AMENDMENT TO THE CLAIMS

Please enter the following amendment to the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

1. (Original) An isolated or non-naturally occurring human monoclonal antibody, wherein said monoclonal antibody neutralizes a HIV-1 virus *in vitro*, and further wherein the monoclonal antibody is selected from the group consisting of VRC-PG-04 or VRC-PG-05.

2. (Original) An isolated or non-naturally occurring anti-HIV antibody, wherein said antibody has a heavy chain with three CDRs comprising an amino acid sequence selected from the group consisting of the amino acid sequences of VRC-PG-04 or VRC-PG-05 of FIG. 8 or FIG. 17C, and a light chain with three CDRs that include an amino acid sequence selected from the group consisting of of the amino acid sequences of VRC-PG-04 or VRC-PG-05 of FIG. 8 or FIG. 17C.

3. (Currently Amended) A method of monitoring the quality of anti-HIV vaccines, comprising the use of the antibody of claim 1 ~~or 2~~, or a fragment thereof, to determine that an antigen of the anti-HIV vaccine contains an epitope in a conformation to elicit an immune response.

4. Currently Amended) A diagnostic composition comprising a labeled antibody of claim 1 ~~or 2~~, or a fragment thereof, to detect the presence of an HIV immunogen, antigen or epitope in a sample.

5. (Original) The composition of claim 4, wherein the sample is a biological sample.

6. (Original) The composition of claim 5, wherein the biological sample is blood, semen or vaginal fluid.

7. (Currently Amended) A method of immunizing or reducing the effect of an HIV infection or an HIV related disease comprising identifying a patient in need of such treatment, and administering to the patient a therapeutically effective amount of at least one antibody of claim 1 ~~or claim 2~~.

8. (Original) The method of claim 7 further comprising administering a second therapeutic agent.

9. (Original) The method of claim 8, wherein the second therapeutic agent is an anti-viral agent.

10. (Original) A method of immunizing or reducing the effect of an HIV infection or an HIV related disease comprising identifying a patient in need of such treatment and administering to the patient a therapeutically effective amount of: a first antibody of the present invention, or fragment thereof, specific for a first epitope which binds to said first antibody and a second antibody of the present invention, or fragment thereof, specific for a second epitope which binds to said second antibody.

11. (Original) The method of claim 10, wherein the first antibody is VRC-PG-04 or VRC-PG-05.

12. (Original) The method of claim 11 wherein the second antibody is VRC-PG-04 or VRC-PG-05.

13. (Original) The method of claim 11 wherein the second antibody is VRC01, VRC02 or VRC03.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/792,098	03/10/2013	John Mascola	43094.02.2014	8268

99562 7590 08/14/2014

Vedder Price P.C.
1633 Broadway, 47th Floor
New York, NY 10019

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
08/14/2014	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):

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Office Action Summary	Application No. 13/792,098	Applicant(s) MASCOLA ET AL.	
	Examiner JEFFREY PARKIN	Art Unit 1648	AIA (First Inventor to File) Status No

-- 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 *03* MONTHS 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 *04/28/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *1-13* is/are pending in the application.

5a) Of the above claim(s) *3 and 7-13* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2 and 4-6* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *03/10/2013; 06/03/2013* 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).

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).

Certified copies:

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)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *05/31/2013; 06/30/2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☒ Other: *Notice to Comply...*.

Detailed Office Action

Status of the Claims

The present application is being examined under the pre-AIA first to invent provisions. Acknowledgement is hereby made of receipt and entry of the communication filed 28 April, 2014. Claims 1-13 are pending in the instant application. Applicants' election of group I (claims 1, 2, and 4-6) with traverse is noted. It was argued that a serious burden would not be present if all the groups were examined concomitantly. Applicants' arguments were carefully considered but are not deemed to be persuasive for the reasons of record clearly set forth in the last Office action. Accordingly the requirement is still deemed proper and is therefore made **FINAL**. Claims 3 and 7-13 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

