 12.

Bailey Declaration

Requester states that the Board erred in the 41.77f Decision because it "overlooked contrary testimony from Requester's declarant, Dr. Bailey" and "does not even cite it." Req. Reh'g 7. Requester contends that Dr. Bailey's testimony "thoroughly undermines the Patent Owner's evidence" and the Decisions does not "explain why . . . the self-serving declarations of the patent inventor and his employees on commercial success should be considered more credible." *Id.*

We considered the Bailey declaration (dated Jan. 13, 2010; "Bailey Decl."), but as discussed below in detail, simply did not find that it had probative value to the obviousness issue, let alone effective to "undermine" the evidence of commercial success as alleged by Requester. Indeed, there is no discussion of commercial success in Dr. Bailey's declaration.

Paragraph 9 of Dr. Bailey's declaration is a discussion of the Jarvis publication. Dr. Bailey describes Jarvis's pre-enrichment steps and

enrichment steps. Bailey Decl. ¶¶ 9d, 9e. Dr. Bailey also describes compositing pre-enrichment broth, after culture, into enrichment media. *Id.* at ¶ 9f. However, the claims require pooling of enrichment broth, a step which was interpreted in the 7983 Decision to be different from pre-enrichment. 7983 Dec. 6–8.

Dr. Bailey also discussed Price. Bailey Decl. ¶ 10. In paragraph 10b of his declaration, Dr. Bailey explained why one of ordinary skill would have had reason to composite samples from the same lot to ensure that a representative sample is obtained. Dr. Bailey testified that such samples are subjected to pre-enrichment and then pooled to form a single enrichment broth. *Id.* However, these steps differ from claim 1 because claim 1 does not pool the samples into a single enrichment broth. Rather, pooling is accomplished after enrichment. Dr. Bailey did not explain in this paragraph why compositing the enrichment broth for testing purposes would have been obvious to one of ordinary skill in the art.

Paragraphs 10c–10e, 10h, 10i of the Bailey Declaration further address the meaning of "pre-enrichment" and the reasons for performing pre-enrichment steps. Pre-enrichment is not required by the claims. The meaning of pre-enrichment was an issue in the interpretation of claim 1, where we interpreted the pre-enrichment step to be different from the enrichment step and accomplished for a different purpose. 7983 Dec. 6.

Dr. Bailey also discusses enrichment and microorganism in his declaration with respect to Price. Bailey Decl. ¶¶ 10f, 10g, 11–16. Dr. Bailey cited additional prior art not cited in the rejections for teaching compositing samples as in steps a and b of the claims. *Id.* at ¶¶ 16–19.

However, this discussion does not provide a rationale for compositing enrichment broths after enrichment has been accomplished as required by the claims.

> Dr. Bailey discusses the Silliker and Gabis publications:
>
> > Each of these publications described taking multiple samples from the lot of food product being tested, compositing those samples in pre-enrichment media, incubating those media, transferring aliquots to a selective enrichment media and testing for the presence of *Salmonella.* In my opinion, each of these publications described the sample-compositing and incubation steps a), b) and c) of the claims of the '584 patent.
>
> Bailey Decl. ¶ 20.

We do not agree with Dr. Bailey that these publications describes steps a, b, c of the claims. Firstly, the claimed steps have been interpreted to require enrichment, not pre-enrichment as discussed in Silliker and Gabis. Silliker 475; Gabis 663; 7983 Dec. 8. Secondly, even if Silliker and Gabis were understood to disclose or suggest enrichment steps, Silliker expressly refers to lumping "samples from individual lots" (Silliker 479) and Gabis discloses directly enriching "lumped samples" (Gabis 657), but does not indicate the samples are from the same lot. In contrast, the claims combine samples from the *same* test lot (claim 1, step b). Dr. Bailey did not address the relevance of this prior art to steps d and e of claim 1 in which compositing and testing after enrichment is performed or why Silliker and Gabis would have rendered these steps obvious.

