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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY.DOCKET NO./TITLE	REQUEST ID
12/360,796	01/27/2009	Mansour Samadpour	0066090-008US1	26038

Acknowledgement of Loss of Entitlement to Entity Status Discount

The entity status change request below filed through Private PAIR on 10/04/2016 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

✕ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be notification of loss of entitlement to small or micro entity status, as applicable.

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Barry L. Davison/
Name:	Barry L. Davison
Registration Number:	47309



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/360,796	03/05/2013	8389233	66090-008US1	7046

22504 7590 02/13/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 694 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Mansour Samadpour, Seattle, WA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.



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Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/360,796	01/27/2009	Mansour Samadpour	66090-008US1	7046

22504 7590 02/11/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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02/11/2013

ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

seapatentdocket@dwt.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/360,796	Applicant(s) SAMADPOUR, MANSOUR	
	Examiner KAILASH C. SRIVASTAVA	Art Unit 1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) KAILASH C. SRIVASTAVA, Examiner. (3) ____.

(2) Dr. Barry L. Davison, Applicant's Representative. (4) ____.

Date of Interview: 04 February 2013.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
 If Yes, brief description: Notice of Allowance mailed 1/17/2013 already of record.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: Those Allowed on 1/17/2013.

Identification of prior art discussed: That of Record.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

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

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/KAILASH C. SRIVASTAVA/ Examiner, Art Unit 1657	
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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

22504 7590 01/17/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Peachie S. Chan	(Depositor's name)
/Peachie S. Chan/ via EFS-Web	(Signature)
February 1, 2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/360,796 01/27/2009 Mansour Samadpour 66090-008US1 7046

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

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$885	\$300	\$0	\$1185	04/17/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
SRIVASTAVA, KAILASH C	1657	435-034000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Barry L. Davison, Ph.D., J.D.

2 Davis Wright Tremaine LLP

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Institute for Environmental Health, Inc. Lake Forest Park, Washington

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 040258 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Barry L. Davison, Ph.D., J.D./

Date February 1, 2013

Typed or printed name Barry L. Davison, Ph.D., J.D.

Registration No. 47,309

This collection of information is required by 37 CFR 1.311. 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 12 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	12360796			
Filing Date:	27-Jan-2009			
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS			
First Named Inventor/Applicant Name:	Mansour Samadpour			
Filer:	Barry Davison/Peachie Chan			
Attorney Docket Number:	66090-008US1			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Publ. Fee- early, voluntary, or normal	1504	1	300	300
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	885 National Beef Ex. 1009	885

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1185

Electronic Acknowledgement Receipt

EFS ID:	14859385
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Peachie Chan
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-008US1
Receipt Date:	01-FEB-2013
Filing Date:	27-JAN-2009
Time Stamp:	19:15:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$1185
RAM confirmation Number	7344
Deposit Account	040258
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

National Fee 1009

Page 009

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Post Allowance Communication - Incoming	CommentsOnStatementOfReasonsForAllowance.pdf	82903 e2076b939d70a0e930dcafeb3436a3fbaa936877	no	3

Warnings:

Information:

2	Issue Fee Payment (PTO-85B)	IssueFeeTransmittalForm.pdf	114169 3479e273f1bdc686a501a9eca6ce68240ddff52a2	no	1
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Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	32038 d04483bd6c201c1454bde22230a46d5806ff0f912	no	2
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Warnings:

Information:

Total Files Size (in bytes):	229110
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour

Filing Date: 27 January 2009

Serial No.: 12/360,796

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

Art Unit: 1657

Examiner: Kailash C. Srivastava

Docket: 66090-008US1

Date: 01 February 2013

Mail Stop Issue Fee
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Sir:

This is a Response (Comments on Statement of Reasons for Allowance) in reply to the Notice of Allowance dated 17 January 2013, and is accompanying payment of the Issue Fee. This Response and the accompanying payment of the Issue Fee are timely filed.

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
Applicant's Name: Mansour Samadpour
Notice of Allowance dated: 17 January 2013
Date of Response and Issue Fee Payment: 01 February 2013
Examiner: Kailash C. Srivastava

REMARKS

Claims 1-34 have been allowed.

Comments on Statement of Reasons for Allowance

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

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
Applicant's Name: Mansour Samadpour
Notice of Allowance dated: 17 January 2013
Date of Response and Issue Fee Payment: 01 February 2013
Examiner: Kailash C. Srivastava

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests entry of the present Comments on Statement of Reasons for Allowance, and issuance of the allowed application and claims.

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 Applicant
Registration No. 47,309



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

NOTICE OF ALLOWANCE AND FEE(S) DUE

22504 7590 01/17/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

DATE MAILED: 01/17/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/360,796

01/27/2009

Mansour Samadpour

66090-008US1

7046

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

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$885	\$300	\$0	\$1185	04/17/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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22504 7590 01/17/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/360,796 01/27/2009 Mansour Samadpour 66090-008US1 7046

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

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$885 \$300 \$0 \$1185 04/17/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
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SRIVASTAVA, KAILASH C 1657 435-034000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

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☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. 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 12 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/360,796	01/27/2009	Mansour Samadpour	66090-008US1	7046

22504 7590 01/17/2013
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 01/17/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 298 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 298 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	12/360,796	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	KAILASH C. SRIVASTAVA	1657	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Communicatin filed 01/03/2013.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-34. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. ☐ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material 4. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____. | <ol style="list-style-type: none"> 5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other ____. |
|--|--|

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 10/04/2012 & 01/03/2013.

EXAMINER'S COMMENTS AND REASONS FOR ALLOWANCE

Acknowledgement

Applicant's response and amendment filed 03 January 2013 to Office Action with Non-Final Rejection mailed 05 July 2012 is acknowledged and entered.

Also acknowledged is the Terminal Disclaimer (TD) filed 3 January 2013, said disclaimer has been approved on 07 January 2013.

Claims Status

According to the response filed 03 January 2013, the following is the status of all the Claims in the instant application:

Claims 1-34 are pending in the instant application and are examined on merit.

Withdrawals

In consideration of Applicant's comments and TD filed 03 January 2013, said TD having been approved, the obvious Type Double Patenting rejection in the Office Action with non-FINAL rejection mailed 05 July 2012 is hereby withdrawn.

Information Disclosure Statement

Applicant's Information Disclosure Statements (i.e., IDS) respectively filed 04 October 2012 and on 03 January 2013 are acknowledged, entered, considered and duly signed copies of form USPTO SB08 is enclosed with the instant Office Action.

Examiner's Reasons for Allowance

The closest applicable art to instantly claimed invention and according to the review of the proceedings in the reexamination of U.S. Application 95/001,294 (See Applicant's IDS filed 03 January 2013) are:

Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

Skov et al., compared four sampling methods for determining *Salmonella* in broiler flocks. At least one method comprised hand-picked 300 fecal samples consisting of samples of pools of 5 samples (i.e., 60 pools). The collected pooled and individual samples were analyzed for *Salmonella* according to art-known standard bacteriological procedures for *Salmonella* isolation Abstract, Lines -20; Page 696, Column 1, Lines 2-10; Column 2, Lines 27-50; Page 697, Column 1, Lines 2-5). Thus, Skov et al. teach methods to determine *Salmonella* from broiler flocks (i.e., chicken) through pooled sampling and analysis of individual samples.

Skov et al's teachings differ from the limitations of the steps 1(d) and 1e in the instant application **in not re-testing individually each of the original specimens** constituting any of the composites in either the pre enrichment culture medium or broth in to the second enrichment culture and subsequently testing for the presence of the target microorganisms. What is construed as pre-enrichment culture and enrichment culture as allegedly retesting the positive sample is merely the conventional procedures at the time of Skov's investigation to be the standard procedure for evaluating the microbiological quality of foods. The pre-enrichment and enrichment are steps to get to the target microorganism, but the test itself is not completed until the point that the target pathogenic microorganism is identified.

Thus, Skov et al., despite evaluating even 60 samples do not teach re-testing of individual original composite lots or each of the specimens constituting the composite lots as is required by steps 1d and 1e in the instant invention when a positive indication of presence of a target pathogenic microorganism is found.

Jarvis, B. 1989. statistical aspects of the microbiological analysis of foods. progress in industrial microbiology, Volume 21, Chapter 8, Pages 117- 142, Submitted as Exhibit 13

in U.S. ReExam Application Number 95/001,294 provided on Applicant's IDS filed 01/03/2013).

Jarvis teaches that testing composite samples reduces the workload on the laboratory (page 141, section 8.4.2.1). Jarvis' methods 2 and 3 comprise collecting a plurality (10) of product samples or portions (25g size); either inoculating the samples separately into one each of a pre-enrichment medium or broth to give test lot samples, each comprising a single specimen (method 2), or alternatively, pooling a plurality (about 5) of specimens and inoculating the pooled specimens into a pre-enrichment culture medium or broth (method 3); incubating the pre-enrichment broth cultures to allow for growth of the target organisms; compositing aliquots of the pre-enrichment cultures and inoculating the of the target organisms; compositing aliquots of the pre-enrichment cultures and inoculating the composite into a second enrichment culture, incubating the composite enrichment culture, and subsequently testing for the pathogenic organism.

Jarvis' teachings differ from the limitations of the steps 1(d) and 1e in the instant application **in not re-testing individually each of the original specimens** constituting any of the composites in either the pre enrichment culture medium or broth in to the second enrichment culture and subsequently testing for the presence of the target microorganisms. What is construed as pre-enrichment culture and enrichment culture as allegedly retesting the positive sample is merely the conventional procedures at the time of Jarvis' investigation to be the standard procedure for evaluating the microbiological quality of foods. The pre-enrichment and enrichment are steps to get to the target microorganism, but the test itself is not completed until the point that the target pathogenic microorganism is identified.

Thus, Jarvis does not teach re-testing of the original individual composite lots or each of the specimens constituting the composite lots as is required by

steps 1d and 1e in the instant invention when a positive indication of presence of a target pathogenic microorganism is found.

FSIS DIRECTIVE 10.010.1, Revision 1, 3/31/2004 UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE, WASHINGTON, DC, Pages 1-27 (henceforth FSIS), Submitted as Exhibit O in U.S. ReExam Application Number 95/001,294 provided on Applicant's IDS filed 01/03/2013).

FSIS teaches methods of sampling ground beef or poultry for *E. coli* 0157:H7 contamination, comprising aseptically collecting a plurality of pieces or samples and combining the pieces for a representative sample of a production lot from the current day's production (a production assemblage, see pages 4 and 27-28 in their entirety). FSIS further teaches follow-up sampling upon identification of contaminated lots and corrective or remedial measures (see the paragraph bridging pages 8-9).

FSIS' teachings differ from the limitations of the steps 1(d) and 1e in the instant application **in not re-testing individually each of the original specimens** constituting any of the composites. FSIS, rather teaches follow-up sampling upon identification of a positive identification of a contaminated lot and corrective or remedial measures, not from the specimens/samples constituting the composite employed for testing that resulted in the positive identification of a target pathogenic organism. This is subsequent sampling which is an entirely different method than what constitutes the test method of the instantly presented invention.

Thus, FSIS does not teach re-testing of the original individual composite lots or each of the specimens constituting the composite lots as is required by steps 1d and 1e in the instant invention when a positive indication of presence of a target pathogenic microorganism is found.

Price et al (1972. *Salmonella* testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples. Applied Microbiology, Volume 23, Number 4, Pages 679-682, Submitted as Exhibit Q in U.S. ReExam Application Number 95/001,294 provided on Applicant's IDS filed 01/03/2013).

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

Midura et al (2001. Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis. In Chapter 2, COMPENDIUM OF METHODS FOR THE MICROBIOLOGICAL EXAMINATION OF FOODS, FOURTH EDITION, DOWNES & ITO (Editors). AMERICAN PUBLIC HEALTH ASSOCIATION, 800 I St., NW., Washington, DC 20001-3710, Pages 13-23; Submitted as Exhibit L in U.S. ReExam Application Number 95/001,294 provided on Applicant's IDS filed 01/03/2013).

Midura et al., teach methods to sample and test foods for microbial contamination. Midura teaches collecting a plurality of samples from a food lot produced in one batch or in some specified period of time (with fish, meats, and shell fish exemplified, pooling the samples to obtain a pooled or composite sample; and testing the composite sample for the presence of microbial contaminants (e.g., coliforms and *Salmonella*). Midura et al., further teach subsequent testing of a second sample depending on the results of the first sample as multiple sampling attribute plans (two or three class (page 17, Column 1, Line 8 to Page -20, Column 2, Line 51). Midura et al., also teach that when products with a low incidence of the target pathogen are tested, additional samples need to be collected and tested to ensure a high probability of detecting the pathogen if present (page 19, Column 1, Line 29 to Column 2, Line 6). Midura et al., exemplify collecting 30 or 60 samples or portions (see, Page 16, Fig. 1, Page 17, column 1, Lines 14-20; Page 19, Column 2, Lines 22-31; Page 20, column 1, Lines 18-27).

Midura et al's teachings differ from the limitations of the steps 1(d) and 1e in the instant application **in not re-testing individually each of the original specimens** constituting any of the composites. Midura et al., , rather teach follow-up sampling or obtaining large number of samples without any step of retesting the individual samples constituting a composite that gave identification of a positive organism employed for first testing for a target pathogenic organism. This is subsequent sampling which is an entirely different method than what constitutes the test method of the instantly presented invention.

Thus, Midura et al., do not teach re-testing of the original individual composite lots or each of the specimens constituting the composite lots as is required by steps 1d and 1e in the instant invention when a positive indication of presence of a target pathogenic microorganism is found.

Absent evidence to the contrary, none of the prior art references cited *supra*, and especially Price et al., either explicitly or inherently teach a method according to each of the step limitations recited in the instantly claimed invention. Absent said steps, the instantly claimed invention is neither anticipated, nor is obvious in view of the teachings from the prior art cited and discussed *supra*. Additionally, the other Exhibits cited in the copending re-examination application 95/001,294 fail teach the limitations in each of the steps of the Quality Assurance methodology of the instant application.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-34 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)

272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (U.S., Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday and every other Friday between 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Patent Examiner
Art Unit 1657
☎:(571) 272-0923

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657

WEST Search History for Application 12360796

Creation Date: 2013010909:11

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
quality control	USPT	ADJ	YES		06-27-2012
composite sample	USPT	ADJ	YES		06-27-2012
Intermediate sample	USPT	ADJ	YES		06-27-2012
ladder sampl\$5	USPT	ADJ	YES		06-27-2012
(mixed lot) same (sample)	USPT	ADJ	YES		06-27-2012
(composite sample) same (Intermediate sample)	USPT	ADJ	YES		06-27-2012
(quality control) same (composite sample)	USPT	ADJ	YES		06-27-2012
(quality control) and (Intermediate sample)	USPT	ADJ	YES		06-27-2012
(stepwise)same (sample analysis)	USPT	ADJ	YES		06-27-2012
discriminat\$8 same sampl\$5	USPT	ADJ	YES		06-27-2012
(stepwise) same (sample analysis)	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and ((stepwise) same (sample analysis))	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and (composite sample)	USPT	ADJ	YES		06-27-2012
(Pharmaceutical sample)	USPT	ADJ	YES		06-27-2012
(quality control) and ((Pharmaceutical sample))	USPT	ADJ	YES		06-27-2012
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ	YES		06-27-2012
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
		ADJ	YES		06-27-2012

(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI				
quality control	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
composite sample	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
discriminat\$8 and sampl\$5	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(discriminat\$8 and sampl\$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))	PGPB, USPT	ADJ	YES		06-27-2012

((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))	PGPB, USPT	ADJ	YES		06-27-2012
(pooled same sample)	PGPB, USPT	ADJ	YES		06-27-2012
sample Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		06-27-2012
((pooled same sample)) same (sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella same sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
(sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
sample and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(pooled and sample)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
sample and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((pooled and sample)) and (sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sample and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))) and ((pooled and sample) and sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot	PGPB, USPT	ADJ	YES		06-27-2012
(target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic	PGPB, USPT	ADJ	YES		06-27-2012

microb\$6))					
(composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	PGPB, USPT	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))	PGPB, USPT	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) same ((target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))	PGPB, USPT	ADJ	YES		06-27-2012
((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot) same ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion))	PGPB, USPT	ADJ	YES		06-27-2012
((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) same ((target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))	PGPB, USPT	ADJ	YES		06-27-2012
quality control	PGPB, USPT	ADJ	YES		06-27-2012
composite sample	PGPB, USPT	ADJ	YES		06-27-2012
((mixed or combined) same lot) same (sample or specimen or material or portion)	PGPB, USPT	ADJ	YES		06-27-2012
(discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)	PGPB, USPT	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	PGPB, USPT	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))	PGPB, USPT	ADJ	YES		06-27-2012
((((mixed or combined) same lot) same (sample or specimen or material or portion)) or ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) same (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella	PGPB, USPT	ADJ	YES		06-27-2012

or(pathogenic microb\$6)))					
((((mixed or combined) same lot) same (sample or specimen or material or portion)) or ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)) or ((composite sample) or ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)))	PGPB, USPT	ADJ	YES		06-27-2012
(((((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion))) or (((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot)) or ((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))))	PGPB, USPT	ADJ	YES		06-27-2012
(((((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))) same (quality control)	PGPB, USPT	ADJ	YES		06-27-2012
(((((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))) same ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	PGPB, USPT	ADJ	YES		06-27-2012
((((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) or (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) or	PGPB, USPT	ADJ	YES		06-27-2012

((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))))					
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same quality control)	PGPB, USPT	ADJ	YES		06-27-2012
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same quality control) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or	PGPB, USPT	ADJ	YES		06-27-2012

pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)					
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same quality control same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))	PGPB, USPT	ADJ	YES		06-27-2012
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or	PGPB, USPT	ADJ	YES		06-27-2012

material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same quality control same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) same (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))					
(caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((mixed or combined) and lot) and(sample or specimen or material or portion)	USOC, EPAB,	ADJ	YES		06-27-2012

	JPAB, DWPI				
(discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot) or ((composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion))) or ((((mixed or combined) and lot) and (sample or specimen or material or portion)) or ((sampl\$5 or specimen or material or portion) and (pooled or composite or lot)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or (((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4) or (slaughter house)))) or ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4) or (slaughter house))) or (sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))) and ((discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4) or (slaughter house))) or (sampl\$5 or specimen or material or portion) and	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012

(enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)) and (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion)) and (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (sampl\$5 or specimen or material or portion) and (pooled or composite or lot)))					
((((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)) and (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion) and (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (sampl\$5 or specimen or material or portion) and (pooled or composite or lot))) and (((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)) and (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion) and (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (sampl\$5 or specimen or material or portion) and (pooled or composite or lot)) and ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) and ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
Escherichia\$12 same Hemorrhage\$6	PGPB, USPT, USOC, EPAB, JPAB,	ADJ	YES		01-09-2013