37 C.F.R. § 1.98

The information disclosure statements filed 31 May, 2013, and 30 June, 2014, have been placed in the application file and the information referred to therein has been considered. The former IDS contained three citations with hyperlinks. These citations have been considered but will not be printed should this application mature into a patent because of the inclusion of said hyperlinks. Applicants are also reminded that the listing of references in the specification (e.g., see pages 71-75 and 87-94) is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and M.P.E.P. § 609.04(a), subsection I. states,

database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database. See 37 C.F.R. § 1.821(a) and M.P.E.P. § 2421.02.Applicants are reminded that sequences appearing in the specification and/or **drawings** (e.g., Figures 8 and 17) must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification.

37 C.F.R. § 1.57(d)

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g., see p. 94). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01.

35 U.S.C. § 101

The following is a quotation of 35 U.S.C. § 101 which reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim(s) 1, 2, and 4-6 are rejected under 35 U.S.C. § 101 because the claimed invention is not directed to patent eligible

subject matter. The claims are directed toward human Mabs (e.g., VRC-PG04 or VRC-PG05) which were amplified directly from single patient B-cells containing the corresponding B-cell receptor. Thus, these antibodies appear to be direct copies of those that normally circulate. Based upon an analysis with respect to the claim as a whole, the claims do not recite something significantly different than a judicial exception. The claimed antibodies are not markedly different in structure from naturally-occurring antibodies or fragments thereof. See *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 106 U.S.P.Q.2d 1972 (U.S. 2013), the Court concluded that claims directed toward isolated DNAs are not patent-eligible because they read on isolated naturally-occurring DNA that is a "product of nature." The Court held that simply isolating a "gene from its surrounding genetic material is not an act of invention."

35 U.S.C. § 112, First Paragraph

The following is a quotation of 35 U.S.C. § 112 (pre-AIA), first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 2 is rejected under 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions of the claims in the application:

1-70. **(Canceled)**

71. **(Previously Presented)** An isolated antibody, or an antigen binding fragment thereof, comprising the CDR1, CDR2, and CDR3 sequences of the heavy and light chain variable region sequences set forth in SEQ ID NOs: 157 and 158, respectively.

72. **(New)** An isolated antibody, or an antigen binding fragment thereof, comprising heavy chain variable region CDR1, CDR2, and CDR3 sequences set forth in SEQ ID NOs: 145, 146, and 147, respectively, and light chain variable region CDR1, CDR2, and CDR3 sequences set forth in SEQ ID NOs: 148, 149, and 150, respectively.

73. **(New)** The antibody or fragment of claim 71, comprising the heavy and light chain variable region sequences set forth in SEQ ID NOs: 157 and 158, respectively.

74. **(New)** An isolated antibody, or antigen binding fragment thereof, comprising heavy and light chain variable region sequences having at least 90% identity to the sequences set forth in SEQ ID NOs: 157 and 159, respectively.

75. **(New)** The antibody or fragment of claim 71, that is specific for a complex of human cytomegalovirus (hCMV) proteins UL128, UL130 and UL131A.

76. **(New)** The antibody or fragment of claim 75, which binds a conformational epitope formed by the three proteins.

77. **(New)** The antibody or fragment of claim 71, which inhibits infection of epithelial cells, wherein the concentration of antibody required for 50% inhibition of hCMV is 0.001 μg/ml or less.

78. **(New)** The antibody or fragment of claim 71, which inhibits infection of epithelial cells, wherein the concentration of antibody required for 90% inhibition of hCMV is 0.0008 μg/ml or less.

79. **(New)** The antibody or fragment of claim 71, wherein the antibody is a human antibody, a monoclonal antibody, a single chain antibody, Fab, Fab', F(ab')2, Fv or scFv.

80. **(New)** A composition comprising the antibody or fragment of claim 71, and a diluent or carrier.

81. **(New)** The composition of claim 80, further comprising a second antibody, or an antigen binding fragment thereof, which inhibits hCMV infection.