Apple v Samsung

Requester contends that rehearing is warranted because of changes in the law decided after submission Requester's response to Patent Owner's comments. Req. Reh'g 12–13. Requester states, citing *Apple Inc. v. Samsung Elec. Co.*, 839 F. 3d 1034 (Fed. Cir. 2016):

> For the first time, the Federal Circuit held in *Apple* that, in every case, "[a] determination of whether a patent claim is invalid as obvious ... requires consideration of all four *Graham* factors," including the secondary considerations. *Id.* at 1048 (majority op.).

Req. Reh'g 13.

We agree that Judge Dyk in his dissent criticized the majority for holding that secondary considerations must "always" be considered. However, Requester's argument is not well taken as we properly considered all aspects of the obviousness inquiry. Chief Judge Prost, in her dissent, opined that the majority had "elevated" the evidence of secondary considerations because "when the prima facie case of obviousness is strong, secondary considerations carry little weight." *Id.* at 1080. Judge Prost was not stating that the factors should not be considered, but rather that they carry less weight in view of the strong case of obviousness. Our reviewing court has long cautioned the Board that when evidence is properly submitted, it must be considered.[3] Properly read in light of other precedents that have not been overruled, *Apple* cannot be read to say that the Board can

[3] *See, e.g., In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007) ("When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence.").

now dismiss or ignore submitted evidence. *Apple*, 839 F.3d at 1039 ("We have applied existing obviousness law to the facts of this case.").

The weighing of secondary factors along with the other evidence of obviousness or non-obviousness is a factual matter that, as illustrated in *Apple v Samsung*, may cause reasonable minds to differ on how much import each factor is to be afforded. We only reiterate that, upon reconsideration of the evidence in this case, that a "strong" case of obviousness based on the cited prior art has not been established because there is a lack of a persuasive reason to have combined enrichment broths after culturing them and then to have tested the composited and diluted enriched sample. This view is buttressed by declarations of two experts in the field who attested to being skeptical that a method utilizing this claimed step would have sufficient sensitivity to be reliable, let alone to have achieved a 30% market share in the United States.

REHEARING DENIED

National Beef Ex. 1007
Page 1871

CC:

Patent Owner:

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, WA 98101-3045

Third Party Requester:

ROTHWELL, FIGG, ERNST, & MANBECK, P.C
607 14th Street, N.W.
Suite 800
Washington, DC 20005

lb

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,294	04/05/2010	7534584	0066090-008US2	1914

22504 7590 01/24/2019

DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
920 Fifth Ave., Suite 3300
SEATTLE, WA 98104-1610

EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
01/24/2019	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Transmittal of Communication to Third Party Requester *Inter Partes* Reexamination	Control No.	Patent Under Reexamination	
	95/001,294	7534584	
	Examiner	Art Unit	AIA Status
	SHARON L TURNER	3991	No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Rothwell, Figg, Ernst & Manbeck, P.C.
607 14th Street, N.W.
Suite 800
Washington, D.C. 20005

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

NOTICE OF INTENT TO ISSUE INTER PARTES REEXAMINATION CERTIFICATE	**Control No.** 95/001,294	**Patent Under Reexamination** 7534584
	Examiner SHARON L TURNER	**Art Unit** 3991

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

1. ☑ Prosecution on the merits is (or remains) closed in this inter partes reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of:
   a. ☐ The communication filed on _____ by _____ .
   b. ☐ Patent owner's failure to file an appropriate timely response to the Office action dated _____.
   c. ☐ The failure to timely file an Appeal with fee by all parties to the reexamination proceeding entitled to do so. 37 CFR 1.959 and 41.61
   d. ☐ The failure to timely file an Appellant's Brief with fee by all parties to the reexamination proceeding entitled to do so. 37 CFR 41.66(a).
   e. ☑ The decision on appeal by the ☑ Board of Patent Appeals and Interferences ☐ Court dated 18 April 2018
   f. ☐ Other: _____

2. ☐ The Reexamination Certificate will indicate the following:
   a. Change in the Specification: ☐ Yes ☑ No
   b. Change in the Drawings: ☐ Yes ☑ No
   c. Status of the Claims:
      (1) Patent claim(s) confirmed _____ .
      (2) Patent claim(s) amended (including dependent on amended claim(s)): 1-23 and 26-33
      (3) Patent claim(s) cancelled: 24-25 .
      (4) Newly presented claim(s) patentable: _____ .
      (5) Newly presented cancelled claims: _____ .
      (6) Patent claim(s) ☐ previously ☐ currently disclaimed: _____
      (7) Patent claim(s) not subject to reexamination: _____ .