	DWPI				
Escherichia\$12 same Hemorrhage\$6	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
Escherichia\$12 and Hemorrhage\$6	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
(Escherichia\$12 and Hemorrhage\$6) and (Escherichia\$6)	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot) or ((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion))	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
((((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house)))) or ((((mixed or combined) and lot) and(sample or specimen or material or portion)) or ((discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5or specimen or material or portion)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
(((((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5or specimen or material or portion))) or ((sampl\$5 or specimen or material or portion) and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
(((((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or (composit\$5 or mixed or	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013

combine\$3 or enrich\$6) and (lot or sample or portion) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5or specimen or material or portion))) and ((sampl\$5 or specimen or material or portion) and (pooled or composite or lot))					
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5or specimen or material or portion)) and (sampl\$5 or specimen or material or portion) and (pooled or composite or lot)) and (Escherichia\$12 and Hemorrhage\$6 and Escherichia\$6)	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion) or ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5or specimen or material or portion))) and ((sampl\$5 or specimen or material or portion) and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		01-09-2013
Escherichia\$13	PGPB, USPT	ADJ	YES		01-09-2013
Escherichia\$12 and Hemorrhage\$6	PGPB, USPT	ADJ	YES		01-09-2013
((((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) or ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)) or ((quality control) or (composite sample))) or ((((mixed or combined) same lot) same (sample or specimen or material or portion)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)))	PGPB, USPT	ADJ	YES		01-09-2013
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or	PGPB,	ADJ	YES		01-09-2013

sample)same lot) or ((target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))) or (((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or (((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	USPT				
Escherichia\$12 same Hemorrhage\$6	PGPB, USPT	ADJ	YES		01-09-2013
(Escherichia\$12 same Hemorrhage\$6) same (Escherichia\$13)	PGPB, USPT	ADJ	YES		01-09-2013
(Escherichia\$12 same Hemorrhage\$6 same Escherichia\$13) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)))	PGPB, USPT	ADJ	YES		01-09-2013
(Escherichia\$12 same Hemorrhage\$6 same Escherichia\$13 same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion))) same (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013
(Escherichia\$12 same Hemorrhage\$6) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)))	PGPB, USPT	ADJ	YES		01-09-2013

(Escherichia\$12 same Hemorrhage\$6 same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion))) same (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013
(((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion))) same (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013
(((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))) same (Escherichia\$13)	PGPB, USPT	ADJ	YES		01-09-2013
(((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion))) same (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013

pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) same Escherichia\$13) same (Escherichia\$12 and Hemorrhage\$6)					
(((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) same Escherichia\$13) same (Escherichia\$12 same Hemorrhage\$6)	PGPB, USPT	ADJ	YES		01-09-2013
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) same ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)))	PGPB, USPT	ADJ	YES		01-09-2013
(((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	PGPB, USPT	ADJ	YES		01-09-2013

or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))) same ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))))					
(sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))	PGPB, USPT	ADJ	YES		01-09-2013
(injured or dehydrated or damaged or non-culturable) same microorganism	PGPB, USPT	ADJ	YES		01-09-2013
((injured or dehydrated or damaged or non-culturable) same microorganism) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013
((injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same	PGPB, USPT	ADJ	YES		01-09-2013

(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) same Escherichia\$13)					
((injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))) same ((((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion))) or (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))))	PGPB, USPT	ADJ	YES		01-09-2013
((injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) or (((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))))	PGPB, USPT	ADJ	YES		01-09-2013

portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) or ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))))) same (Escherichia\$12 same Hemorrhage\$6)					
((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same ((injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house)))))	PGPB, USPT	ADJ	YES		01-09-2013
((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)) same (injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same	PGPB, USPT	ADJ	YES		01-09-2013

(sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminate or separate or isolate) same (sample or specimen or material or portion)) same ((carcass or meat or food or pharmaceutical or sample) same lot or (target or test) same (microbe or microorganism or (Escherichia coli) or salmonella or (pathogenic microbe))) or ((composite or mixed or combine or enrich) same (lot or sample or portion) or ((microbe or microbiology) same (quality control)) same ((Meat same process) or (slaughter house)))) same (((discriminate or separate or isolate) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminate or separate or isolate) same (sample or specimen or material or portion)))					
((sample or specimen or material or portion) same (enrich same ((pathogenic bacteria) or Salmonella or Listeria)) same (injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminate or separate or isolate) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminate or separate or isolate) same (sample or specimen or material or portion)) same ((carcass or meat or food or pharmaceutical or sample) same lot or (target or test) same (microbe or microorganism or (Escherichia coli) or salmonella or (pathogenic microbe))) or ((composite or mixed or combine or enrich) same (lot or sample or portion) or ((microbe or microbiology) same (quality control)) same ((Meat same process) or (slaughter house))) same (((discriminate or separate or isolate) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminate or separate or isolate) same (sample or specimen or material or portion))) same (((carcass or meat or food or pharmaceutical or	PGPB, USPT	ADJ	YES		01-09-2013

sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))))					
20090291086.pn.	PGPB, USPT	ADJ	YES		01-09-2013
20050197295.pn.	PGPB, USPT	ADJ	YES		01-09-2013
7407475.pn.	PGPB, USPT	ADJ	YES		01-09-2013
6962903.pn.	PGPB, USPT	ADJ	YES		01-09-2013
3097141.pn.	PGPB, USPT	ADJ	YES		01-09-2013
435/7.2.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/7.32.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/31.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/32.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/33.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/34.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/36.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/38.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/39.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/40.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/308.1.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
435/849.ccls.		ADJ	YES		01-09-2013

	PGPB, USPT				
435/973.ccls.	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls.) and (435/7.32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls.) and (435/31.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls.) and (435/32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls.) and (435/33.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls.) and (435/34.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls.) and (435/36.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls.) and (435/38.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls.) and (435/39.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/39.ccls.) and (435/40.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/39.ccls.) and (435/308.1.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/39.ccls.) and (435/849.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls.) and (435/849.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls.) and (435/308.1.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls.) and (435/40.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls.) and (435/39.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls.) and (435/38.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls.) and (435/36.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013

(435/973.ccls. and 435/849.ccls.) and (435/34.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls. and 435/34.ccls.) and (435/33.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls. and 435/34.ccls.) and (435/32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls. and 435/34.ccls.) and (435/31.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls. and 435/34.ccls.) and (435/7.32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/849.ccls. and 435/34.ccls.) and (435/7.2.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls.) and (435/32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls.) and (435/33.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls.) and (435/34.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls.) and (435/36.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls.) and (435/38.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls. and 435/38.ccls.) and (435/39.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls. and 435/38.ccls.) and (435/40.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls. and 435/38.ccls.) and (435/308.1.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/849.ccls. and 435/32.ccls.) and (435/973.ccls. and 435/7.32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls.) and (435/973.ccls. and 435/7.32.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/973.ccls. and 435/849.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/973.ccls. and 435/849.ccls. and 435/34.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013

(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/849.ccls. and 435/32.ccls. and 435/33.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls. and 435/38.ccls.)	PGPB, USPT	ADJ	YES		01-09-2013
(435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and ((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)) same (injured or dehydrated or damaged or non-culturable) same microorganism same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb\$6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))) same (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same (sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5 or specimen or material or portion)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) same lot or (target or test) same (microb\$6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion) or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))))	PGPB, USPT	ADJ	YES		01-09-2013

Search Notes 	Application/Control No. 12360796	Applicant(s)/Patent Under Reexamination SAMADPOUR, MANSOUR
	Examiner KAILASH C SRIVASTAVA	Art Unit 1657

SEARCHED			
Class	Subclass	Date	Examiner
Partial Search in EAST	Partial Search in EAST and in WEST	6/26/2012	KCS
NONE	NONE	6/26/2012	KCS
Partial Search in WEST	Partial Search in WEST	6/27/2012	KCS
NONE	NONE	6/27/2012	KCS
Updated Partial Search in WEST	Updated Partial Search in WEST	1/9/2013	KCS
435	7.2, 7.32, 31, 32, 33, 34, 36, 38, 39, 40, 308.1, 849, 973	1/9/2013	KCS

SEARCH NOTES		
Search Notes	Date	Examiner
Case discussed with Dr. Weber for ODP rejection	6/19/2012	KCS
Inventor Name search	6/26/2012	KCS
Assignee Name search	6/26/2012	KCS
Verified Application priority data (e.g., 60/599,473 filed 08/06/2004 and CON of 11/199,871 filed 08/08/2005 now USPATENT 7,534,584) in e-DAN	6/26/2012	
EAST Search in DWPI, EPAB, JPAB, PGPB, USPT with following Search Strategy:	6/26/2012	KCS
(caracass\$8 or meat\$7 or food or ,pharmaceutic\$5 or sample)and lot (target or test) and (microb6 or microorganism or (Escherichia coli) or,salmonella or(pathogenic microb\$6)) , (composit\$5 or mixed or combine\$3 or,enrich\$6) and (lot or sample or portion) , ((micro\$4 or microbiolo\$5) and(qualitycontrol)) and ((Meat and process\$4)or(slaughter house))	6/26/2012	KCS
WEST Search in DWPI, EPAB, JPAB, PGPB, USOC, USPT	6/27/2012	KCS
WEST Sarch Strategy: (((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (qualitycontrol)) and ((Meat and process\$4)or(slaughter house)) or (sampl\$5 or specimen or material or portion) and(enrich\$5 and ((pathogenic bacteria) or Salmonella orListeria\$9)) and (discriminat\$8 or separat\$7 or isolat\$8)and (sampl\$5 or specimen or material or portion) and((caracass\$8 or meat\$7 or food or pharmaceu	6/27/2012	KCS

/KAILASH C SRIVASTAVA/ Examiner.Art Unit 1657	
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SEARCH NOTES

Search Notes	Date	Examiner
sample) and lot or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((mixed or combined) and lot) and (sample or specimen or material or portion) or (sampl\$5 or specimen or material or portion) and (pooled or composite or lot)) and ((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4) or (slaughter house))) and ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))	6/27/2012	KCS
Discussed with Dr. Weber to allow the pending Claims 1-34 in consideration of filing and approval of a TD for ODP rejection	1/7/2013	KCS
Inventor Name search updated	1/9/2013	KCS
Updated Assignee Name search	1/9/2013	KCS
Reverified Application priority data (e.g., 60/599,473 filed 08/06/2004 and CON of 11/199,871 filed 08/08/2005 now USPATENT 7,534,584) in e-DAN	1/9/2013	KCS
Updated WEST Search in DWPI, EPAB, JPAB, PGPB, USOC, USPT with the search of 06/27/2012 substantiated with following search strategy	1/9/2013	KCS
((sampl\$5 or specimen or material or portion) same(enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)) same (injured or dehydrated or damaged or non-culturable) same microorganism same(((discriminat\$8 or separat\$7 or isolat\$8) same(sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or coldcut) same Salmonella) or (quality control or composite	1/9/2013	KCS
sample)) or (((mixed or combined) same lot) same(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same(sampl\$5 or specimen or material or portion)) same((caracass\$8 or meat\$7 or food or pharmaceutical\$5 or sample) same lot or (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or ((composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion)	1/9/2013	KCS
or ((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4) or (slaughter house))) same(((discriminat\$8 or separat\$7 or isolat\$8) same(sampl\$5 or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or coldcut) same Salmonella) or (quality control or composite sample)) or (((mixed or combined) same lot) same	1/9/2013	KCS
(sample or specimen or material or portion) or (discriminat\$8 or separat\$7 or isolat\$8) same(sampl\$5 or specimen or material or portion))) same(((caracass\$8 or meat\$7 or food or pharmaceutical\$5 or (435/973.ccls. and 435/7.32.ccls. and 435/34.ccls. and 435/973.ccls. and 435/7.32.ccls.) and (435/849.ccls. and 435/32.ccls. and 435/33.ccls. and 435/34.ccls. and 435/38.ccls.) PGPB, USPTADJ YES 01-09-2013 (435/973.ccls. and 435/7.32.ccls.	1/9/2013	KCS

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
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/KAILASH C SRIVASTAVA/
Examiner, Art Unit 1657

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
Updated Partial Search in WEST	Updated Partial Search in WEST	1/9/2013	KCS
435	7.2, 7.32, 31, 32, 33, 34, 36, 38, 39, 40, 308.1, 849, 973	1/9/2013	KCS

/KAILASH C SRIVASTAVA/
Examiner.Art Unit 1657

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known	
			Application Number	12/360,796
			Filing Date	January 27, 2009
			First Named Inventor	Mansour Samadpour
			Art Unit	1657
			Examiner Name	Kailash C. Srivastava
			Attorney Docket Number	66090-008US1
Sheet	1	of	2	

[illegible][illegible]

Examiner Signature	/Kailash Srivastava/	Date Considered	01/08/2013
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DWT 20851032x1 0066090-008US1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2
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Complete if Known

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

NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner
Signature

/Kailash Srivastava/

Date Considered

01/08/2013

DWT 20851032x1 0066090-008US1

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if you need assistance in completing the form, call 1-800-FTO-9199 and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.S./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			Complete if Known Application Number 12/360,796 Filing Date January 27, 2009 First Named Inventor Mansour Samadpour Art Unit 1657 Examiner Name Kailash C. Srivastava Attorney Docket Number 66090-008US1	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				
Sheet	1	of	2	

[illegible][illegible]

Examiner Signature	/Kailash Srivastava/	Date Considered	01/07/2013
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DWT 20279871x1 0066090-008US1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

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

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Andrews, et al., "Salmonella," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 37, American Public Health Association, pp. 357-380	
	2	Budiman, et al., "Localization of Jointless-2 Gene in the Centromeric Region of Tomato Chromosome 12 based on High Resolution Genetic and Physical Mapping," Theoretical and Applied Genetics, Volume 108, 2004, published online September 2003, pp. 190-196	
	3	Cousin, et al., "Psychotrophic Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 13, American Public Health Association, pp. 159-166	
	4	Entis, et al., "Rapid Methods for Detection, Identification, and Enumeration," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 10, American Public Health Association, pp. 89-126	
	5	The International Committee on Microbiological Specifications for Foods (ICMSF), "Microorganisms in Foods, 1 Their Significance and Methods of Enumeration," 2 nd Edition, 1978, University of Toronto Press, pp. 3-10 and 91-172	
	6	Kuo, et al., "Sample Pooling to Expedite Bioanalysis and Pharmacokinetic Research," Journal of Pharmaceutical and Biomedical Analysis, Volume 16, 1998, pp. 837-846	
	7	Meng, et al., "Pathogenic Escherichia coli," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 35, American Public Health Association, pp. 331-341	
	8	Midura, et al., "Sampling Plans, Sample Collection, Shipment and Preparation for Analysis," Compendium of Methods for the Microbiological Examination of Foods, 4 th Edition, 2001, Ch. 2, American Public Health Association, pp. 13-23	
	9	Skov, et al., "Evaluation of Sampling Methods for the Detection of Salmonella in Broiler Flocks," Journal of Applied Microbiology, Volume 86, 1999, pp. 695-700	
	10	Sperber, et al., "Cultural Methods for the Enrichment and Isolation of Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 5, American Public Health Association, pp. 45-51	

Examiner
Signature

/Kailash Srivastava/

Date
Considered

01/07/2013

DWT 20279871v1 0066090-008US1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.S./

Application Number 	Application/Control No. 12/360,796	Applicant(s)/Patent under Reexamination SAMADPOUR, MANSOUR	

Document Code - DISQ	Internal Document – DO NOT MAIL
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TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 1/3/13	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Felicia D. Roberts

7,534,584

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

National Beef Ex. 1009
Page 060

Electronic Patent Application Fee Transmittal

Application Number:	12360796			
Filing Date:	27-Jan-2009			
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS			
First Named Inventor/Applicant Name:	Mansour Samadpour			
Filer:	Barry Davison/Peachie Chan			
Attorney Docket Number:	66090-008US1			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	645	645

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Statutory or terminal disclaimer	2814	1	80	80
Total in USD (\$)				905

Electronic Acknowledgement Receipt

EFS ID:	14607391
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Peachie Chan
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-008US1
Receipt Date:	03-JAN-2013
Filing Date:	27-JAN-2009
Time Stamp:	14:47:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$905
RAM confirmation Number	4739
Deposit Account	040258
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

National Fee 1009

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	134013 7d61b878f064cdb0e7d653253038619c29e0a166	yes	10
Multipart Description/PDF files in .zip description					
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	8	
	Applicant Arguments/Remarks Made in an Amendment		9	10	
Warnings:					
Information:					
2	Terminal Disclaimer Filed	TerminalDisclaimerPatNo7534584B2.pdf	119664 0a33a142dbc210a6b9c3a7aa26b6d85fa832add7	no	1
Warnings:					
Information:					
3	Transmittal Letter	IDS3Letter.pdf	66161 3e3d342800345e35388ca3b7d5daa1a14a30e7c8	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	IDS3.pdf	130441 1b7dc05da4dfbb4cc1f16752464d5be635cc4b2	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Fee Worksheet (SB06)	fee-info.pdf	33879 981229b5f8e15828d9339129c4ade2ba0a8d378e7	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			484158		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

ATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour
Application No.: 12/360,796
Filing Date: 27 January 2009
For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL
CONTAMINANTS AND/OR CONSTITUENTS

Art Unit	1657
Examiner	Kailash C. Srivastava
Docket No.:	66090-008US1
Date:	03 January 2013

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR § 1.111

This is a Response in reply to a non-final Office Action dated 05 July 2012, in the above-identified application. Please extend the time for response three months, up to and including 07 January 2013 (05 January 2013 falling on a Saturday). The required fees are submitted herewith.

Kindly amend the above-identified application as follows:

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

No amendments to the claims are made with this Response.

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

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

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

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

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

e) testing of the modular composite sample, and individual testing of each of the enriched separate test lot samples, using at least one suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated,

and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual enriched separate test lot sample, individual separate test lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate test lot samples using the same or a more sensitive protocol and obtaining a negative test result.

2. (Original) The method of claim 1, wherein 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.

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

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

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

6. (Previously presented) 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.

7. (Previously presented) The method of claim 1, wherein testing of the modular composite sample and enriched test lot samples, using at least one suitable detection assay further comprises a concentration step to concentrate the microbial agent or organism.

8. (Previously presented) 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.

9. (Previously presented) The method of claim 8, wherein the more sensitive protocol further comprises a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Previously presented) 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 results.

11. (Previously presented) 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.

12. (Previously presented) 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.

13. (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.

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

15. (Previously presented) 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.

16. (Previously presented) The method of claim 1, wherein, in a), separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions from 5 to 100.

17. (Previously presented) 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.

18. (Previously presented) 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.

19. (Previously presented) 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.

20. (Previously presented) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein each single-unit production lot is separately sampled by taking said plurality of portions thereof;

b) combining the collected 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, and individual testing of each of the enriched separate test lot samples, using at least one 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, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual separate enriched test lot sample, individual separate single-unit production lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate single-unit production lot samples using the same or a more sensitive protocol and obtaining a negative test result.

21. (Previously presented) The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate test lot samples.

22. (Previously presented) The method of claim 20, 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.

23. (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*.

24. (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.

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

26. (Previously presented) 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.

27. (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.

28. (Original) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Previously presented) The method of claim 1, wherein the separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. (Original) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Original) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Non-final Office Action Dated: 05 July 2012
Date of Response: 03 January 2013
Examiner: Kailash C. Srivastava

32. (Previously presented) The method of claim 1, wherein the separate test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

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

34. (Previously presented) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
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Examiner: Kailash C. Srivastava

REMARKS

Claims 1-34 are pending and stand rejected, based on the ground of non-statutory obviousness-type double patenting.

No claims have been amended herein.

Formalities

Restriction/Election. Applicant thanks the Examiner for considering the Response to Restriction Requirement and Preliminary Amendment submitted 28 February 2012.

Priority. Applicant thanks the Examiner for acknowledging the claim for domestic priority under 35 U.S.C. §119 (e) to U.S. 60/599,473 filed 06 August 2004 and the claim for domestic priority under 35 U.S.C. §121 to U.S. 11/199,871 filed 08 August 2005, now US Patent 7,534,584 B2.

IDS. Applicant thanks the Examiner for considering Applicant's IDS submitted 16 April 2012.

Terminal Disclaimer. A Terminal Disclaimer in view of Applicant's U.S. Patent No. 7,534,584 B2 is included with this Response.

Non-Statutory Double Patenting

The Examiner rejected claims 1-34 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 7,534,584 B2.

Applicant, without acquiescing to the merits of the Examiner's rejections, nonetheless herein provides a signed **Terminal Disclaimer** in view of U.S. Patent No. 7,534,584 B2.

Applicant, therefore, respectfully requests withdrawal of the Examiner's non-statutory obviousness-type double patenting rejection.