82. **(New)** The composition of claim 81, wherein the second antibody binds to an hCMV gB protein.

83. **(New)** A method of inhibiting hCMV infection in a subject, comprising administering an effective amount of the antibody of claim 71, wherein hCMV infection is inhibited.

84. **(New)** The method of claim 83, further comprising the step of administering a second antibody, or an antigen binding fragment thereof, which inhibits hCMV infection, wherein the antibodies or fragments are administered simultaneously or sequentially.

85. **(New)** A method of inhibiting hCMV infection in a cell, comprising contacting the cell with the antibody of claim 71, wherein hCMV infection is inhibited.

86. **(New)** The method of claim 85, further comprising the step of contacting the cell with a second antibody, or an antigen binding fragment thereof, which inhibits hCMV infection, wherein the cell is contacted by the antibodies or fragments simultaneously or sequentially.

87. **(New)** A method of inhibiting hCMV infection in a subject, comprising administering an effective amount of the composition of claim 80, wherein hCMV infection is inhibited.

88. **(New)** A method of inhibiting hCMV infection in a subject, comprising administering an effective amount of the composition of claim 81, wherein hCMV infection is inhibited.

89. **(New)** A method of inhibiting hCMV infection in a subject, comprising administering an effective amount of the composition of claim 82, wherein hCMV infection is inhibited.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/138,531	12/23/2013	Antonio LANZAVECCHIA	NVJ-003DV4	9037

959 7590 08/14/2014

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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
08/14/2014	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):

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chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Office Action Summary	Application No. 14/138,531	Applicant(s) LANZAVECCHIA ET AL.	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	AIA (First Inventor to File) Status No

-- 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* MONTHS 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 *4/9/14*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *71-89* 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) *71-89* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *12/23/13* 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).

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).

Certified copies:

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)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *1/16/14 and 3/14/14*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

specification is objected to because page 59 contains a nucleic acid sequence that does not contain a specific SEQ ID NO:.

Applicants must comply with sequence rules in order to be considered a complete response to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 71-89 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a naturally-occurring element of nature that is not patent-eligible pursuant to the Supreme Court decision in Association for *Molecular Pathology v. Myriad Genetics*, Inc., -- U.S. -- (June 13, 2013) (hereafter "Myriad").

Presently, the claimed invention is drawn to an isolated antibody or antigen binding fragment thereof that comprises the CDRs of SEQ ID NO:s 157 and 158 or the antibody comprises the heavy and variable chains of SEQ ID NO:s 157 and 158, antibody binding fragments of different types and a composition comprising a second antibody that can bind to the gB or gH proteins of hCMV. However, the variable heavy and light chains of SEQ ID NO:s 157 and 158 were isolated form human B cells from two donors with high hCMV neutralizing antibody titers (see Example 1 of specification). Therefore, the instant invention is interpreted to a naturally occurring antibody or fragment thereof and a combination of at least two naturally occurring antibodies and therefore is not patent eligible at this time. Furthermore, since the claimed antibody is interpreted as a naturally occurring product, the methods of claims 83-89 are

further interpreted as naturally occurring processes (antibody production in a subject (human, which the cell of claim 85 includes)).

As pursuant to the Office's interpretation of the Myriad decision, a recitation of a naturally-occurring nucleic acid, protein, or any natural product of nature that does not have a substantial or markedly difference from the natural product is not patent eligible subject matter. Therefore, claims 71-82 as written, read upon a naturally occurring human monoclonal antibody or fragment thereof that were found to have occurred naturally in nature without being subject to the "hand-of-man" and resulting in a substantial or markedly different product from that found in nature.

This is a new rejection necessitated by expanded 35 USC §101 USPTO training in view of the interpretation of Myriad. Applicant is directed towards the USPTO memo which supports the new analysis of the claims (http://www.uspto.gov/patents/law/exam/examguide.jsp); please review the new materials regarding 35 USC §101 rejections. It is suggested that the claims be cancelled or drawn to read upon the claimed antibody or antigen binding fragment thereof which is conjugated to a detectable label or therapeutic moiety which are ***not naturally occurring*** and are substantially or markedly different from the sequences found naturally for which the application would have support.