3. ☐ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

4. ☐ Note attached NOTICE OF REFERENCE CITED, (PTO-892).

5. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).

6. ☐ The drawings filed on _____ is: ☐ approved ☐ disapproved.

7. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. § 119(a) - (d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have
   ☐ been received.
   ☐ not been received.
   ☐ been filed in Application No. _____ .
   ☐ been filed in reexamination Control No. _____ .
   ☐ been received by the International Bureau in PCT Application No. _____ .

   * Certified copies not received: _____ .

8. ☐ Note Examiner's Amendment.

9. ☐ Other: _____ .

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

/Sharon Turner/ /Padmashri Ponnaluri/ Patent Reexam Specialist CRU 3991	/Jean C. Witz/ Supervisory Patent Reexam Specialist CRU 3991

US007534584C1

(12) INTER PARTES REEXAMINATION CERTIFICATE (1596th)
United States Patent
Samadpour

(10) Number: US 7,534,584 C1
(45) Certificate Issued: Mar. 6, 2019

(54) **MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS**

(75) Inventor: **Mansour Samadpour**, Seattle, WA (US)

(73) Assignee: **INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.**, Lake Forest Park, WA (US)

Reexamination Request:
No. 95/001,294, Apr. 5, 2010

Reexamination Certificate for:

Patent No.:	**7,534,584**
Issued:	**May 19, 2009**
Appl. No.:	**11/199,871**
Filed:	**Aug. 8, 2005**

Related U.S. Application Data

(60) Provisional application No. 60/599,473, filed on Aug. 6, 2004.

(51) **Int. Cl.**

C12Q 1/24	(2006.01)
C12Q 1/10	(2006.01)
C12Q 1/18	(2006.01)
C12Q 1/04	(2006.01)
G01N 1/28	(2006.01)

(52) **U.S. Cl.**
CPC ***C12Q 1/10*** (2013.01); ***C12Q 1/04*** (2013.01); ***C12Q 1/18*** (2013.01); ***C12Q 1/24*** (2013.01); ***G01N 1/28*** (2013.01); *Y10S 435/849* (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 95/001,294, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Sharon Turner

(57) **ABSTRACT**

Particular aspects provide a method of sampling, testing and validating test lots (e.g., single-unit production lots), comprising: assembling a plurality of product portions from each of a plurality of test lots and combining the collected product portions to provide a corresponding set of test lot samples (wherein each test lot sample is attributed to a particular corresponding test lot); enriching the set of test lot samples; removing equal portions of each enriched sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample for the target agent/organism, wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a respective enriched test lot sample and obtaining a negative test result. The methods have broad utility for monitoring all sort of test lots (e.g., environmental lots, production lots, pharmaceutical lots, etc.) and for efficiently affecting informed, targeted remedial measures.

INTER PARTES REEXAMINATION CERTIFICATE

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **24-25** are cancelled.

Claims **1**, **2**, **17** and **32-33** are determined to be patentable as amended.

Claims **3-16**, **18-23** and **26-31**, dependent on an amended claim, are determined to be patentable.

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*).

2. The method of claim **1**, wherein *each of* the test **[**lot**]** *lots* is a single-unit production lot, comprised of operationally-linked product specimens.

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*).

32. The method of claim **[24]** *1*, wherein the **[**meat or poultry**]** *beef* specimens are meat trim pieces**[**or poultry trim pieces, respectively**]**.

33. The method of claim **[24]** *17*, wherein the meat is that of beef, pork, sheep or bison.

* * * * *