Applicant respectfully contends that all claims are allowable as presently presented.

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
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CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Response and Amendment and allowance of the pending claims. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

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

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**TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**Docket Number (Optional)
66090-008US1

In re Application of: Mansour Samadpour

Application No.: 12/360,796

Filed: January 27, 2009

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

The owner*, Institute for Environmental Health, Inc., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 7,534,584 B2 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

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 or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 47,309

/Barry L. Davison, Ph.D., J.D./

Signature

January 3, 2013

Date

Barry L. Davison, Ph.D., J.D.

Typed or printed name

(206) 757-8023

Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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.**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mansour Samadpour
Application No. : 12/360,796
Filed : 27 January 2009
For : MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL
CONTAMINANTS AND/OR CONSTITUENTS

Examiner : Kailash C Srivastava
Art Unit : 1657
Docket No. : 66090-008US1
Date : 03 January 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

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

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

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the

information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

A fee of \$180.00 accompanies the PTO/SB/08 Equivalent and this letter, all submitted herewith, for which the Commissioner is authorized to charge Deposit Account No. 04-0258. Additionally, the Commissioner is authorized to credit overpayments or to charge any deficiency in a required fee to Deposit Account No. 04-0258 of Davis Wright Tremaine LLP.

Respectfully submitted,

Mansour Samadpour
DAVIS WRIGHT TREMAINE LLP

By /Barry L. Davison/
Barry L. Davison, Ph.D.
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/360,796		Filing Date 01/27/2009		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☒ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	01/03/2013	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 34	Minus	** 34	= 0	X \$31 =	0	OR	X \$	=
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0	X \$125 =	0	OR	X \$	=
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR	X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR	X \$	=
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/DEBORAH DOTSON/

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

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

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Andrews, et al., "Salmonella," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 37, American Public Health Association, pp. 357-380	
	2	Budiman, et al., "Localization of Jointless-2 Gene in the Centromeric Region of Tomato Chromosome 12 based on High Resolution Genetic and Physical Mapping," Theoretical and Applied Genetics, Volume 108, 2004, published online September 2003, pp. 190-196	
	3	Cousin, et al., "Psychotrophic Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 13, American Public Health Association, pp. 159-166	
	4	Entis, et al., "Rapid Methods for Detection, Identification, and Enumeration," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 10, American Public Health Association, pp. 89-126	
	5	The International Committee on Microbiological Specifications for Foods (ICMSF), "Microorganisms in Foods, 1 Their Significance and Methods of Enumeration," 2 nd Edition, 1978, University of Toronto Press, pp. 3-10 and 91-172	
	6	Kuo, et al., "Sample Pooling to Expedite Bioanalysis and Pharmacokinetic Research," Journal of Pharmaceutical and Biomedical Analysis, Volume 16, 1998, pp. 837-846	
	7	Meng, et al., "Pathogenic Escherichia coli," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 35, American Public Health Association, pp. 331-341	
	8	Midura, et al. "Sampling Plans, Sample Collection, Shipment and Preparation for Analysis," Compendium of Methods for the Microbiological Examination of Foods, 4 th Edition, 2001, Ch. 2, American Public Health Association, pp. 13-23	
	9	Skov, et al., "Evaluation of Sampling Methods for the Detection of Salmonella in Broiler Flocks," Journal of Applied Microbiology, Volume 86, 1999, pp. 695-700	
	10	Sperber, et al. "Cultural Methods for the Enrichment and Isolation of Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 5, American Public Health Association, pp. 45-51	

Examiner
SignatureDate
Considered

DWT 20279871v1 0066090-008US1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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 2 hours 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.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mansour Samadpour
Application No. : 12/360,796
Filed : January 27, 2009
For : MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS
AND/OR CONSTITUENTS

Examiner : Kailash C Srivastava
Art Unit : 1657
Docket No. : 66090-008US1
Date : October 4, 2012

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

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

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing ten (10) references to be considered by the Examiner. Also enclosed are copies of references, as listed on the Information Disclosure Statement by Applicant (PTO/SB/08 Equivalent) submitted herewith.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that

the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

A fee of \$180.00 accompanies the PTO/SB/08 Equivalent and this letter, all submitted herewith, for which the Commissioner is authorized to charge Deposit Account No. 04-0258. Additionally, the Commissioner is authorized to credit overpayments or to charge any deficiency in a required fee to Deposit Account No. 04-0258 of Davis Wright Tremaine LLP.

Respectfully submitted,
Mansour Samadpour
DAVIS WRIGHT TREMAINE LLP

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Electronic Patent Application Fee Transmittal

Application Number:	12360796			
Filing Date:	27-Jan-2009			
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS			
First Named Inventor/Applicant Name:	Mansour Samadpour			
Filer:	Barry Davison/Justinia Ells			
Attorney Docket Number:	66090-008US1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt

EFS ID:	13904158
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Justinia Ells
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-008US1
Receipt Date:	04-OCT-2012
Filing Date:	27-JAN-2009
Time Stamp:	12:58:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 180
RAM confirmation Number	5770
Deposit Account	040258
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 1009

National Fee ES

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	66090-008US1_IDS.pdf	131692	no	2
			f89dc66c646cfac8b86c5f1647561f3f0f604e2d		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Transmittal Letter	66090-008US1_IDS_Letter.pdf	71039	no	2
			d11d6e1e41aa88b900d2bbfa0ce87542ac24fa99		
Warnings:					
Information:					
3	Non Patent Literature	Andrews_Salmonella.pdf	3039517	no	26
			55c3883f31e813596de9095ea69c01a9512f8623		
Warnings:					
Information:					
4	Non Patent Literature	BUDIMANLocalizationofJointless2.pdf	4292773	no	7
			c0e073f3393925700c1322c5de0275bcc191c2a8		
Warnings:					
Information:					
5	Non Patent Literature	Cousin_PsychotropicMicroorganisms.pdf	2352079	no	10
			7b83645bb5c51efb53449cbd30d96b9bb1fee478		
Warnings:					
Information:					
6	Non Patent Literature	Entis_RapidMethodsforDetection.pdf	14304243	no	40
			37b0d8747e7fa0edd0c6e3e475b89dac1a341b51		
Warnings:					
Information:					
7	Non Patent Literature	ICMSF_MicroorganismsinFoods.pdf	21464433	no	57
			7b05b5834829690ead405212f78411d401d56e84		
Warnings:					
Information:					
8	Non Patent Literature	KUO_Samplepoolingtoexpedite.pdf	4316120	no	10
			fa3bb4f827cbb52a5774e1628d12a893cb6fd8af		

Warnings:					
Information:					
9	Non Patent Literature	Meng_PathogenicEColi.pdf	3628874	no	13
			e573a056e605eea933b4495e6f906d41276e1887		
Warnings:					
Information:					
10	Non Patent Literature	Midura_SamplingPlans.pdf	2989112	no	13
			8e2a41ba3dae6cba3013361d72faab5ab714774c		
Warnings:					
Information:					
11	Non Patent Literature	SKOV_EvaluationofSamplingMethods.pdf	2975581	no	6
			1b333cbc5739ddc3286cc5bbb2cc2fe5a21a0c2b		
Warnings:					
Information:					
12	Non Patent Literature	Sperber_CulturalMethods.pdf	4112185	no	9
			ec9c33007f27568bb0a9be608b7b2c5ffd8347a0		
Warnings:					
Information:					
13	Fee Worksheet (SB06)	fee-info.pdf	30458	no	2
			94802efcc18b335cce9437f3f4cbeb9e737babf3		
Warnings:					
Information:					
Total Files Size (in bytes):			63708106		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/360,796

01/27/2009

Mansour Samadpour

66090-008US1

7046

22504

7590

07/05/2012

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

07/05/2012

ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

seapatentdocket@dwt.com

Office Action Summary	Application No. 12/360,796	Applicant(s) SAMADPOUR, MANSOUR	
	Examiner KAILASH C. SRIVASTAVA	Art Unit 1657	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-34 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/16/2012</u> . | 6) ☐ Other: ____. |

DETAILED ACTION

Applicant's response filed 28 February 2012 to Office Action with Election/Restriction requirement mailed 29 August 2011 is acknowledged and entered.

Claims Status

According to the response filed 28 February 2012, Claims 1-34 are presented for examination.

Restriction/Election

Applicant's election with traverse filed 28 February 2012 to Office Action with Election/Restriction requirement mailed 29 August 2011 is acknowledged and entered. Applicants have elected Group I, encompassing Claims 1-19, 21 and 23-34 and species (A) - Single Unit Production lot as in Claim 2 and (B) - "a single-combo" for further prosecution.

In accordance with Applicant's arguments that patentably the species are obvious variants, the election requirement of Groups and species is hereby withdrawn. Groups I and II together with their respective species are hereby rejoined and Claims 1-34 are fully examined for patentability under 37 C.F.R. §1.104. As a result of rejoinder *supra*, former groups I-II are regrouped as invention of group I encompassing Claims 1-34.

Claims 1-34 are examined on merits.

Informals

The instant application (i.e., 12/360,796) has been assigned to Kailash C. Srivastava now in Art Unit 1657 at the United States Patent and Trademark Office (i.e., USPTO). To aid in correlating any papers for the instant application (i.e., 12/360,796), all further correspondence regarding the instant application (i.e., 12/360,796) should be directed to **Examiner Kailash C. Srivastava in Art Unit 1657**.

Priority

Claim for domestic priority under 35 U.S.C. §119 (e) to U.S. 60/599,473 filed 06 August 2004 is acknowledged.

Claim for domestic priority under 35 U.S.C. §121 to U.S. 11/199,871 filed 08 August 2005, now US Patent 7,534,584 B2 is acknowledged.

Information Disclosure Statement

Information Disclosure Statement (i.e., IDS) filed on 16 April 2012 is acknowledged, has been made of record, considered and duly initialed FORM PTO/SB/08A is enclosed with the instant Office Action.

Non –Statutory Double Patenting

The following non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being un-patentable over claims 1-33 of U.S. Patent 7,534,584 B2 to Samadpour. Although, the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compositions (e.g., test specimens (e.g., Claim 1a, Line 3), lots (e.g., Claim 2 of the patent), method steps (e.g., evaluation criteria (e.g., Claim 6 of the Patent) of the instant application (e.g., Claims 1a- 1d 17 a-e),

or target microorganisms (e.g., Claims 19 and 20 of the patent 7,534,584 B2 $\cong$ Claims 23-24) are used in the methods and compositions of cited U.S Patent 7,534,584 B2. Thus, one of skill in the art would have expected successful results for the method and composition instantly claimed and would have been motivated to claim methods and compositions based on the claimed subject matter in the U.S. Patent cited *supra*.

The claimed invention in the instant application is also not distinct from the invention claimed in U.S. Patent No. 7,534,584 B2 (i.e., the parent application) because the instant claims are obvious variants of the patented claims. Furthermore, the instant claims appear not to have been filed strictly in response to a restriction requirement, but appear to be a new set of claims and the instant application is a CON of the USSN 11/199,871 which resulted in the U.S. Patent 7,534,584 B2.

Applicant is apprised that The United States Patent and Trademark Office now provides for an e-Terminal Disclaimer in EFS-Web. For more information please see <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>. The new e-Terminal Disclaimer provides applicants with many advantages and promotes greater efficiency in the patent examination process. This web-based e-Terminal Disclaimer can be filled out completely online through web-screens and no EFS-Web fillable forms are required. E-Terminal Disclaimers are auto-processed and approved immediately upon submission if the request meets all of the requirements.

Fees must be paid immediately which will then provide users more financial flexibility. A paper filed Terminal Disclaimer requires a fee but does not guarantee a Terminal Disclaimer approval. Each e-Terminal Disclaimer filed requires a single terminal disclaimer fee, but can include up to 50 "reference applications" and 50 "prior patents".

Conclusion

For the aforementioned reasons, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (U.S. Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C. Srivastava/

Examiner

Art Unit 1657

☎: (571) 272-0923

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657

Notice of References Cited	Application/Control No. 12/360,796		Applicant(s)/Patent Under Reexamination SAMADPOUR, MANSOUR	
	Examiner KAILASH C. SRIVASTAVA		Art Unit 1657	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,534,584 B2	05-2009	Samadpour, Mansour	435/34
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	"6080437"	USPAT	OR	OFF	2012/06/26 08:35
L2	1	"7919232"	USPAT	OR	OFF	2012/06/26 08:36
L3	2	WO-2006017832-\$.did.	EPO; DERWENT	OR	OFF	2012/06/26 08:45
L4	907	(caracass\$8 or meat\$7 or food or pharmaceutical\$5 or sample) same lot	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:30
L5	10084	(target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:34
L6	163463	(composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:38
L7	95	L4 same L6	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:40
L8	4	L7 same L5	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:41
L9	1572	(caracass\$8 or meat\$7 or food or pharmaceutical\$5 or sample) and lot	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:43
L10	20265	(target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:43
L11	275247	(composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:44
L12	351	L9 and L11	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:44
L14	1237	((micro\$4 or microbiolo\$5) and(quality control)) and ((Meat and process\$4) or(slaughter house))	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:52
L15	4	L14 and L9	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:53
L16	51	L14 and L10	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:53
L19	75	L11 and L14	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:55
L20	3	L9 and L19	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:55
L22	51	L10 and L14	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:56
L23	12	L19 and L22	EPO; JPO; DERWENT	OR	OFF	2012/06/26 09:56
L24	907	(caracass\$8 or meat\$7 or food or pharmaceutical\$5 or sample) same lot	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:00

EAST Search History (Prior Art)

L25	10084	(target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:01
L26	163463	(composit\$5 or mixed or combine\$3 or enrich\$6) same (lot or sample or portion)	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:01
L27	20265	(target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:02
L28	95	L24 same L26	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:03
L29	4	L28 same L25	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:04
L30	4	L29 same L4	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:05
L31	4	L29 same L5	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:05
L32	4	L29 same L6	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:05
L33	4	L29 same L7	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:06
L34	4	L29 same L8	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:06
L35	4	L30 same L34	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:06
L36	4	L35 same L33	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:07
L37	4	L36 same L32	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:07
L38	4	L37 same L31	EPO; JPO; DERWENT	OR	OFF	2012/06/26 10:07

Search Notes 	Application/Control No. 12360796	Applicant(s)/Patent Under Reexamination SAMADPOUR, MANSOUR
	Examiner KAILASH C SRIVASTAVA	Art Unit 1657

SEARCHED			
Class	Subclass	Date	Examiner
Partial Search in EAST	Partial Search in EAST and in WEST	6/26/2012	KCS
NONE	NONE	6/26/2012	KCS
Partial Search in WEST	Partial Search in WEST	6/27/2012	KCS
NONE	NONE	6/27/2012	KCS

SEARCH NOTES		
Search Notes	Date	Examiner
Case discussed with Dr. Weber for ODP rejection	6/19/2012	KCS
Inventor Name search	6/26/2012	KCS
Assignee Name search	6/26/2012	KCS
Verified Application priority data (e.g., 60/599,473 filed 08/06/2004 and CON of 11/199,871 filed 08/08/2005 now USPATENT 7,534,584) in e-DAN	6/26/2012	
EAST Search in DWPI, EPAB, JPAB, PGPB, USPT with following Search Strategy:	6/26/2012	KCS
(caracass\$8 or meat\$7 or food or ,pharmaceutic\$5 or sample)and lot (target or test) and (microb6 or microorganism or (Escherichia coli) or,salmonella or(pathogenic microb\$6)) , (composit\$5 or mixed or combine\$3 or,enrich\$6) and (lot or sample or portion) , ((micro\$4 or microbiolo\$5) and(qualitycontrol)) and ((Meat and process\$4)or(slaughter house))	6/26/2012	KCS
WEST Search in DWPI, EPAB, JPAB, PGPB, USOC, USPT	6/27/2012	KCS
WEST Sarch Strategy: (((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)) or ((micro\$4 or microbiolo\$5) and (qualitycontrol)) and ((Meat and process\$4)or(slaughter house)) or (sampl\$5 or specimen or material or portion) and(enrich\$5 and ((pathogenic bacteria) or Salmonella orListeria\$9)) and (discriminat\$8 or separat\$7 or isolat\$8)and (sampl\$5 or specimen or material or portion) and((caracass\$8 or meat\$7 or food or pharmaceu	6/27/2012	KCS

/KAILASH C SRIVASTAVA/ Examiner.Art Unit 1657	
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SEARCH NOTES

Search Notes	Date	Examiner
sample) and lot or (composit\$5 or mixed or combine\$3or enrich\$6) and (lot or sample or portion)) or (((mixedor combined) and lot) and(sample or specimen ormaterial or portion) or (sampl\$5 or specimen or materialor portion) and (pooled or composite or lot)) and((micro\$4 or microbiolo\$5) and (quality control)) and((Meat and process\$4)or(slaughter house))) and((sampl\$5 or specimen or material or portion) and(enrich\$5 and ((pathogenic bacteria) or Salmonella orListeria\$9))	6/27/2012	KCS

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/KAILASH C SRIVASTAVA/
Examiner.Art Unit 1657

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

U.S. PATENT DOCUMENTSFOREIGN PATENT DOCUMENTS

Examiner
Signature

/Kailash Srivastava/

Date
Considered

06/12/2012

DWT 193662774 0066090-008UN1

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	12/360,796
Filing Date	January 27, 2009
First Named Inventor	Mansour Samadpour
Art Unit	~~1655~~ 1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-008US1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ANDREWS et al., "BAM: Food Sampling/Preparation of Sample Homogenate," Bacteriological Analytical Manual, 2003, Chapter 1.	
		BERRI, et al., "The Detection of <i>Coxiella Burnetii</i> from Ovine Genital Swabs, Milk and Fecal Samples by the Use of a Single Touchdown Polymerase Chain Reaction," Veterinary Microbiology, 2000, 2:285-293	
Citation Incomplete		"Cultural Methods for the Enrichment and Isolation of Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 5, American Public Health Association	
		DAVIES et al., "Evaluation of the Use of Pooled Serum, Pooled Muscle Tissue Fluid (meat juice) and Pooled Faeces for Monitoring Pig Herds for <i>Salmonella</i> ," Journal of Applied Microbiology, 2003, 95:1016-1025	
		"Diarrheagenic <i>Escherichia coli</i> ," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4A, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4a.html on June 17, 2008	
		"Enumeration of <i>Escherichia coli</i> and the Coliform Bacteria," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4.html on June 17, 2008	
Citation Incomplete		GABIS, et al., "ICMSF Methods Studies. II. Comparison of Analytical Schemes for Detection of <i>Salmonella</i> in High-Moisture Foods," Canadian Journal of Microbiology, 1974, 20:663-669	
		The International Committee on Microbiological Specifications for Foods, <i>Food Microbiology: Principles and Methods of Enumeration</i> , 2 nd Edition, 1978, University of Toronto Press	
		JARVIS, B., "Errors Associated with Dilution Count and Presence/Absence Methods," Statistical Aspects of the Microbiological Analysis of Foods, Progress in Industrial Microbiology, 1989, Ch. 8, Vol. 21, Elsevier Science	
		JARVIS, B., "Errors Associated with Quantal Response Methods," Statistical Aspects of the Microbiological Examination of Foods, 2008, Ch. 8:143-176, Academic Press, Amsterdam, London, and San Diego	
		JARVIS, B., "On the Compositing of Samples for Qualitative Microbiological Testing," Letters in Applied Microbiology, 2007, 45:592-598	
		JARVIS, B., "Statistical Aspects of the Microbiological Analysis of Foods, Progress in Industrial Microbiology," 1989, 21: 117-142, Elsevier Science Publishers B.V.	
		"Microbiological Testing Program and other Verification Activities for <i>Escherichia coli</i> O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components," US Department of Agriculture, FSIS Directive, 2004, 10 010.1, Rev. 1	
Citation Incomplete		"Pathogenic <i>Escherichia coli</i> ," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 35, American Public Health Association	
		PRICE et al., " <i>Salmonella</i> Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples," Applied Microbiology, April 1972, Vol. 23, No. 4, 679-682	
Citation Incomplete		"Psychotrophic Microorganisms," Compendium of Methods for the Microbiological Examination of Foods, 4 th Ed., 2001, Ch. 12, American Public Health Association	

Examiner Signature	/Kailash Srivastava/	Date Considered	06/13-14/2012
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DWT 19366877v1 0066090-008US1

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* citation is incomplete because author name and oages are not recited Page 101

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known	
			Application Number	12/360,796
			Filing Date	January 27, 2009
			First Named Inventor	Mansour Samadpour
			Art Unit	~~1653~~ 1657
			Examiner Name	Kailash C. Srivastava
			Attorney Docket Number	66090-008US1
Sheet	3	of	3	

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, page(s), volume-issue number(s), publisher, city and/or country where published.	T ‡
n Incomplete		"Rapid Methods for Detection, Identification, and Enumeration," ~~Compendium of Methods for the Microbiological Examination of Foods, 4th Ed., 2001, Ch. 10~~ American Public Health Association	
		RENTER, et al., "Diversity, Frequency, and Persistence of <i>Escherichia coli</i> O157 Strains from Range Cattle Environments," <i>Applied and Environmental Microbiology</i> , 2003, Vol. 69, No. 1:542-547	
		ROHLF, F.J., et al., "Optimizing Composite Sampling Protocols," <i>Environmental Science and Technology</i> , 1996, Vol. 30, No. 10:2899-2905	
n Incomplete		" <i>Salmonella</i> ," ~~Compendium of Methods for the Microbiological Examination of Foods, 4th Ed., 2001, Ch. 37~~ American Public Health Association	
		SAMADPOUR, et al., "Laboratory Investigation of an <i>E. coli</i> O157:H7 Outbreak Associated with Swimming in Battle Ground Lake, Vancouver, Washington," <i>Journal of Environmental Health</i> , 2002, Vol. 64, No. 10:16-20	
n Incomplete		"Sampling Plans, Sample Collection, Shipment and Preparation for Analysis," ~~Compendium of Methods for the Microbiological Examination of Foods, 4th Edition, 2001, Ch. 2~~ American Public Health Association	
		SILLIKER et al., "ICMSF Methods Studies. I. Comparison of Analytical Schemes for Detection of <i>Salmonella</i> in Dried Foods," <i>Canadian Journal of Microbiology</i> , 1973, 19: 475-479	
		SILLIKER et al., "Laboratory Methods," <i>Food-Borne Infections and Intoxicants</i> , 1989, Ch. XI: 455-474, Academic Press, New York and London.	
		THOMAS et al., "Examination of Stockfeeds for <i>Salmonella</i> ," <i>Australian Veterinary Journal</i> , February 1981, 57:69-71.	

*Citation is incomplete because author name and page numbers are not recited.

Examiner Signature	/Kailash Srivastava/	Date Considered	06/15/2012
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DWT 193662774 000090-008081

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WEST Search History for Application 12360796

Creation Date: 2012062712:41

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
quality control	USPT	ADJ	YES		06-27-2012
composite sample	USPT	ADJ	YES		06-27-2012
Intermediate sample	USPT	ADJ	YES		06-27-2012
ladder sampl\$5	USPT	ADJ	YES		06-27-2012
(mixed lot) same (sample)	USPT	ADJ	YES		06-27-2012
(composite sample) same (Intermediate sample)	USPT	ADJ	YES		06-27-2012
(quality control) same (composite sample)	USPT	ADJ	YES		06-27-2012
(quality control) and (Intermediate sample)	USPT	ADJ	YES		06-27-2012
(stepwise)same (sample analysis)	USPT	ADJ	YES		06-27-2012
discriminat\$8 same sampl\$5	USPT	ADJ	YES		06-27-2012
(stepwise) same (sample analysis)	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and ((stepwise) same (sample analysis))	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and (composite sample)	USPT	ADJ	YES		06-27-2012
(Pharmaceutical sample)	USPT	ADJ	YES		06-27-2012
(quality control) and ((Pharmaceutical sample))	USPT	ADJ	YES		06-27-2012
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ	YES		06-27-2012
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
(discriminat\$8 same sampl\$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		06-27-2012
		ADJ	YES		06-27-2012

(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI				
quality control	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
composite sample	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
discriminat\$8 and sampl\$5	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(discriminat\$8 and sampl\$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))	PGPB, USPT	ADJ	YES		06-27-2012

((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))	PGPB, USPT	ADJ	YES		06-27-2012
(pooled same sample)	PGPB, USPT	ADJ	YES		06-27-2012
sample Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		06-27-2012
((pooled same sample)) same (sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella same sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
(sample same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		06-27-2012
sample and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(pooled and sample)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
sample and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((pooled and sample)) and (sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sample and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))) and ((pooled and sample) and sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot	PGPB, USPT	ADJ	YES		06-27-2012
(target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic	PGPB, USPT	ADJ	YES		06-27-2012

microb\$6))					
(composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	PGPB, USPT	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))	PGPB, USPT	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) same ((target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))	PGPB, USPT	ADJ	YES		06-27-2012
((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot) same ((composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion))	PGPB, USPT	ADJ	YES		06-27-2012
((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) same ((target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))	PGPB, USPT	ADJ	YES		06-27-2012
quality control	PGPB, USPT	ADJ	YES		06-27-2012
composite sample	PGPB, USPT	ADJ	YES		06-27-2012
((mixed or combined) same lot) same (sample or specimen or material or portion)	PGPB, USPT	ADJ	YES		06-27-2012
(discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)	PGPB, USPT	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	PGPB, USPT	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))	PGPB, USPT	ADJ	YES		06-27-2012
((((mixed or combined) same lot) same (sample or specimen or material or portion)) or ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)) same ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) same (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella	PGPB, USPT	ADJ	YES		06-27-2012

or(pathogenic microb\$6)))					
((((mixed or combined) same lot) same (sample or specimen or material or portion)) or ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)) or ((composite sample) or ((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)))	PGPB, USPT	ADJ	YES		06-27-2012
(((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion))) or (((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot)) or ((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))))	PGPB, USPT	ADJ	YES		06-27-2012
(((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))) same (quality control)	PGPB, USPT	ADJ	YES		06-27-2012
(((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9)))) same ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	PGPB, USPT	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house))) or (((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion)) or	PGPB, USPT	ADJ	YES		06-27-2012

((sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))))					
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Salmonella)					
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same quality control same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))	PGPB, USPT	ADJ	YES		06-27-2012
(((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)) or ((discriminat\$8 or separat\$7 or isolat\$8) same (sampl\$5or specimen or material or portion) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (((micro\$4 or microbiolo\$5) same (quality control)) same ((Meat same process\$4)or(slaughter house)))	PGPB, USPT	ADJ	YES		06-27-2012

Salmonella or Listeria\$9))) same quality control same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) or (composite sample or (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)) or ((sampl\$5 or specimen or material or portion) Same (pooled or composite or lot) or (sampl\$5 or specimen or material or portion) same (enrich\$5 same ((pathogenic bacteria) or Salmonella or Listeria\$9))) same (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (((mixed or combined) same lot) same (sample or specimen or material or portion) or (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample)same lot same (composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion) same (target or test) same (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6)))					
(caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or(pathogenic microb\$6))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composit\$5 or mixed or combine\$3 or enrich\$6) same(lot or sample or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4)or(slaughter house))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
((mixed or combined) and lot) and(sample or specimen or material or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012

(discriminat\$8 or separat\$7 or isolat\$8) and (sampl\$5 or specimen or material or portion)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot) or ((composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion))) or ((((mixed or combined) and lot) and (sample or specimen or material or portion)) or ((sampl\$5 or specimen or material or portion) and (pooled or composite or lot)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
(((target or test) and (microb6 or microorganism or (Escherichia coli) or salmonella or (pathogenic microb\$6))) or (((micro\$4 or microbiolo\$5) and (quality control)) and ((Meat and process\$4) or (slaughter house)))) or ((sampl\$5 or specimen or material or portion) and (enrich\$5 and ((pathogenic bacteria) or Salmonella or Listeria\$9)))	USOC, EPAB, JPAB, DWPI	ADJ	YES		06-27-2012
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(((caracass\$8 or meat\$7 or food or pharmaceutic\$5 or sample) and lot or (composit\$5 or mixed or combine\$3 or enrich\$6) and (lot or sample or portion)) or (((mixed or combined) and lot) and(sample or specimen or material or portion) or (sampl\$5 or specimen or material or portion) and (pooled or composite or lot)))					
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<i>Application Number</i>	12/360,796
<i>Filing Date</i>	January 27, 2009
<i>First Named Inventor</i>	Mansour Samadpour
<i>Art Unit</i>	1653
<i>Examiner Name</i>	Kailash C. Srivastava
<i>Attorney Docket Number</i>	66090-008US1

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STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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Complete if Known

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Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-008US1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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Examiner
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Considered

DWT 19366877v1 0066090-008US1

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(Use as many sheets as necessary)

Sheet	3	of	3
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Complete if Known

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<i>Filing Date</i>	January 27, 2009
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Examiner Name	Kailash C. Srivastava
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(72) Inventor; and

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(74) Agents: **DAVISON, Barry, L.** et al.; 2600 Century Square, 1501 Fourth Avenue, Seattle, WA 98101-1688 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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(54) Title: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

(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.

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

FIELD OF THE INVENTION

5 Aspects of the present invention relate generally to improving the efficiency of producing food and health related (*e.g.*, pharmaceutical) products, and the safety and quality thereof. Particular embodiments relate to novel methods for microbial pathogen testing that allow for enhanced sensitivity, cost savings and traceability (*e.g.* source tracking) for remedial purposes. The methods are broadly applicable to many product areas including, but not limited
10 to beef, pork, sheep, bison, deer, elk, poultry (*e.g.*, chicken and turkey) and fish and other seafoods, produce, juices, dairy products, dry goods (cereals, nuts, etc), fruits and vegetables, herbs and spices, and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, air samples taken by impingers and filtration, etc), pharmaceuticals, and other types of samples to be analyzed using microorganism enrichment-
15 detection protocols.

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of priority to United States Provisional Patent Application Serial Number 60/599,473, filed 06 August 2004 and entitled MODULAR WET
20 COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, which is incorporated by reference herein in its entirety.

BACKGROUND

Manufacturers and respective regulatory agencies strive to continually improve the safety
25 and the quality of foods, pharmaceuticals, nutraceuticals, water and the environment. Under recent United States Department of Agriculture, Food Safety and Inspection Service (FSIS) directives and guidelines, many food producers in the United States have adopted sampling plans that involve testing, for example, of raw beef trims and/or ground beef for *E. coli* O157:H7, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella*. Similar
30 trends are observed in other countries, for products detained for domestic consumption and/or

export. For example, the pharmaceutical industry spends considerable resources on sterility testing and environmental monitoring, and the water and wastewater industry and their respective regulatory agencies allocate considerable resources to monitor the quality of water (e.g., drinking, recreational and fisheries resources), wastewater (treated and untreated) and sludge (biosolids). Concern for the quality of air has resulted in monitoring of indoor air for the presence of microbial contaminants and pathogens. These sampling plans associated with such testing determine, for example, the disposition of products and the production lots, or result in decisions regarding the safety of water, receiving waters and recreational waters, and the impact of wastewater discharge, and quality of air.

The operative art with respect to such product "hold and release" monitoring efforts comprises various different sampling plans, typically pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA or EPA guidelines, or intuitive sampling plans. The common feature of these sampling plans is that several samples representing production lots, or a number of environmental samples, are combined into a combined production lot prior to sampling. For example, a typical plan for microbial pathogen detection calls for taking more than one sample, for instance ten (10) to sixty (60) sample pieces from a given sample lot (combined production lot), to form a *composite sample* for testing. The number of pieces taken to form the composite sample depends, under ICMSF or other regulatory guidelines, on the outcome of infection/poisoning (e.g., the severity), the level of hazards, and potential increase in the hazard levels due to storage. The same holds true in detecting microbial constituents and/or spoilage organisms. With respect to *E. coli* O157 testing, for example, a typical plan calls for taking 60 samples (e.g., sample pieces) from a production lot to form a single composite sample. With respect to *Listeria monocytogenes*, thirty (30) samples are typically taken from a production lot to form a composite sample. With respect to sterility testing, a typical plan may call for compositing 10-100 units of the product, and in the case of environmental sampling, 2-10 samples are often composited. Generally, the number of samples that are composited reflects: the overall sensitivity of the test method and the limit of detection that applies to the test unit; the ability to concentrate/enrich the composite sample to achieve the desired sensitivity; and the cost of

sampling compared with the cost of analysis.

The costs associated with testing food are substantial, and consequently manufacturer's often resort to increasing the size of the "production lot" to be tested. For instance, the standard size production lot for trim testing for *E. coli* O157 in the U.S. beef industry is five (5) 'combos' (each combo weighing approximately 2,000 pounds), and for *Listeria* and *Salmonella* in ready-to-eat (RTE) products, it is one composite sample per production line per shift. A primary problem associated with the use of large size test lots is that a large quantity of products must be downgraded or destroyed when there is a positive finding of a pathogen. Additionally, because of the nature of combination 'lotting' (combining, for purposes of forming the test lot, several independent sub-lots that collectively span a long period of production time), it is very difficult to investigate the cause of the failure and pinpoint the source/cause, and remedial measures cannot be effectively taken. Furthermore, compositing a large number of samples may result in reduced sensitivity for the test unit and adversely effect the limit of detection.

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

The above-described prior art has several substantial deficiencies. *First*, even though the prior art production lot encompasses several production sublots (for instance 5 combo/pallets of products, or an entire shift of production), if a positive finding is obtained for the production lot (composite test sample), the entire production lot is rejected (all 5 combos/pallets, or one shift of production) and diverted to economically undesirable end uses (*e.g.*, cooking or disposal), even though the pathogen of concern may be confined to only a limited portion of the production sublots (corresponding to one or two combos/pallets or an hour of production) comprising the

production lot.

Second, the current art does not allow for retesting of any production sublots, primarily because microbial contaminants are unevenly spread throughout the products, and in many instances the levels of contamination are minute and may be present on very small portions of the products in each subplot. Therefore, once a composite sample is constructed if it tests positive all of the sublots are destroyed. The regulatory agencies do not allow for re-testing of the sublots, premised on the argument that after a production lot tests positive, negative test results obtained for production sublots, or even a new production lot composite sample, are meaningless since the microbial contaminants are not uniformly present throughout the products.

Third, the current protocols for collecting a composite sample representing a production lot often group together production sublots that are unrelated by virtue of product type or hours of production. This makes investigating the nature of the failure a difficult task even when relevant information is available. As an example, information is frequently available on a 'per combo' basis including (but not limited to) hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated combos/pallets are included in a production lot it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option since it may not yield the same result). Likewise, for sterility testing, when the composite sample tests positive, the entire production will be disposed.

Therefore, there is a pronounced need in the art to implement novel and effective testing protocols that provide a greater measure of assurance that the food product is safe, that provide economic relief to the producer, and that allow for effective tracking of the contaminated lot(s) for remedial purposes (*e.g.*, pinpointing the time of the contamination and determine the segment of production which was impacted).

SUMMARY OF THE INVENTION

Aspects of the present invention provide novel enrichment, testing and detection methods for detection of pathogens or other microbes in, for example, food, water, wastewater,

industrial, pharmaceutical, botanical, environmental samples and other types of samples analyzed by detection methods (e.g., enrichment-detection methods). According to particular aspects, where any microbiological testing program involves compositing a number of samples to form a test lot, independent enrichment of each of the components of the composite sample is performed with subsequent formation of a modular (e.g., wet modular) composite sample by combining portions from each independent enrichment, which allows for determining the outcome of the test for each individual subunit of the composite as opposed to generalizing the results of the test sample to all of its subunits. This individual outcome determination is achieved by retesting the individual enrichment samples in the event that the composite enrichment tests positive.

In preferred aspects, a reportable lot is defined as a single unit of a modular (e.g., modular wet) composite lot, rather than as an entire composite lot comprised of multiple sublots. For example, a reportable production lot is defined as a single unit of production and corresponds to a single unit of a modular wet composite production lot, rather than (as in the prior art) as an entire composite lot comprised of multiple production units (multiple sublots). 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. Multiple aliquots of the enrichment media may be removed for analysis, thus circumventing the prior art problem of having to re-sample a test production lot where microbial contaminants are not uniformly present throughout the product.

In the exemplary context of enriched single units of production, equal portions of enrichment buffer are removed (aseptically) from each single-unit production lot sample and combined to form a *Modular Wet Composite Sample* (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target agent (e.g., target organism). If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are

released. Significantly, if a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single-unit production lot samples are separately (individually) tested, using the same test protocol, or a test protocol with enhanced sensitivity, or any appropriate test protocol. According to particular preferred aspects, the signal obtained from a MWCS is due to one or more of its components (*e.g.*, reportable lots (*e.g.*, individually enriched single production units)), and it is, therefore, possible in all cases to trace a positive signal to one or more individual subunits by testing each individual enrichment sample for the same target. When a *positive* finding is obtained for any individual reportable lot sample (*e.g.*, single-unit production lot sample), that particular reportable lot (*e.g.*, single-unit production lot) is deemed to be positive, and appropriate actions are taken based on the result. In the case of pathogen/microbial testing for foods, the individual positive sublots can be diverted to cooking, disposal, or other acceptably safe endpoint. The rest of the individually enriched test units that test negative are deemed to be negative and will be reported as such (are validated).

DETAILED DESCRIPTION OF THE INVENTION

Particular aspects provide novel enrichment, testing and validation methods for detection of pathogens or other microbes in any type of samples (*e.g.*, food production lots, water, wastewater, industrial, pharmaceutical, botanical, environmental samples, etc.) analyzable by enrichment-detection methods. In preferred aspects, a test lot (single-unit production lot), rather than (as in the prior art) a composite lot comprised of multiple test lots (*e.g.*, single-unit production lot units), is defined and established as the single unit of production. A plurality of portions (*e.g.*, product portions) are separately collected from each test lot (*e.g.*, single-unit production lot) and composited to form a corresponding set of test lot samples (*e.g.*, single-unit production lot samples), which are enriched using suitable enrichment protocols to allow target agents/organisms to reach detectable levels and sample uniformity. In particular embodiments, equal portions of enrichment buffer are removed (preferably aseptically) from the enriched samples, and combined to form a modular composite sample (*e.g.*, modular wet composite sample; MWCS). The MWCS, for example, is tested using a suitable detection assay for the target agent/organism. If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are validated and releasable. If a *positive* result is obtained

from a MWCS, the enrichment sample corresponding to individual test lots (*e.g.*, individual single-unit production lots) are separately (individually) tested, using the same, or a more sensitive test protocol. If a *positive* finding is obtained for any test lot sample (*e.g.*, individual single-unit production lot sample), that particular respective lot is diverted to cooking, disposal, or other acceptably safe endpoint. If a *negative* finding is obtained for any individual test lot sample (*e.g.*, single-unit production lot sample), then that particular lot is validated and releasable. In this manner, any member lot of the MWCS that tests *negative* using the same method (about 5-fold more sensitive relative to the prior art), or an enhanced method (about fifty times more sensitive), will be validated and releasable for consumption.

DEFINITIONS

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

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 “product portion” as used herein refers to a product piece (*e.g.*, a piece of solid beef trim, etc.), aliquot of product (*e.g.*, a volume of liquid juice) or weight of product (*e.g.*, a weight of semi-solid pudding). A single unit of production is composed of multiple product portions. In preferred embodiments, the number of product portions which comprise a single unit of production is great enough that removal of some product portions to form a sample does not impose an unacceptable economic loss to the producer. In particular instances, a product

portion may be a specimen of a test lot as defined above.

The term “compositing” as used herein refers to combining a number of single product portions to form one larger sample. In preferred embodiments, the number and selection of single product portions to be combined conform to statistical-based sampling plans which seek to form a typical or average sample that is representative of the test lot (*e.g.*, single production unit) being sampled.

The term “test lot sample” or “single-unit production lot sample” or “single production unit lot sample,” as used herein refers to a sample formed by combining multiple product portions from a test lot (*e.g.*, single production unit), such that each test sample (*e.g.*, each single-unit production lot sample) is attributed to a particular corresponding test lot (*e.g.*, production unit). For production lot samples, the number of portions/pieces combined may be essentially any number, but preferably is selected so as to conform to statistical-based sampling plans. Preferably the number of pieces combined is selected from the range group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 product portions. Preferably, the number of independent product portions is selected so as to yield a sample size that is equal to or greater than that required by the subsequent analysis to be applied.

The term “enrichment” as used herein refers to incubating a test lot sample (*e.g.*, single-unit production lot sample) under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform throughout the enriched test lot sample (*e.g.*, single-unit production lot sample). Preferably, enrichment comprises addition of an amount of an enrichment medium or buffer to a sample, and incubating the sample at a favorable temperature for a period of time sufficient to allow the organism to grow and multiply.

The term “enrichment medium” as used herein refers to a mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism. Preferably, the enrichment medium is formulated to mimic the environment of the target agent/organism or take advantage of a known metabolic property of the target agent/organism. Preferably, the enrichment medium will omit nutrients needed by

competing undesired agents/organisms. Preferably, the enrichment medium will include selective agents that will inhibit competing undesired agents/organisms. An example of an enrichment medium is that used for the isolation of nitrogen fixing bacteria (those that can use nitrogen gas as their sole nitrogen source) contains no source of fixed nitrogen in the medium.

5 A second example is an enrichment medium for the isolation of bacteria capable of utilizing 2,4-dichlorophenoxyacetic acid (also know as 2,4-D, a common herbicide) as a source of carbon and energy. The enrichment medium is formulated to contain benzoate as the only organic compound.

The term “wet enrichment” as used herein refers to diluting a solid, semisolid or liquid single-unit production lot sample (single production unit lot sample) with enrichment medium in a ratio of approximately 1:10 (wt./v), consistent with conventional methods for expanding and testing a variety of target agents/organisms as set forth in widely recognized published methods. For example, the conventional method for expanding and testing for coliforms, fecal coliforms and *E. Coli* in food, comprises a 1:10 dilution of the samples (*e.g.*, 50 g into 450 ml) (*see, e.g.*,
15 U.S. FDA Bacteriology Analytical Manual Online, Chapter 4 and 4A, describing standard 1:10 dilution procedures for testing of coliforms, fecal coliforms and *E. Coli* in food, shellfish and juices).

The term “dry enrichment” as used herein refers to enriching a solid, semisolid or liquid single unit production lot sample either with no addition of other compounds if the sample’s
20 intrinsic properties (water activity, nutrients and pH) are sufficient/proper to promote the growth of the target agent/organism, or by dilution of the sample with minimal amounts of enrichment medium in ratios ranging from about 0.1 (wt/v) to about 1 (wt/v).

The term “modular composite sample” as used herein refers to a sample formed by removing, preferably aseptically, equal portions of each of a plurality of enriched single-unit
25 production lot samples, and combining the removed portions.

The phrase “suitable detection assay” as used herein refers to any assay that is suitable for detecting a particular agent/organism. Preferably, the assay is optimized to detect the particular agent/organism, and may be combined with one or more concentration steps for concentration of the agent/organism being assayed.

The term “validation” as used herein with respect to production lots refers to determining that a particular sample tests *negative* using the detection assay. Where a modular composite sample tests *negative*, all single-unit production lot samples comprising the composite sample are validated along with the respective single-unit production lots, which are thus cleared for release. Where a modular composite sample tests *positive*, individual single unit production lots may nonetheless yet be validated if particular respective single-unit production lot samples test *negative*.

“Trim” refers to small pieces of meat and fat which are excised during, for example, the beef fabrication process in order to produce primal and subprimal pieces and marketable cuts.

“Trim testing” refers to the process of testing trim, or raw materials which are to be used for ground meat production for microbial/pathogen content.

A “combo” or “combo-bin” refers, in the beef industry, to the single production unit packaging unit. Alternatively raw materials corresponding to a single production unit to be tested can be packaged into boxes, bags or other appropriate containers, which can be placed, for example, on pallets.

A “composite lot-unit” or “five-combo-lot unit” refers to a *composite* unit, comprised of five combos (combo-bins). In prior art sampling plans, the composite lot-unit represents the raw material (composite trim) upon which sampling, testing and acceptance or rejection is based.

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.

In preferred embodiments, a number of pieces or portions of sample are collected from a test lot (*e.g.*, from a single production unit (*e.g.*, from the single combo, bin, pallet, or segment of production, etc.)), and composited to form one ‘*single-unit test sample*’ (or ‘*single-unit*

production lot sample.' In particular embodiments (e.g., wet enrichment), enrichment buffer is added to the sample. In alternate embodiments, 'dry enrichment' (as defined herein above) is done.

Significantly, in the inventive modular (e.g., wet modular) compositing method, samples taken from each unit of production are enriched *separately* 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. In preferred aspects, such enrichment obviates the prior art problem of having microbial contaminants that are not uniformly present throughout the product sample. Specifically, while microbes are not necessarily uniformly distributed in food, water, air, pharmaceuticals, etc, after enriching a sample as described herein, the target microbes are uniformly, or as least substantially uniformly, present in the enrichment medium or extract from dry or semi dried enrichments.

Following incubation for the target organism, equal portions of enrichment buffer or sample are removed (aseptically) from each of several test lot samples (e.g., from several single-unit production lot samples; preferably 5) and pulled together to form a Modular Wet Composite Sample (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target organism. If a *negative* result is obtained from the MWCS, then all of the individual single unit production Lots are released.

If a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single unit production lot samples are then separately (individually) tested, using the same test protocol, or any other appropriate tests. Alternately, an augmented protocol that uses a concentration step for the target organism, such as immunomagnetic bead separation, affinity chromatography, etc., followed by an appropriate detection method is used to test the enriched individual test lot samples (e.g., the individual single-unit production lot samples).

In preferred aspects, the inventive methods of analysis are modified by introducing a concentration step (e.g., employing antibody-coated paramagnetic beads into the procedure (e.g., DNA-based detection, biosensor based detection, classical microbiological detections, etc)). Antibody-coated paramagnetic beads, for example, afford an approximately 10-fold increase in sensitivity. This concentration step, combined with the fact that the individual test lot samples

(e.g., individual single-unit production lot samples) are not 5-fold diluted relative to the MWCS, allows for an overall 50-fold increase in sensitivity relative to prior art sampling and testing protocols. If a lateral flow device is used for detection, such immunomagnetic concentration may or may not be used, in which case the detection sensitivity is increased by about 5-fold.

5 Where a *positive* finding (test result) is obtained for any individual test lot sample (e.g., single-unit production lot sample), that particular corresponding test lot (e.g., single-unit production lot) is deemed to be positive, and appropriate decisions are then made on the positive results (e.g., in the case of food products, diversion to cooking, disposal, or other acceptably safe endpoint). For each of the rest of the test lot samples (e.g., single-unit production lot samples) 10 belonging to the positive MWCS, where a *negative* finding is obtained, that particular test lot sample (e.g., that single-unit production lots sample) is deemed to be negative. In this manner, any test lot (e.g., any single-unit production lot) that is a member of the group of test lots (e.g., single-unit production lots) that comprise a corresponding MWCS, will be considered to be negative, if it tests *negative* using the same method (about 5-fold more sensitive relative to the 15 prior art), or the enhanced method (about fifty times more sensitive).

 In alternate preferred embodiments, a new Modular Wet Composite Sample is reconstructed from the member lots (test lots) that have tested *negative*, and subjected to a third layer of testing to again show (confirm) that they are negative. Specifically if one of the five individual test lots (e.g., individual single-unit production lots) has tested positive (and the other 20 four negative), and the protocols call for testing of composites consisting of five test lots, a new single test lot sample can formed from a new test lot, and can be used along with the four negative samples to form a new MWCS.

 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 25 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.

5 Additionally, and significantly, it is easier to trace the source of the contamination and apply remedial measures, because the single-unit test component points, for example, to single point of production or a single sampling site.

Particular Preferred Aspects:

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.

25 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.

In particular aspects, where testing of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol. Preferably, the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

In particular aspects, the methods further comprise forming an additional modular composite sample from the enriched test lot samples and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status. In particular aspects, the methods further comprise forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples that test negative, and testing the additional modular composite sample, using the same or a different suitable assay. In particular aspects, the methods further comprise, where testing of the modular composite sample is negative, forming an additional modular composite sample from the enriched test lot samples, and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

In particular aspects, the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a segment of production. Preferably, the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

In particular aspects, the methods further comprise, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application

of remedial measures that are specific to one or more individual test lots that test positive. In particular aspects, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions. Alternatively, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

Particular aspects provide a method of sampling, testing and validating test lots, comprising: separately 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 product specimens, wherein the assemblage can be sampled by taking portions thereof; combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot; incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched single-unit production lot samples; removing, aseptically, equal portions of each enriched single-unit production 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 single-unit production lot samples are validated, and wherein where such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

The following Examples are exemplary are not intended, and should not be construed to limit the scope of the aspects of the present conception that are claimed hereunder.

EXAMPLE I

(The present inventive methods were shown to provide a substantial economic advantage, while providing for enhanced safety, and implementation of remedial measures)

At present, the standard size 'production lot' for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five *combos*, where each *combo* represents a single production unit and weighs approximately 2,000 pounds. An inventive modular composite sample method, and in particular a Modular Wet Composite Sample (MWCS) method was implemented at a United States beef producer. TABLE 1 shows, according particular aspects, the result of testing 62,919 MWCS samples, and then retesting the individual single-unit production lot (combo) samples whenever a *positive* result was obtained from the MWCS sample.

TABLE 1 shows that out of 62,919 MWCS samples, a total of 217 yielded a *positive* testing result for *E. coli* O157. Using prior art protocols, all of the single-unit production lots that comprised the 271 positive samples would go to rendering or be downgraded for cooking. As each MWCS represents five single-unit production lots of 2,000 lbs each, this would represent approximately 2,710,000 pounds of product (*i.e.*, $271 \times 5 \times 2,000$ pounds = 2,710,000 pounds).

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.

Furthermore, as outlined above under “BACKGROUND,” information is frequently available on a ‘per combo’ basis including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated *combos* are included in a combined ‘production lot’ (as in the prior art) it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option since it may not yield the same result).

By contrast, in this Example I and according to preferred aspects of the present invention, any *combo*-specific information including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps can be brought to bear in the context of the 391 individual single-unit production lots yielding a *positive* sample result, thereby providing an effective means not only to trace contamination, but also to affect remedial measures in view thereof.

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

EXAMPLE II

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of Ready-to-Eat (RTE) products (e.g., meat and poultry products))

Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may adapt an 'end product' sampling program as verification that their product is free of the pathogen *Listeria monocytogenes*. The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (e.g., from 'cleanup to cleanup'), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis.

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

Individual single-unit production lot samples are collected, to which, in wet enrichment embodiments, enrichment medium/buffer is added. Following incubation under conditions suitable to allow levels of a target agent or organism that is present to reach detectable levels and become uniform or substantially uniform throughout the respective sample(s), aliquots of the enrichment medium/buffers from individual single-unit production lot samples are combined to form a MWCS. The MWCS is then analyzed for the presence or absence of, for example, *Listeria* spp. or *L. monocytogenes*. In the event that a *positive* result is obtained for the MWCS, enrichment medium/buffer sample from the individual single-unit production lot samples comprising that MWCS is analyzed using the same, or augmented testing protocols.

Individual single-unit production lots for which the enrichment medium/buffer from the corresponding sample yields a *positive* result are diverted to cooking, disposal or other safety

endpoint. Individual single-unit production lots for which the enrichment medium/buffer from the corresponding sample yields a *negative* result are released into commerce. The latter fraction represents a direct cost savings to the producer relative to a prior art approaches where a 'production lot' is defined to include multiple single-unit production lots (e.g., multiple product lines and an extended period of time ('cleanup to cleanup')).

Furthermore, by defining and establishing the individual single-unit production lots in such a fashion as to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply remediative resources more effectively and efficiently. For example, where a *positive* result(s) is associated with one or more specific production lines, targeted aggressive sanitation is used to resolve the problem. Alternatively, for example, where a *positive* result(s) is associated with one or more specific products, determining whether raw materials are contaminated, or whether process microbial intervention steps were operating properly are effectively and efficiently used.

EXAMPLE III

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility for providing cost-effective and effective monitoring means for pathogen levels in nut products (e.g., almond products) and the like)

A large number of almond products may be produced by using one or more processes including slivering, scalding, blanching, slicing, roasting, and dicing. Anti-microbial treatments may also be applied, such as use of propylene oxide. In practice, these processes may be used in many various combinations, and the output from one process may be the input for another. This makes it very difficult to trace finished product all the way back to raw materials.

As indicated by a recent outbreak, almond products are susceptible to contamination by *Salmonella* spp. According to additional aspects, the present inventive methods provide a cost-effective means of implementing an effective monitoring program for pathogen levels in nut products (e.g., almond products). In such embodiments, final almond products of each type are collected at random times over a production shift. The producer defines and establishes individual single-unit production lots as the amount of product produced during a production shift (from 'cleanup to cleanup'), or as some smaller production unit (e.g., a 'truckload'),

provided that one sample was collected from each such single-unit production lot. The single-unit production lot samples are combined to form a corresponding composite sample, and, in wet enrichment embodiments, enrichment medium/buffer is added to the composite sample to allow *Salmonella* spp. to grow and multiply under the favorable conditions of enrichment (as described herein above), thereby providing more material that can be detected by subsequent analysis.

Aliquots of the enrichment medium/buffers from individual single-unit production lot samples are combined to form a MWCS. The MWCS are analyzed for the presence or absence, for example, of *Salmonella* spp. Where a *positive* result is obtained for the MWCS, each enrichment buffer from the individual single-unit production lot samples comprising that MWCS is analyzed using the same, or augmented testing protocols.

Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *positive* result are returned for application of additional microbial intervention steps (*e.g.*, roasting), or are diverted to a safe endpoint (*e.g.*, a cooked product). Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *negative* result are thereby validated and are releasable into commerce. The latter fraction represents a direct cost savings to the producer relative to prior art approaches where effective testing is not done, and discovery of contamination with a pathogen leads to large scale recalls of product.

Furthermore, by defining and establishing the individual production single-unit production lots in such a fashion as to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply remedial resources more effectively and efficiently. For example, the processes used to produce the almond product(s) yielding *positive* result(s) are rationally analyzed, and associations between the pathogen contamination and one or more of the processes of slivering, scalding, blanching, slicing, roasting, and dicing are determined, and targeted effective and efficient remedial measures are applied.

EXAMPLE IV

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of contaminants that enter a production line at a given time point, and then clear)

5 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
10 (operationally linked test lots) flanking the contamination event.

EXAMPLE V

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of environmental monitoring (*e.g.*, with samples of water,
15 wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids))

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
20 for the microbe of concern.

CLAIMS

1. A method of sampling, testing and validating test lots, comprising:

a) 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 specimens, wherein the assemblage can be
5 sampled by taking portions thereof;

b) 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;

c) incubating the set of test lot samples under conditions suitable to allow levels of a
10 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;

d) removing, aseptically, equal portions of each enriched 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
15 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.

2. The method of claim 1, wherein the test lot is selected from the group consisting
20 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.

3. The method of claim 1, wherein the test lot is a single-unit production lot,
25 comprised of operationally-linked product specimens.

4. The method of claim 3, wherein product specimens are synonymous with product portions.

5. The method of claim 1, further comprising incubating the modular composite

sample of d), prior to testing in e).

6. The method of claim 1, wherein incubating each test lot sample in c) comprises adding an amount of enrichment medium to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. The method of claim 1, wherein where testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

9. The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched 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.

12. 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 enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. 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 segment of production.

14. The method of claim 1, wherein the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

15. The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive.

16. The method of claim 1, wherein, in a) separately collecting a plurality of portions
5 from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions.

17. The method of claim 1, wherein, in a) separately collecting a plurality of portions
10 from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions.

18. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions.

19. The method of claim 1, wherein, in a) separately collecting a plurality of portions
15 from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. A method of sampling, testing and validating test lots, comprising:

a) separately collecting a plurality of portions from each of a plurality of single-unit
20 production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

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

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

production lot samples;

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

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

10

Electronic Acknowledgement Receipt

EFS ID:	12554284
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Peachie Chan
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-008US1
Receipt Date:	16-APR-2012
Filing Date:	27-JAN-2009
Time Stamp:	19:34:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS1.pdf	143232 970c86a375c1e178aaa515c5878e2280c3b946ab	no	3

Warnings:

Information:

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2	Foreign Reference	WO2006017832InstituteForEnv ironmentalHealth.PDF	1525370 f45c94cdcedac9b5e9cdc25faa27d998c77b4a36	no	26
Warnings:					
Information:					
3	Non Patent Literature	AndrewsEtAlBAMFoodSamplin gPreparation.PDF	974961 0bd27a392470ee90d55d908656df89a87098038f	no	11
Warnings:					
Information:					
4	Non Patent Literature	BerriEtAlTheDetectionOfCoxiell aBurnetiiFromOvine.pdf	606214 21fc41f8bfcbe9de2ea58fe59e994495d2756e46	no	9
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Information:					
5	Non Patent Literature	CulturalMethodsForTheEnrich mentAmericanPublicHealthAss ociation.pdf	4120609 c00defac0654d705eea9620f1d66d1a8d507b3af	no	9
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Information:					
6	Non Patent Literature	DaviesEtAlEvaluationOfTheUse OfPooledSerum.pdf	714285 c0cf9954f0e9bd326fc9d15915bc37a066c6f003	no	11
Warnings:					
Information:					
7	Non Patent Literature	DiarrheagenicEscherichiaColiU SFoodAndDrugAdministration. PDF	3384784 913f51dbc752990a3048b4b71ded268787372562	no	11
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Information:					
8	Non Patent Literature	EnumerationOfEscherichiaColi AndTheColiformBacteriaUSFoo dAndDrugAdministration.PDF	4577551 2ddcc19ff41bea250b5dc8c9708f444f96d473ca	no	15
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Information:					
9	Non Patent Literature	GabisEtAlICMSFMethodsStudie sIIComparisonOfAnalytical.PDF	1167171 d68bd1b51690a862216b58269f4b1a97e98c8d0d	no	7
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10	Non Patent Literature	TheIntlCommitteeOnMicrobiol ogicalSpecificationsForFoodsT heirSignificanceAndMethodsOf Enumeration.pdf	21472435 8c8ee48fd3d37cd94d88d757574ac2565f25036c	no	57

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14	Non Patent Literature	JarvisBStatisticalAspectsOfTheMicrobiologicalAnalysis.pdf	10568880	no	28
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15	Non Patent Literature	MicrobiologicalTestingProgramAndOtherVerificationActivitiesUSDeptOfAgriculture.pdf	5139938	no	28
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16	Non Patent Literature	PathogenicEscherichiaColiCompendiumOfMethodsForTheMicrobiologicalAmericanPublicHealthAssociation.pdf	3631104	no	13
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18	Non Patent Literature	PsychotrophicMicroorganismsAmericanPublicHealthAssociation.pdf	2351837	no	10
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19	Non Patent Literature	RapidMethodsForDetectionAmericanPublicHealthAssociation.pdf	14303247	no	40
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20	Non Patent Literature	RenterEtAlDiversityFrequencyAndPersistenceOfEscherichiaColi.pdf	669369	no	6
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21	Non Patent Literature	RohlFJEtAlOptimizingCompositeSamplingProtocols.pdf	548369	no	7
			4e4a05d2ae2e323ee7bb227f112e5f33d3bd127c		
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22	Non Patent Literature	SalmonellaCompendiumOfMethodsForTheMicrobiologicalExaminationAmericanPublicHealthAssociation.pdf	3038907	no	26
			a95a242d8172d29f8ce16d64213039f110bd7836		
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23	Non Patent Literature	SamadpourEtAlLaboratoryInvestigationOfAnEColi.PDF	598501	no	5
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24	Non Patent Literature	SamplingPlansSampleCompendiumOfMethodsForTheMicrobiologicalAmericanPublicHealthAssociation.pdf	2988799	no	13
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25	Non Patent Literature	SillikerEtAlCMSFMethodsStudiesComparisonOfAnalyticalSchemesForDetection.pdf	671363	no	5
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26	Non Patent Literature	SillikerEtAlLaboratoryMethodsFoodBourneInfectionsAndIntoxicants.pdf	1388660	no	23
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27	Non Patent Literature	ThomasEtAlExaminationOfStockfeedsForSalmonella.pdf	386130	no	3
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Total Files Size (in bytes):			93404952		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour
Application No.: 12/360,796
Filing Date: 27 January 2009
For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL
CONTAMINANTS AND/OR CONSTITUENTS

Art Unit 1653
Examiner Kailash C. Srivastava
Attorney Docket No.: 66090-008US1
Date: 28 February 2012

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

This is a Response to a Restriction Requirement dated August 29, 2011, in the above-identified application. Please extend the time for response five months, up to and including February 29, 2012. The requisite fee is provided.

Remarks begin on page 9 of this Response.

Application No.: 12/360,796
Attorney Docket No.: 66090-008US1
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Restriction Requirement: 29 August 2011
Date of Preliminary Amendment: 28 February 2012
Examiner: Kailash C. Srivastava

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

There are no claim amendments made by this Response.

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

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

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

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

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

e) testing of the modular composite sample, and individual testing of each of the enriched separate test lot samples, using at least one suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive with respect to the modular composite sample, or with

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respect to an individual enriched separate test lot sample, individual separate test lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate test lot samples using the same or a more sensitive protocol and obtaining a negative test result.

2. (Original) The method of claim 1, wherein 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.

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

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

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

6. (Previously presented) 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.

7. (Previously presented) The method of claim 1, wherein testing of the modular composite sample and enriched test lot samples, using at least one suitable detection assay further comprises a concentration step to concentrate the microbial agent or organism.

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8. (Previously presented) 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 ~~use of~~ the more sensitive protocol.

9. (Previously presented) The method of claim 8, wherein the more sensitive protocol further comprises a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Previously presented) 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 results.

11. (Previously presented) 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.

12. (Previously presented) 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.

13. (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.

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

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15. (Previously presented) 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.

16. (Previously presented) The method of claim 1, wherein, in a), separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions from 5 to 100.

17. (Previously presented) 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.

18. (Previously presented) 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.

19. (Previously presented) 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.

20. (Previously presented) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein each single-unit production lot is separately sampled by taking said plurality of portions thereof;

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b) combining the collected 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, and individual testing of each of the enriched separate test lot samples, using at least one 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, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual separate enriched test lot sample, individual separate single-unit production lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate single-unit production lot samples using the same or a more sensitive protocol and obtaining a negative test result.

21. (Previously presented) 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.

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22. (Previously presented) The method of claim 20, 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.

23. (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*.

24. (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.

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

26. (Previously presented) 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.

27. (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.

28. (Original) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Previously presented) The method of claim 1, wherein the separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

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30. (Original) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Original) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (Previously presented) The method of claim 1, wherein the separate test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

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

34. (Previously presented) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism.

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REMARKS

Claims 1-34 are pending and subject to restriction. No claims have been amended herein.

Group Election

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

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

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

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

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

Additional Species Election

The Examiner is requiring a species election.

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

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

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

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

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Examiner: Kailash C. Srivastava

Applicants respectfully contend that the claims are all allowable as presented herein.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests entry of the present Response provided herein and allowance of all claims. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8075
Facsimile: 206-757-7075

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Kaye D. Fleming, Ph.D./
Kaye D. Fleming, Ph.D.
Attorney for Applicants
Registration No. 63,880

Electronic Patent Application Fee Transmittal

Application Number:	12360796			
Filing Date:	27-Jan-2009			
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS			
First Named Inventor/Applicant Name:	Mansour Samadpour			
Filer:	Kaye Denning Fleming/Peachie Chan			
Attorney Docket Number:	66090-008US1			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 5 months with \$0 paid	2255	1	1345	1345

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				1345

Electronic Acknowledgement Receipt

EFS ID:	12181498
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Kaye Denning Fleming/Peachie Chan
Filer Authorized By:	Kaye Denning Fleming
Attorney Docket Number:	66090-008US1
Receipt Date:	28-FEB-2012
Filing Date:	27-JAN-2009
Time Stamp:	16:58:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1345
RAM confirmation Number	4637
Deposit Account	040258
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

National Fee \$ 1009

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ResponseToRestrictionRequirement.pdf	131450 fcb6e551a084009eddbeea61fd0a55645974d6b9	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Response to Election / Restriction Filed	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	10

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30649 b4a25c5e71d9189d81c51a28d965ddbc1ebeda89	no	2
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Warnings:

Information:

Total Files Size (in bytes):	162099
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/360,796		Filing Date 01/27/2009		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☒ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
			TOTAL			TOTAL				
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	02/26/2012	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 34	Minus	** 34	=	0		X \$	=	
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	=	0		X \$	=	
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	0		TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	Total (37 CFR 1.16(i))	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			X \$	=	
	Independent (37 CFR 1.16(h))	*	Minus	***	=			X \$	=	
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE			TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/PATRICIA WARNER/

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/360,796

01/27/2009

Mansour Samadpour

66090-008US1

7046

22504

7590

08/29/2011

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1653

NOTIFICATION DATE

DELIVERY MODE

08/29/2011

ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

seapatentdocket@dwt.com

Office Action Summary	Application No. 12/360,796	Applicant(s) SAMADPOUR, MANSOUR
	Examiner KAILASH C. SRIVASTAVA, Examiner	Art Unit 1653

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) ☐ Notice of References Cited (PTO-892)</p> <p>2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) ☐ Notice of Informal Patent Application</p> <p>6) ☐ Other: _____.</p> |
|---|--|

DETAILED ACTION

1. The Preliminary Amendment filed 29 June 2009 is acknowledged and entered.

Claims Status

2. According to the Preliminary Amendment filed 29 June 2009, following is the current Claims status in the instant application:

- Claims 1, 6-12, 14-22, 26, 29 and 32-34 have currently been amended; and
- Claims 1-34 are presented for examination.

Informals

3. The instant application (i.e., 12/360,796) currently under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been assigned to Kailash C. Srivastava in the Art Unit 1653. To aid in correlating any papers for this application (i.e., 12/360,796), all further correspondence regarding this application (i.e., 12/360,796) should be directed to Examiner Kailash C. Srivastava in Art Unit 1653.

Priority

4. Applicant's Claim for priority under 35 U.S.C. §119 (e) to 60/599,473 filed 06 August 2004 is acknowledged.
5. Applicants' Claim for priority under 35 U.S.C. §121 to U. S. Non Provisional Application 11/199,871 filed 08 August 2005; now U.S. Patent 7,534,584 is acknowledged.

Election/Restriction

6. Restriction to one of the following inventions is required under 35 U.S.C. §121:
 - Group I comprising Claims 1-19, 21 and 23-34 drawn to a method to sample, test and validate test lots for microbial contamination comprising sampling a plurality of test lots, classified under Class 435, Subclass 30 for example.

- Group II comprising Claims 20 and 22 drawn to a method to sample, test and validate test lots for microbial contamination comprising sampling a plurality of single-unit production lots, classified under Class 435, Subclass 34 for example.

Inventions are Independent and Distinct

7. The inventions are distinct, each from the other because of the following reasons:

Method inventions in Groups I-II are related to each other as methods disclosed as usable together. The methods are distinct from each other if they are shown to be separately usable. In the instant case for example, invention in Group II despite employing the generic component in Group I is drawn to a method requiring a step to sample a plurality of single-unit production lot, whereas the invention in inventive group I is to sample and validate any lot of sample for being free of microbial contamination.

8. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. §101 and/or 35 U.S.C. §112, first paragraph.

Additionally, the distinct inventions of groups I-II), as discussed above, have acquired separate status in the art in view of their different classifications (i.e. designated classes/subclasses) and owing to their recognized divergent subject matter. The inventions, as currently presented, would require different fields of search that would necessitate, for example, searching different classes/subclasses and/or electronic databases/resources, in addition to employing different search queries for appropriate examination of various claimed inventions. It is also noted that the prior art applicable to one invention would not necessarily be applicable to another invention, and therefore would impose a serious search and examination burden on the examiner. In addition, the inventions, as presented, are likely to require different search/examination for non-patent literature, foreign patents, and examination of the claim language and specification for non-prior art issues such as compliance with the statutes concerning new matter, distinctness and scope of enablement, to name a few.

9. Applicants are advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 C.F.R. §1.143) and (ii) identification of the claims encompassing the elected invention group.

10. The election of an invention group may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. §1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicants must indicate which of these claims are readable upon the elected invention.

Should applicants traverse on the ground that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Species Election

11. The instant application contains claims directed to the following patentably distinct species of the claimed invention. Accordingly, if Applicant elects Group I invention for further prosecution, Restriction to one of the following Species is required under 35 U.S.C. §121:

- A. Only one test lot of samples among: environmental lot, or pharmaceutical lot, or single-unit product lot as detailed in Claim 2; and
- B. Only one lot selected from the group consisting of a single combo, single bin, single pallet, or a production assemblage as detailed in Claim 13.

12. The non-taxonomic species listed in previous paragraph are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these species are not obvious variants of each other based on the current record. Accordingly, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention.

13. Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generics claim is finally held to be allowable. Currently Claims 1 and 20 are generic claims.

There is an examination and search burden for the above-mentioned patentably distinct species due to their mutually exclusive characteristics. The species require a special field of

search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 U.S.C. §101 and or 35 U.S.C. §112, first paragraph.

14. **Applicant is advised that the reply to this requirement to be complete must include:**

- (i) an election of only one species to be examined** from the categories listed, even though the requirement may be traversed (37 C.F.R. §1.143); **and**
- (ii) identification of the claims encompassing the elected species**, including any claims subsequently added.

An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

15. The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. §1.144. If claims are added after the election, applicants must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

16. In accordance with 37 C.F.R. §1.499, applicants are required that a reply to this requirement must include an identification of the non-taxonomic species that are listed in I-II *supra*, and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [M.P.E.P. §809.02(a)].

17. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(I).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue X. Liu can be reached at (571)-272-5539 Monday through Friday 9:00 A.M. to 4:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Kailash C. Srivastava
Examiner, Art Unit 1653
(571) 272-0923

/SUE LIU/

Supervisory Patent Examiner, Art Unit 1653



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BIB DATA SHEET

CONFIRMATION NO. 7046

SERIAL NUMBER 12/360,796	FILING or 371(c) DATE 01/27/2009 RULE	CLASS 435	GROUP ART UNIT 1653	ATTORNEY DOCKET NO. 66090-008US1	
APPLICANTS Mansour Samadpour, Seattle, WA; ** CONTINUING DATA ***** This application is a CON of 11/199,871 08/08/2005 PAT 7,534,584 which claims benefit of 60/599,473 08/06/2004 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY ** 07/01/2009					
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and /KAILASH C SRIVASTAVA/2011.08.10 Acknowledged Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY WA	SHEETS DRAWINGS 0	TOTAL CLAIMS 34	INDEPENDENT CLAIMS 2
ADDRESS DAVIS WRIGHT TREMAINE, LLP/Seattle 1201 Third Avenue, Suite 2200 SEATTLE, WA 98101-3045 UNITED STATES					
TITLE MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS					
FILING FEE RECEIVED 891	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/360,796	01/27/2009	Mansour Samadpour	66090-58

CONFIRMATION NO. 7046

PUBLICATION NOTICE



OC000000038287606

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

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

Publication No.US-2009-0258359-A1

Publication Date:10/15/2009

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
12/360,796	01/27/2009	1797	891	66090-58	34	2

CONFIRMATION NO. 7046

22504

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

UPDATED FILING RECEIPT



OC000000036751454

Date Mailed: 07/06/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Mansour Samadpour, Seattle, WA;

Assignment For Published Patent Application

Institute for Environmental Health, Lake Forest Park, WA

Power of Attorney: The patent practitioners associated with Customer Number 22504

Domestic Priority data as claimed by applicant

This application is a CON of 11/199,871 08/08/2005 PAT 7,534,584
which claims benefit of 60/599,473 08/06/2004

Foreign Applications

If Required, Foreign Filing License Granted: 07/01/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/360,796**

Projected Publication Date: 10/15/2009

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

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

Preliminary Class

422

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/360,796	01/27/2009	Mansour Samadpour	66090-58

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

CONFIRMATION NO. 7046
POA ACCEPTANCE LETTER



Date Mailed: 07/06/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/29/2009.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/mbayou/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Mansour Samadpour
Application No. : 12/360,796
Filed : January 27, 2009
For : MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL
CONTAMINANTS AND/OR CONSTITUENTS

Art Unit : 1797
Examiner : Not yet assigned
Docket No. : 66090-58
Date : June 29, 2009

MS Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION

Commissioner for Patents:

In response to the Notice to File Missing Parts dated February 18, 2009, please
find enclosed the following documents:

- ☒ Fee
- ☒ Oath/Declaration
- ☐ Copy of Notice to File Missing Parts
- ☐ Sheets of Formal Drawings
- ☒ Other: Statement Under 37 CFR 3.73(b); Power of Attorney;
Preliminary Amendment

Respectfully submitted,
Mansour Samadpour
DAVIS WRIGHT TREMAINE LLP

By /Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Registration No. 47,309

1201 Third Avenue
Seattle, WA 98101-3045
Phone: (206) 757-8023
Facsimile: (206) 757-7023

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

**Title of
Invention**

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

As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ Application No. 12/360,796, filed on January 27, 2009,
- ☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR(S)

Inventor one: Mansour Samadpour, 6050 50th Avenue NE, Seattle, Washington 98115 Date: 3/27/09

Signature:  Citizen of: US

Inventor two: _____

Signature: _____ Citizen of: _____

Inventor three: _____

Signature: _____ Citizen of: _____

Inventor four: _____

Signature: _____ Citizen of: _____

Inventor five: _____

Signature: _____ Citizen of: _____

☐ Additional inventors or a legal representative are being named on _____ additional form(s) attached hereto.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Mansour Samadpour

Application No./Patent No.: 12/360,796

Filed/Issue Date: January 27, 2009

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

Institute for Environmental Health, Inc., a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title, and interest

The extent (by percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____

To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____

To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____

To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

- ☐ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.



Signature

3.27.09

Date

Mansour Samadpour

Printed or Typed Name

Telephone Number

Principal

Title

This collection of information is required by 37 CFR 3.73(b). 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ASSIGNMENT

WHEREAS, I, Mansour Samadpour (hereinafter referred to as ASSIGNOR), having a post office address of 6050 50th Avenue Northeast, Seattle, Washington 98155, am the sole inventor of an invention entitled "MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS," as described and claimed in the specification forming part of an application for United States letters patent filed January 27, 2009, and assigned Application No. 12/360,796 (said application being a continuation of U.S. Patent Application No. 11/199,871 filed August 8, 2005, which claims priority to U.S. Provisional Patent Application No. 60/599,473 filed August 6, 2004); and

WHEREAS, Institute for Environmental Health, Inc. (hereinafter referred to as ASSIGNEE), a corporation of the State of Washington, having a place of business at 15300 Bothell Way Northeast, Lake Forest Park, Washington 98155, is desirous of acquiring the entire right, title, and interest in and to the invention and in and to any letters patent that may be granted therefor in the United States and in any and all foreign countries;

NOW, THEREFORE, in exchange for good and valuable consideration, the receipt of which is hereby acknowledged, ASSIGNOR hereby sells, assigns and transfers unto said ASSIGNEE, the entire right, title and interest in and to said invention, said application and any and all letters patent which may be granted for said invention in the United States of America and its territorial possessions and in any and all foreign countries, and in any and all divisions, reissues and continuations thereof, including the right to file foreign applications directly in the name of ASSIGNEE and to claim priority rights deriving from said United States application to which said foreign applications are entitled by virtue of international convention, treaty or otherwise, said invention, application and all letters patent on said invention to be held and enjoyed by ASSIGNEE and its successors and assigns for their use and benefit and of their successors and assigns as fully and entirely as the same would have been held and enjoyed by ASSIGNOR had this assignment, transfer and sale not been made. ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks to issue all

letters patent on said invention to ASSIGNEE. ASSIGNOR agrees to execute all instruments and documents required for the making and prosecution of applications for United States and foreign letters patent on said invention, for litigation regarding said letters patent, or for the purpose of protecting title to said invention or letters patent therefor.

Date 3.27.09

By Mansour Samadpour

STATE OF WASHINGTON)
COUNTY OF KING) ss.

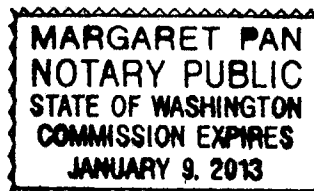
I certify that I know or have satisfactory evidence that Mansour Samadpour is the person who appeared before me, and said person acknowledged that he signed this instrument and acknowledged it to be his free and voluntary act for the uses and purposes mentioned in the instrument.

Dated 03-27-2009

Signature of Notary Public Margaret Pan

Printed Name MARGARET PAN

My appointment expires 01-09-2013



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POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM	Application Number	12/360,796
	Filing Date	January 27, 2009
	First Named Inventor	Mansour Samadpour
	Title	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned
	Attorney Docket Number	66090-58

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

☒ Practitioners associated with the Customer Number:
OR

22504

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or
Individual Name

Address

City

State

ZIP

Country

Telephone

Email

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature



Date

3.27.09

Name

Mansour Samadpour

Telephone

Title and Company

Principal, Institute for Environmental Health, Inc.

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 minutes 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.**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour
Application No.: 12/360,796
Filing Date: 27 January 2009
For: MODULAR COMPOSITING-MULTIPLE LOT SCREENING
PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL
CONTAMINANTS AND/OR CONSTITUENTS

Art Unit 1797
Examiner Not yet assigned
Attorney Docket No.: 66090-58
Date: 29 June 2009

Mail Stop Missing Parts
Commissioner for Patents
Via Electronic Submission

PRELIMINARY AMENDMENT UNDER 37 CFR § 1.115

Sir:

This is a Preliminary Amendment for the above-identified patent application to accompany a Response to File Missing Parts.

Prior to examination on the merits, kindly amend the above-identified application as follows:

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

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

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

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

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

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

e) testing of the modular composite sample, and individual testing of each of the enriched separate test lot samples, using at least one suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual enriched separate test lot sample, individual separate test lots may

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate test lot samples using the same or a more sensitive protocol and obtaining a negative test result.

2. (Original) The method of claim 1, wherein 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.

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

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

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

6. (Currently amended) 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, ~~to the sample~~, 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.

7. (Currently amended) The method of claim 1, wherein testing of the modular composite sample and enriched test lot samples, using at least one suitable detection assay further comprises ~~use of~~ a concentration step to concentrate the microbial agent or organism.

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

8. (Currently amended) The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples~~lots~~ are further tested, such further testing comprises ~~use of~~ the more sensitive protocol.

9. (Currently amended) The method of claim 8, wherein the more sensitive protocol further comprises ~~use of~~ a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Currently amended) 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 results~~status~~.

11. (Currently amended) 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.

12. (Currently amended) 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.

13. (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.

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

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

15. (Currently amended) 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.

16. (Currently amended) The method of claim 1, wherein, in a) ₂ separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions from 5 to 100.

17. (Currently amended) The method of claim 1, wherein, in a) separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot 30 to 60 portions.

18. (Currently amended) The method of claim 1, wherein, in a) separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting 30 portions from each separate test lot.

19. (Currently amended) The method of claim 1, wherein, in a) separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot about 60 portions.

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

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

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

b) combining the collected 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, and individual testing of each of the enriched separate test lot samples, using at least one 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, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual separate enriched test lot sample, individual separate single-unit production lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched separate single-unit production lot samples using the same or a more sensitive protocol and obtaining a negative test result.

21. (Currently amended) 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.

Application No.: 12/360,796
Attorney Docket No.: 66090-58
First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
Date of Preliminary Amendment: 29 June 2009
Examiner: Not yet assigned

22. (Currently amended) The method of claim 20, 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.

23. (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*.

24. (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.

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

26. (Currently amended) 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.

27. (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.

28. (Original) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Currently amended) The method of claim 1, wherein the separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

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Attorney Docket No.: 66090-58
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30. (Original) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Original) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (Currently amended) The method of claim 1, wherein the separate test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

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

34. (Currently amended) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism[[s]].

Application No.: 12/360,796
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Filing Date: 27 January 2009
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REMARKS

This is a Preliminary Amendment to accompany the present Response to Missing Requirements.

Claim amendments:

Applicant has herein made minor, fully-supported preliminary amendments to clarify the claimed subject matter. The amendments, reciting "separately" at various point, strictly conform to identical amendments suggested and introduced by the Examiner in Applicants' underlying parent U.S. Application Serial No. 11/199,871 (now U.S. Patent 7,534,584). Support for the amendments is found throughout the originally filed Specification and including, in particular, the originally-filed claims.

Additionally, claim 7 has been amended to recite "wherein testing of the modular composite sample and enriched test lot samples," to conform with step e) of original claim 1.

Claim 34 has been amended to recite "organism" in place of "organisms."

No new matter has been added.

Applicants respectfully contend that the claims are all allowable as presented herein.

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First Applicant's Name: Mansour Samadpour
Filing Date: 27 January 2009
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CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Preliminary Amendment provided herein and allowance of all claims. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7700

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

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

Electronic Patent Application Fee Transmittal

Application Number:	12360796			
Filing Date:	27-Jan-2009			
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS			
First Named Inventor/Applicant Name:	Mansour Samadpour			
Filer:	Barry Davison/Judy Redmayne			
Attorney Docket Number:	66090-58			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Claims in excess of 20	2202	14	26	364
Miscellaneous-Filing:				
Late filing fee for oath or declaration	2051	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	555	555
Miscellaneous:				
Total in USD (\$)				1446

Electronic Acknowledgement Receipt

EFS ID:	5609965
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-58
Receipt Date:	29-JUN-2009
Filing Date:	27-JAN-2009
Time Stamp:	19:42:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1446
RAM confirmation Number	5599
Deposit Account	040258
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	66090_58_RSP.pdf	3492	no	2
			d87741fe5e007fa3986e5f88b222f44a621e7968		
Warnings:					
Information:					
2	Oath or Declaration filed	66090_58_DEC.pdf	55745	no	1
			06ef5db988ebb52b7483ca610f64d380416efd2d		
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73(b).	66090_58_STM.pdf	146848	no	3
			eb18c66530a05cd94ffe48d21404a9d0689e4889		
Warnings:					
Information:					
4	Power of Attorney	66090_58_POA.pdf	49767	no	1
			a75dc0f5ec84f90bd44432a7f1b944782b520628		
Warnings:					
Information:					
5		66090_58_AMD.pdf	57888	yes	10
			4a86a8956c66a77d7b81bc2459aae5c5be266561		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Preliminary Amendment	1	1		
	Claims	2	8		
	Applicant Arguments/Remarks Made in an Amendment	9	10		
Warnings:					
Information:					
6	Fee Worksheet (PTO-875)	fee-info.pdf	40366	no	2
			89fe82657b0150607bc03b09acaf2dcfb4cf12d9		
Warnings:					
Information:					
Total Files Size (in bytes):			354106		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	5609965
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-58
Receipt Date:	29-JUN-2009
Filing Date:	27-JAN-2009
Time Stamp:	19:42:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
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Payment was successfully received in RAM	\$ 1446
RAM confirmation Number	5599
Deposit Account	040258
Authorized User	

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	66090_58_RSP.pdf	3492	no	2
			d87741fe5e007fa3986e5f88b222f44a621e7968		
Warnings:					
Information:					
2	Oath or Declaration filed	66090_58_DEC.pdf	55745	no	1
			06ef5db988ebb52b7483ca610f64d380416efd2d		
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73(b).	66090_58_STM.pdf	146848	no	3
			eb18c66530a05cd94ffe48d21404a9d0689e4889		
Warnings:					
Information:					
4	Power of Attorney	66090_58_POA.pdf	49767	no	1
			a75dc0f5ec84f90bd44432a7f1b944782b520628		
Warnings:					
Information:					
5		66090_58_AMD.pdf	57888	yes	10
			4a86a8956c66a77d7b81bc2459aae5c5be266561		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Preliminary Amendment	1	1		
	Claims	2	8		
	Applicant Arguments/Remarks Made in an Amendment	9	10		
Warnings:					
Information:					
6	Fee Worksheet (PTO-875)	fee-info.pdf	40366	no	2
			89fe82657b0150607bc03b09acaf2dcfb4cf12d9		
Warnings:					
Information:					
Total Files Size (in bytes):			354106		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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New International Application Filed with the USPTO as a Receiving Office

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/360,796		Filing Date 01/27/2009		☐ To be Mailed			
APPLICATION AS FILED – PART I												
(Column 1)			(Column 2)		SMALL ENTITY ☒		OR		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A		N/A		N/A		N/A			
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A		N/A		N/A		N/A			
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A		N/A		N/A		N/A			
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	X \$	=	X \$	=	X \$	=		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	X \$	=	X \$	=	X \$	=		
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).											
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))												
* If the difference in column 1 is less than zero, enter "0" in column 2.												
APPLICATION AS AMENDED – PART II												
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR		OTHER THAN SMALL ENTITY	
AMENDMENT	06/29/2009	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)
Total (37 CFR 1.16(i))	*	34	Minus	** 34	=	0	X \$	=	X \$	=	X \$	=
Independent (37 CFR 1.16(h))	*	2	Minus	*** 3	=	0	X \$	=	X \$	=	X \$	=
☐ Application Size Fee (37 CFR 1.16(s))												
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))												
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE			
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR		OTHER THAN SMALL ENTITY	
AMENDMENT	Total (37 CFR 1.16(i))	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)
Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	X \$	=	X \$	=	X \$	=
Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	X \$	=	X \$	=	X \$	=
☐ Application Size Fee (37 CFR 1.16(s))												
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))												
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.												
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".												
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".												
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												

Legal Instrument Examiner:
/ANDREW JAMES JR/

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/360,796	01/27/2009	Mansour Samadpour	66090-58

CONFIRMATION NO. 7046

FORMALITIES LETTER



OC000000034421059

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

Date Mailed: 02/18/2009

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$82 to complete the basic filing fee for a small entity.
- The oath or declaration is missing.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$364** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **\$65** for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$891** for a small entity

- **\$82** Statutory basic filing fee.
- **\$65** Surcharge.
- The application search fee has not been paid. Applicant must submit **\$270** to complete the search fee.

- The application examination fee has not been paid. Applicant must submit **\$110** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.
- Total additional claim fee(s) for this application is **\$364**
 - **\$364** for **14** total claims over 20.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/mkibret/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
12/360,796	01/27/2009	1797	0.00	66090-58	34	2

CONFIRMATION NO. 7046

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

FILING RECEIPT



OC000000034421058

Date Mailed: 02/18/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Mansour Samadpour, Seattle, WA;

Assignment For Published Patent Application

Institute for Environmental Health, Lake Forest Park, WA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 11/199,871 08/08/2005
which claims benefit of 60/599,473 08/06/2004

Foreign Applications

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

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

Preliminary Class

422

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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

FIELD OF THE INVENTION

5 Aspects of the present invention relate generally to improving the efficiency of producing food and health related (*e.g.*, pharmaceutical) products, and the safety and quality thereof. Particular embodiments relate to novel methods for microbial pathogen testing that allow for enhanced sensitivity, cost savings and traceability (*e.g.* source tracking) for remedial purposes. The methods are broadly applicable to many product areas including, but not limited to beef,
10 pork, sheep, bison, deer, elk, poultry (*e.g.*, chicken and turkey) and fish and other seafoods, produce, juices, dairy products, dry goods (cereals, nuts, etc), fruits and vegetables, herbs and spices, and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, air samples taken by impingers and filtration, etc), pharmaceuticals, and other types of samples to be analyzed using microorganism enrichment-detection protocols.

15
CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of United States Provisional Patent Application Serial Number 11/199,871, filed 08 August 2005, which claims the benefit of priority to United States Provisional Patent Application Serial Number 60/599,473, filed 06 August 2004 and
20 entitled MODULAR WET COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, both which are incorporated by reference herein in their entirety.

BACKGROUND

25 Manufacturers and respective regulatory agencies strive to continually improve the safety and the quality of foods, pharmaceuticals, nutraceuticals, water and the environment. Under recent United States Department of Agriculture, Food Safety and Inspection Service (FSIS)

directives and guidelines, many food producers in the United States have adopted sampling plans that involve testing, for example, of raw beef trims and/or ground beef for *E. coli* O157:H7, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella*. Similar trends are observed in other countries, for products detained for domestic consumption and/or export. For example, the pharmaceutical industry spends considerable resources on sterility testing and environmental monitoring, and the water and wastewater industry and their respective regulatory agencies allocate considerable resources to monitor the quality of water (e.g., drinking, recreational and fisheries resources), wastewater (treated and untreated) and sludge (biosolids). Concern for the quality of air has resulted in monitoring of indoor air for the presence of microbial contaminants and pathogens. These sampling plans associated with such testing determine, for example, the disposition of products and the production lots, or result in decisions regarding the safety of water, receiving waters and recreational waters, and the impact of wastewater discharge, and quality of air.

The operative art with respect to such product “hold and release” monitoring efforts comprises various different sampling plans, typically pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA or EPA guidelines, or intuitive sampling plans. The common feature of these sampling plans is that several samples representing production lots, or a number of environmental samples, are combined into a combined production lot prior to sampling. For example, a typical plan for microbial pathogen detection calls for taking more than one sample, for instance ten (10) to sixty (60) sample pieces from a given sample lot (combined production lot), to form a *composite sample* for testing. The number of pieces taken to form the composite sample depends, under ICMSF or other regulatory guidelines, on the outcome of infection/poisoning (e.g., the severity), the level of hazards, and potential increase in the hazard levels due to storage. The same holds true in detecting microbial constituents and/or spoilage organisms. With respect to *E. coli* O157 testing, for example, a typical plan calls for taking 60 samples (e.g., sample pieces) from a production lot to form a single composite sample. With respect to *Listeria monocytogenes*, thirty

(30) samples are typically taken from a production lot to form a composite sample. With respect to sterility testing, a typical plan may call for compositing 10-100 units of the product, and in the case of environmental sampling, 2-10 samples are often composited. Generally, the number of samples that are composited reflects: the overall sensitivity of the test method and the limit of detection that applies to the test unit; the ability to concentrate/enrich the composite sample to achieve the desired sensitivity; and the cost of sampling compared with the cost of analysis.

The costs associated with testing food are substantial, and consequently manufacturer's often resort to increasing the size of the "production lot" to be tested. For instance, the standard size production lot for trim testing for *E. coli* O157 in the U.S. beef industry is five (5) 'combos' (each combo weighing approximately 2,000 pounds), and for *Listeria* and *Salmonella* in ready-to-eat (RTE) products, it is one composite sample per production line per shift. A primary problem associated with the use of large size test lots is that a large quantity of products must be downgraded or destroyed when there is a positive finding of a pathogen. Additionally, because of the nature of combination 'lotting' (combining, for purposes of forming the test lot, several independent sub-lots that collectively span a long period of production time), it is very difficult to investigate the cause of the failure and pinpoint the source/cause, and remedial measures cannot be effectively taken. Furthermore, compositing a large number of samples may result in reduced sensitivity for the test unit and adversely effect the limit of detection.

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

The above-described prior art has several substantial deficiencies. *First*, even though the prior art production lot encompasses several production sublots (for instance 5 combo/pallets of products, or an entire shift of production), if a positive finding is obtained for the production lot (composite test sample), the entire production lot is rejected (all 5 combos/pallets, or one shift of production) and diverted to economically undesirable end uses (*e.g.*, cooking or disposal), even though the pathogen of concern may be confined to only a limited portion of the production sublots (corresponding to one or two combos/pallets or an hour of production) comprising the production lot.

Second, the current art does not allow for retesting of any production sublots, primarily because microbial contaminants are unevenly spread throughout the products, and in many instances the levels of contamination are minute and may be present on very small portions of the products in each subplot. Therefore, once a composite sample is constructed if it tests positive all of the sublots are destroyed. The regulatory agencies do not allow for re-testing of the sublots, premised on the argument that after a production lot tests positive, negative test results obtained for production sublots, or even a new production lot composite sample, are meaningless since the microbial contaminants are not uniformly present throughout the products.

Third, the current protocols for collecting a composite sample representing a production lot often group together production sublots that are unrelated by virtue of product type or hours of production. This makes investigating the nature of the failure a difficult task even when relevant information is available. As an example, information is frequently available on a ‘per combo’ basis including (but not limited to) hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated combos/pallets are included in a production lot it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option since it may not yield the same result). Likewise, for sterility testing, when the composite sample tests positive, the entire production will be disposed.

Therefore, there is a pronounced need in the art to implement novel and effective testing protocols that provide a greater measure of assurance that the food product is safe, that provide economic relief to the producer, and that allow for effective tracking of the contaminated lot(s) for remedial purposes (*e.g.*, pinpointing the time of the contamination and determine the segment of production which was impacted).

SUMMARY OF THE INVENTION

Aspects of the present invention provide novel enrichment, testing and detection methods for detection of pathogens or other microbes in, for example, food, water, wastewater, industrial, pharmaceutical, botanical, environmental samples and other types of samples analyzed by detection methods (*e.g.*, enrichment-detection methods). According to particular aspects, where any microbiological testing program involves compositing a number of samples to form a test lot, independent enrichment of each of the components of the composite sample is performed with subsequent formation of a modular (*e.g.*, wet modula) composite sample by combining portions from each independent enrichment, which allows for determining the outcome of the test for each individual subunit of the composite as opposed to generalizing the results of the test sample to all of it's subunits. This individual outcome determination is achieved by retesting the individual enrichment samples in the event that the composite enrichment tests positive.

In preferred aspects, a reportable lot is defined as a single unit of a modular (*e.g.*, modular wet) composite lot, rather than as an entire composite lot comprised of multiple sublots. For example, a reportable production lot is defined as a single unit of production and corresponds to a single unit of a modular wet composite production lot, rather than (as in the prior art) as an entire composite lot comprised of multiple production units (multiple sublots). 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. Multiple aliquots of the enrichment media may be removed for analysis, thus circumventing the prior art problem of having to re-sample a test production lot where microbial contaminants are not uniformly present throughout the product.

In the exemplary context of enriched single units of production, equal portions of enrichment buffer are removed (aseptically) from each single-unit production lot sample and combined to form a *Modular Wet Composite Sample* (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target agent (*e.g.*, target organism). If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are released. Significantly, if a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single-unit production lot samples are separately (individually) tested, using the same test protocol, or a test protocol with enhanced sensitivity, or any appropriate test protocol. According to particular preferred aspects, the signal obtained from a MWCS is due to one or more of its components (*e.g.*, reportable lots (*e.g.*, individually enriched single production units)), and it is, therefore, possible in all cases to trace a positive signal to one or more individual subunits by testing each individual enrichment sample for the same target. When a *positive* finding is obtained for any individual reportable lot sample (*e.g.*, single-unit production lot sample), that particular reportable lot (*e.g.*, single-unit production lot) is deemed to be positive, and appropriate actions are taken based on the result. In the case of pathogen/microbial testing for foods, the individual positive sublots can be diverted to cooking, disposal, or other acceptably safe endpoint. The rest of the individually enriched test units that test negative are deemed to be negative and will be reported as such (are validated).

DETAILED DESCRIPTION OF THE INVENTION

Particular aspects provide novel enrichment, testing and validation methods for detection of pathogens or other microbes in any type of samples (*e.g.*, food production lots, water,

wastewater, industrial, pharmaceutical, botanical, environmental samples, etc.) analyzable by enrichment-detection methods. In preferred aspects, a test lot (single-unit production lot), rather than (as in the prior art) a composite lot comprised of multiple test lots (e.g., single-unit production lot units), is defined and established as the single unit of production. A plurality of portions (e.g., product portions) are separately collected from each test lot (e.g., single-unit production lot) and composited to form a corresponding set of test lot samples (e.g., single-unit production lot samples), which are enriched using suitable enrichment protocols to allow target agents/organisms to reach detectable levels and sample uniformity. In particular embodiments, equal portions of enrichment buffer are removed (preferably aseptically) from the enriched samples, and combined to form a modular composite sample (e.g., modular wet composite sample; MWCS). The MWCS, for example, is tested using a suitable detection assay for the target agent/organism. If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are validated and releasable. If a *positive* result is obtained from a MWCS, the enrichment sample corresponding to individual test lots (e.g., individual single-unit production lots) are separately (individually) tested, using the same, or a more sensitive test protocol. If a *positive* finding is obtained for any test lot sample (e.g., individual single-unit production lot sample), that particular respective lot is diverted to cooking, disposal, or other acceptably safe endpoint. If a *negative* finding is obtained for any individual test lot sample (e.g., single-unit production lot sample), then that particular lot is validated and releasable. In this manner, any member lot of the MWCS that tests *negative* using the same method (about 5-fold more sensitive relative to the prior art), or an enhanced method (about fifty times more sensitive), will be validated and releasable for consumption.

DEFINITIONS

The term “test lot” or “reportable lot” as used herein to refer to an assemblage of one or more specimens of a medium or process (e.g., assemblage of specimens of air, water, solids, or of products of a production process, etc.), where such assemblage can be sampled by taking

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

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 “product portion” as used herein refers to a product piece (*e.g.*, a piece of solid beef trim, etc.), aliquot of product (*e.g.*, a volume of liquid juice) or weight of product (*e.g.*, a weight of semi-solid pudding). A single unit of production is composed of multiple product portions. In preferred embodiments, the number of product portions which comprise a single unit of production is great enough that removal of some product portions to form a sample does not impose an unacceptable economic loss to the producer. In particular instances, a product portion may be a specimen of a test lot as defined above.

The term “compositing” as used herein refers to combining a number of single product portions to form one larger sample. In preferred embodiments, the number and selection of single product portions to be combined conform to statistical-based sampling plans which seek to form a typical or average sample that is representative of the test lot (*e.g.*, single production unit) being sampled.

The term “test lot sample” or “single-unit production lot sample” or “single production unit lot sample,” as used herein refers to a sample formed by combining multiple product portions from a test lot (*e.g.*, single production unit), such that each test sample (*e.g.*, each single-unit production lot sample) is attributed to a particular corresponding test lot (*e.g.*, production unit). For production lot samples, the number of portions/pieces combined may be essentially any number, but preferably is selected so as to conform to statistical-based sampling plans.

Preferably the number of pieces combined is selected from the range group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 product portions. Preferably, the number of independent product portions is selected so as to yield a sample size that is equal to or greater than that required by the subsequent analysis to be applied.

The term “enrichment” as used herein refers to incubating a test lot sample (*e.g.*, single-unit production lot sample) under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform throughout the enriched test lot sample (*e.g.*, single-unit production lot sample). Preferably, enrichment comprises addition of an amount of an enrichment medium or buffer to a sample, and incubating the sample at a favorable temperature for a period of time sufficient to allow the organism to grow and multiply.

The term “enrichment medium” as used herein refers to a mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism. Preferably, the enrichment medium is formulated to mimic the environment of the target agent/organism or take advantage of a known metabolic property of the target agent/organism. Preferably, the enrichment medium will omit nutrients needed by competing undesired agents/organisms. Preferably, the enrichment medium will include selective agents that will inhibit competing undesired agents/organisms. An example of an enrichment medium is that used for the isolation of nitrogen fixing bacteria (those that can use nitrogen gas as their sole nitrogen source) contains no source of fixed nitrogen in the medium. A second example is an enrichment medium for the isolation of bacteria capable of utilizing 2,4-dichlorophenoxyacetic acid (also know as 2,4-D, a common herbicide) as a source of carbon and energy. The enrichment medium is formulated to contain benzoate as the only organic compound.

The term “wet enrichment” as used herein refers to diluting a solid, semisolid or liquid single-unit production lot sample (single production unit lot sample) with enrichment medium in

a ratio of approximately 1:10 (wt./v), consistent with conventional methods for expanding and testing a variety of target agents/organisms as set forth in widely recognized published methods. For example, the conventional method for expanding and testing for coliforms, fecal coliforms and *E. Coli* in food, comprises a 1:10 dilution of the samples (*e.g.*, 50 g into 450 ml) (*see, e.g.*,
5 U.S. FDA Bacteriology Analytical Manual Online, Chapter 4 and 4A, describing standard 1:10 dilution procedures for testing of coliforms, fecal coliforms and *E. Coli* in food, shellfish and juices).

The term “dry enrichment” as used herein refers to enriching a solid, semisolid or liquid single unit production lot sample either with no addition of other compounds if the sample’s
10 intrinsic properties (water activity, nutrients and pH) are sufficient/proper to promote the growth of the target agent/organism, or by dilution of the sample with minimal amounts of enrichment medium in ratios ranging from about 0.1 (wt/v) to about 1 (wt/v).

The term “modular composite sample” as used herein refers to a sample formed by removing, preferably aseptically, equal portions of each of a plurality of enriched single-unit
15 production lot samples, and combining the removed portions.

The phrase “suitable detection assay” as used herein refers to any assay that is suitable for detecting a particular agent/organism. Preferably, the assay is optimized to detect the particular agent/organism, and may be combined with one or more concentration steps for concentration of the agent/organism being assayed.

20 The term “validation” as used herein with respect to production lots refers to determining that a particular sample tests *negative* using the detection assay. Where a modular composite sample tests *negative*, all single-unit production lot samples comprising the composite sample are validated along with the respective single-unit production lots, which are thus cleared for release. Where a modular composite sample tests *positive*, individual single unit production lots
25 may nonetheless yet be validated if particular respective single-unit production lot samples test *negative*.

“Trim” refers to small pieces of meat and fat which are excised during, for example, the

beef fabrication process in order to produce primal and subprimal pieces and marketable cuts.

“Trim testing” refers to the process of testing trim, or raw materials which are to be used for ground meat production for microbial/pathogen content.

A “combo” or “combo-bin” refers, in the beef industry, to the single production unit packaging unit. Alternatively raw materials corresponding to a single production unit to be tested can be packaged into boxes, bags or other appropriate containers, which can be placed, for example, on pallets.

A “composite lot-unit” or “five-combo-lot unit” refers to a *composite* unit, comprised of five combos (combo-bins). In prior art sampling plans, the composite lot-unit represents the raw material (composite trim) upon which sampling, testing and acceptance or rejection is based.

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.

In preferred embodiments, a number of pieces or portions of sample are collected from a test lot (*e.g.*, from a single production unit (*e.g.*, from the single combo, bin, pallet, or segment of production, etc.), and composited to form one ‘*single-unit test sample*’ (or ‘*single-unit production lot sample*.’ In particular embodiments (*e.g.*, wet enrichment), enrichment buffer is added to the sample. In alternate embodiments, ‘dry enrichment’ (as defined herein above) is done.

Significantly, in the inventive modular (*e.g.*, wet modular) compositing method, samples taken from each unit of production are enriched *separately* 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. In preferred aspects, such enrichment obviates the prior art problem of having microbial contaminants that are not uniformly present throughout the product sample. Specifically, while microbes are not necessarily uniformly distributed in food, water, air, pharmaceuticals, etc, after enriching a sample as described herein, the target microbes are uniformly, or as least substantially uniformly, present in the enrichment medium or extract from dry or semi dried enrichments.

Following incubation for the target organism, equal portions of enrichment buffer or sample are removed (aseptically) from each of several test lot samples (e.g., from several single-unit production lot samples; preferably 5) and pulled together to form a Modular Wet Composite Sample (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target organism. If a *negative* result is obtained from the MWCS, then all of the individual single unit production Lots are released.

If a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single unit production lot samples are then separately (individually) tested, using the same test protocol, or any other appropriate tests. Alternately, an augmented protocol that uses a concentration step for the target organism, such as immunomagnetic bead separation, affinity chromatography, etc., followed by an appropriate detection method is used to test the enriched individual test lot samples (e.g., the individual single-unit production lot samples).

In preferred aspects, the inventive methods of analysis are modified by introducing a concentration step (e.g., employing antibody-coated paramagnetic beads into the procedure (e.g., DNA-based detection, biosensor based detection, classical microbiological detections, etc)). Antibody-coated paramagnetic beads, for example, afford an approximately 10-fold increase in sensitivity. This concentration step, combined with the fact that the individual test lot samples (e.g., individual single-unit production lot samples) are not 5-fold diluted relative to the MWCS, allows for an overall 50-fold increase in sensitivity relative to prior art sampling and testing protocols. If a lateral flow device is used for detection, such immunomagnetic concentration may or may not be used, in which case the detection sensitivity is increased by about 5-fold.

Where a *positive* finding (test result) is obtained for any individual test lot sample (e.g., single-unit production lot sample), that particular corresponding test lot (e.g., single-unit production lot) is deemed to be positive, and appropriate decisions are then made on the positive results (e.g., in the case of food products, diversion to cooking, disposal, or other acceptably safe endpoint). For each of the rest of the test lot samples (e.g., single-unit production lot samples) belonging to the positive MWCS, where a *negative* finding is obtained, that particular test lot sample (e.g., that single-unit production lots sample) is deemed to be negative. In this manner, any test lot (e.g., any single-unit production lot) that is a member of the group of test lots (e.g., single-unit production lots) that comprise a corresponding MWCS, will be considered to be negative, if it tests *negative* using the same method (about 5-fold more sensitive relative to the prior art), or the enhanced method (about fifty times more sensitive).

In alternate preferred embodiments, a new Modular Wet Composite Sample is reconstructed from the member lots (test lots) that have tested *negative*, and subjected to a third layer of testing to again show (confirm) that they are negative. Specifically if one of the five individual test lots (e.g., individual single-unit production lots) has tested positive (and the other four negative), and the protocols call for testing of composites consisting of five test lots, a new single test lot sample can be formed from a new test lot, and can be used along with the four negative samples to form a new MWCS.

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.

Additionally, and significantly, it is easier to trace the source of the contamination and apply remedial measures, because the single-unit test component points, for example, to single point of production or a single sampling site.

Particular Preferred Aspects:

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.

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
5 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.

10 In particular aspects, where testing of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol. Preferably, the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

15 In particular aspects, the methods further comprise forming an additional modular composite sample from the enriched test lot samples and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status. In particular aspects, the methods further comprise forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples that
20 test negative, and testing the additional modular composite sample, using the same or a different suitable assay. In particular aspects, the methods further comprise, where testing of the modular composite sample is negative, forming an additional modular composite sample from the enriched test lot samples, and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

25 In particular aspects, the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a segment of production. Preferably, the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

In particular aspects, the methods further comprise, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive. In particular aspects, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions. Alternatively, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

Particular aspects provide a method of sampling, testing and validating test lots, comprising: separately 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 product specimens, wherein the assemblage can be sampled by taking portions thereof; combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot; incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched single-unit production lot samples; removing, aseptically, equal portions of each enriched single-unit production 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 single-unit production lot samples are validated, and wherein where such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

5

The following Examples are exemplary are not intended, and should not be construed to limit the scope of the aspects of the present conception that are claimed hereunder.

EXAMPLE I

10 (The present inventive methods were shown to provide a substantial economic advantage, while providing for enhanced safety, and implementation of remedial measures)

At present, the standard size ‘production lot’ for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five *combos*, where each *combo* represents a single production unit and weighs approximately 2,000 pounds. An inventive modular composite sample method, and in particular a Modular Wet Composite Sample (MWCS) method was
15 implemented at a United States beef producer. TABLE 1 shows, according particular aspects, the result of testing 62,919 MWCS samples, and then retesting the individual single-unit production lot (combo) samples whenever a *positive* result was obtained from the MWCS sample.

20 TABLE 1 shows that out of 62,919 MWCS samples, a total of 217 yielded a *positive* testing result for *E. coli* O157. Using prior art protocols, all of the single-unit production lots that comprised the 271 positive samples would go to rendering or be downgraded for cooking. As each MWCS represents five single-unit production lots of 2,000 lbs each, this would represent approximately 2,710,000 pounds of product (*i.e.*, $271 \times 5 \times 2,000$ pounds = 2,710,000
25 pounds).

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 19,280,000 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.

Furthermore, as outlined above under “BACKGROUND,” information is frequently available on a ‘per combo’ basis including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated *combos* are included in a combined ‘production lot’ (as in the prior art) it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option since it may not yield the same result).

By contrast, in this Example I and according to preferred aspects of the present invention, any *combo*-specific information including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps can be brought to bear in the context of the 391 individual single-unit production lots yielding a *positive* sample result, thereby providing an effective means not only to trace contamination, but also to affect remedial measures in view thereof.

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

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EXAMPLE II

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of Ready-to-Eat (RTE) products (*e.g.*, meat and poultry products))

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Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may adapt an ‘end product’ sampling program as verification that their product is free of the pathogen *Listeria monocytogenes*. The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (*e.g.*, from ‘cleanup to cleanup’), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis.

15

20

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

25

of time), a volume of product such as a pallet of packed boxes produced on a particular production line, or a production area in the plant, etc.

Individual single-unit production lot samples are collected, to which, in wet enrichment
embodiments, enrichment medium/buffer is added. Following incubation under conditions
5 suitable to allow levels of a target agent or organism that is present to reach detectable levels and
become uniform or substantially uniform throughout the respective sample(s), aliquots of the
enrichment medium/buffers from individual single-unit production lot samples are combined to
form a MWCS. The MWCS is then analyzed for the presence or absence of, for example,
Listeria spp. or *L. monocytogenes*. In the event that a *positive* result is obtained for the MWCS,
10 enrichment medium/buffer sample from the individual single-unit production lot samples
comprising that MWCS is analyzed using the same, or augmented testing protocols.

Individual single-unit production lots for which the enrichment medium/buffer from the
corresponding sample yields a *positive* result are diverted to cooking, disposal or other safety
endpoint. Individual single-unit production lots for which the enrichment medium/buffer from
15 the corresponding sample yields a *negative* result are released into commerce. The latter fraction
represents a direct cost savings to the producer relative to a prior art approaches where a
'production lot' is defined to include multiple single-unit production lots (e.g., multiple product
lines and an extended period of time ('cleanup to cleanup')).

Furthermore, by defining and establishing the individual single-unit production lots in
20 such a fashion as to maximize the information available for investigating the nature of a failure,
the producer is able to narrow the scope of investigation and apply remediative resources more
effectively and efficiently. For example, where a *positive* result(s) is associated with one or
more specific production lines, targeted aggressive sanitation is used to resolve the problem.
Alternatively, for example, where a *positive* result(s) is associated with one or more specific
25 products, determining whether raw materials are contaminated, or whether process microbial
intervention steps were operating properly are effectively and efficiently used.

EXAMPLE III

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility for providing cost-effective and effective monitoring means for pathogen levels in nut products (*e.g.*, almond products) and the like)

5 A large number of almond products may be produced by using one or more processes including slivering, scalding, blanching, slicing, roasting, and dicing. Anti-microbial treatments may also be applied, such as use of propylene oxide. In practice, these processes may be used in many various combinations, and the output from one process may be the input for another. This makes it very difficult to trace finished product all the way back to raw materials.

10 As indicated by a recent outbreak, almond products are susceptible to contamination by *Salmonella* spp. According to additional aspects, the present inventive methods provide a cost-effective means of implementing an effective monitoring program for pathogen levels in nut products (*e.g.*, almond products). In such embodiments, final almond products of each type are collected at random times over a production shift. The producer defines and establishes
15 individual single-unit production lots as the amount of product produced during a production shift (from ‘cleanup to cleanup’), or as some smaller production unit (*e.g.*, a ‘truckload’), provided that one sample was collected from each such single-unit production lot. The single-unit production lot samples are combined to form a corresponding composite sample, and, in wet enrichment embodiments, enrichment medium/buffer is added to the composite sample to allow
20 *Salmonella* spp. to grow and multiply under the favorable conditions of enrichment (as described herein above), thereby providing more material that can be detected by subsequent analysis.

 Aliquots of the enrichment medium/buffers from individual single-unit production lot samples are combined to form a MWCS. The MWCS are analyzed for the presence or absence, for example, of *Salmonella* spp. Where a *positive* result is obtained for the MWCS, each
25 enrichment buffer from the individual single-unit production lot samples comprising that MWCS is analyzed using the same, or augmented testing protocols.

 Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *positive* result are returned for application of additional microbial

intervention steps (*e.g.*, roasting), or are diverted to a safe endpoint (*e.g.*, a cooked product). Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *negative* result are thereby validated and are releasable into commerce. The latter fraction represents a direct cost savings to the producer relative to prior art approaches where effective testing is not done, and discovery of contamination with a pathogen leads to large scale recalls of product.

Furthermore, by defining and establishing the individual production single-unit production lots in such a fashion as to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply remediative resources more effectively and efficiently. For example, the processes used to produce the almond product(s) yielding *positive* result(s) are rationally analyzed, and associations between the pathogen contamination and one or more of the processes of slivering, scalding, blanching, slicing, roasting, and dicing are determined, and targeted effective and efficient remedial measures are applied.

EXAMPLE IV

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of contaminants that enter a production line at a given time point, and then clear)

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.

EXAMPLE V

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of environmental monitoring (*e.g.*, with samples of water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids))

5 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.

10

CLAIMS

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

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

b) 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;

c) incubating the set of 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 samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of test lot samples enriched for the target microbial agent or organism;

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

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

2. The method of claim 1, wherein 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.

3. The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

5 4. The method of claim 3, wherein product specimens are synonymous with product portions.

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

6. The method of claim 1, wherein incubating each test lot sample in c) comprises
10 incubating with enrichment medium suitable to enrich for the target microbial agent or organism, to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. The method of claim 1, wherein testing of the modular composite sample, using at
15 least one suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

20 9. The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional modular
25 composite sample, using the same or a different suitable assay, to confirm the testing status.

11. The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched 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.

12. 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 enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. 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.

14. The method of claim 1, wherein the number of test lots is from 3 to 10.

15. The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, application of remedial measures to said positive test lots, and validating by further testing of a portion of the respective remediated test lots and obtaining a negative test result.

16. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions from 5 to 100.

17. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot 30 to 60 portions.

18. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting 30 portions from each test lot.

19. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

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

c) incubating the set of 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 single-unit production lot samples to reach detectable levels and become uniform, or substantially
10 uniform, throughout the respective one or more samples, to provide a set of single-unit production lot samples enriched for the target microbial agent or organism;

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

e) testing of the modular composite sample, and individual testing of each of the enriched
15 test lot samples, using at least one suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all single-unit production lot samples are validated, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual enriched test lot sample, individual single-unit
20 production lots may nonetheless yet be validated by further testing of a portion of respective initially negative enriched single-unit production lot samples using the same or a more sensitive protocol and obtaining a negative test result.

21. The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched test lot samples.

22. The method of claim 20, wherein removing portions in step d) is removing equal
25 portions, aseptically, so as to preclude contamination of the enriched single-unit production lot samples.

23. 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*.

24. 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*,
5 *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

25. The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

26. The method of claim 1, wherein removing portions of each enriched test lot sample comprises removing equal volume portions of each enriched test lot sample.

10 27. 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.

28. The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

15 29. The method of claim 1, wherein the test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

20 31. The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. The method of claim 1, wherein the test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

33. The method of claim 1, wherein the test lots are production lots of a ready-to-eat
25 product.

34. The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organisms.

ABSTRACT OF THE DISCLOSURE

Provided are methods for sampling, testing and validating test lots, comprising: assembling a plurality of product portions from each of a plurality of test lots and combining the portions to provide a corresponding set of test lot samples; enriching the test lot samples; removing portions of each enriched sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample, and individual testing of the enriched test lot samples, using at least one suitable detection assay for a target microbe or organism, wherein when such testing is negative all test lots are validated, and wherein when such testing is positive with respect to the modular composite sample, or with respect to an individual enriched test lot sample, individual test lots may nonetheless yet be validated by further testing of a portion of respective initially-negative enriched test lot samples and obtaining negative results.

Electronic Acknowledgement Receipt

EFS ID:	4687221
Application Number:	12360796
International Application Number:	
Confirmation Number:	7046
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-58
Receipt Date:	27-JAN-2009
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Time Stamp:	19:46:15
Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	66090_58_ADS.pdf	6161 de29a096b15a836d3796e187f1a20dda039563c7	no	3

Warnings:

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Page 240

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	Multipart Description/PDF files in .zip description				
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	Claims		24	28	
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Filing Date: 01/27/09

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/360,796	
APPLICATION AS FILED – PART I						
(Column 1)		(Column 2)		SMALL ENTITY		OR
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	82		
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	270		
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		
TOTAL CLAIMS (37 CFR 1.16(i))	34	minus 20 =	14	x\$26	364	OR
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 =	*	x\$110		
APPLICATION SIZE FEE (37 CFR 1.16(s))			If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			195		390	
			TOTAL	826	TOTAL	
* If the difference in column 1 is less than zero, enter "0" in column 2.						
APPLICATION AS AMENDED – PART II						
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR
	Total (37 CFR 1.16(i))	Minus	**	=	X =	OR
	Independent (37 CFR 1.16(h))	Minus	***	=	X =	OR
	Application Size Fee (37 CFR 1.16(s))					OR
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		OR
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR
	Total (37 CFR 1.16(i))	Minus	**	=	X =	OR
	Independent (37 CFR 1.16(h))	Minus	***	=	X =	OR
	Application Size Fee (37 CFR 1.16(s))					OR
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		OR
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 12/360,796	
APPLICATION AS FILED – PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	82	N/A	
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A	270	N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	110	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	34	minus 20	=	x\$26	364	OR x\$52	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3	=	x\$110		OR x\$220	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	826	TOTAL	
APPLICATION AS AMENDED – PART II							
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)
Total (37 CFR 1.16(i))	*	Minus	**	X	=	OR X	=
Independent (37 CFR 1.16(h))	*	Minus	***	X	=	OR X	=
Application Size Fee (37 CFR 1.16(s))							
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
				TOTAL		OR TOTAL	
				ADD'T FEE		OR ADD'T FEE	
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)
Total (37 CFR 1.16(i))	*	Minus	**	X	=	OR X	=
Independent (37 CFR 1.16(h))	*	Minus	***	X	=	OR X	=
Application Size Fee (37 CFR 1.16(s))							
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
				TOTAL		OR TOTAL	
				ADD'T FEE		OR ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.