Double Patenting

The nonstatutory 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. A nonstatutory double patenting rejection is appropriate

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

1. (currently amended) An isolated antibody that specifically binds to *Clostridium difficile* toxin A comprising ~~or to toxin B, or that binds to, or cross reacts with, both toxin A and B, wherein~~:

~~a) the isolated antibody or antigen-binding fragment thereof that specifically binds toxin A of *Clostridium difficile* comprises~~ the three heavy chain complementarity determining regions (HCDR1, HCDR2 and HCDR3) contained within a heavy chain variable region (HCVR) amino acid sequence selected from the group consisting of SEQ ID NOs: 2, 98, 114, 130, 146 and 162; and the three light chain complementarity determining regions (LCDR1, LCDR2 and LCDR3) contained within a light chain variable region (LCVR) amino acid sequence selected from the group consisting of SEQ ID NOs: 10, 106, 122, 138, 154 and 170~~;~~

~~b) the isolated antibody or antigen-binding fragment thereof that specifically binds toxin B of *Clostridium difficile* comprises the HCDR1, HCDR2 and HCDR3 contained within a HCVR amino acid sequence selected from the group consisting of SEQ ID NOs: 178, 194, 210, 226, 242, 258, 274, 290, 306, 322, 338 and 354; and the LCDR1, LCDR2 and LCDR3 contained within a LCVR amino acid sequence selected from the group consisting of SEQ ID NOs: 186, 202, 218, 234, 250, 266, 282, 298, 314, 330, 346 and 362; and~~

~~c) the isolated antibody or antigen-binding fragment that binds to, or cross reacts with both toxin A and toxin B of *Clostridium difficile* comprises the HCDR1, HCDR2 and HCDR3 contained within a HCVR amino acid sequence selected from the group consisting of SEQ ID NOs: 18, 34, 50, 66 and 82; and the LCDR1, LCDR2 and LCDR3 contained within a LCVR amino acid sequence selected from the group consisting of SEQ ID NOs: 26, 42, 58, 74 and 90~~.

2. (currently amended) The isolated antibody or antigen-binding fragment thereof of claim 1 ~~that specifically binds toxin A of *Clostridium difficile*,~~ wherein the antibody, or antigen-

binding fragment thereof comprises: (a) a HCVR having an amino acid sequence of SEQ ID NO: 146; and (b) a LCVR having an amino acid sequence of SEQ ID NO: 154.

3. (currently amended) The isolated antibody or antigen-binding fragment thereof of claim 1 ~~that specifically binds toxin A of *Clostridium difficile*~~, wherein the antibody, or antigen-binding fragment thereof comprises a HCVR/LCVR amino acid sequence pair selected from the group consisting of SEQ ID NOs: 2/10, 98/106, 114/122, 130/138, 146/154 and 162/170.

4. (currently amended) The isolated antibody of claim 1, or an antigen-binding fragment thereof ~~that specifically binds toxin A of *Clostridium difficile*~~, wherein the antibody comprises:

(a) a HCDR1 domain having an amino acid sequence selected from SEQ ID NOs: 4, 100, 116, 132, 148 and 164;

(b) a HCDR2 domain having an amino acid sequence selected from SEQ ID NOs: 6, 102, 118, 134, 150 and 166;

(c) a HCDR3 domain having an amino acid sequence selected from SEQ ID NOs: 8, 104, 120, 136, 152 and 168;

(d) a LCDR1 domain having an amino acid sequence selected from SEQ ID NOs: 12, 108, 124, 140, 156, and 172;

(e) a LCDR2 domain having an amino acid sequence selected from SEQ ID NOs: 14, 110, 126, 142, 158 and 174; and

(f) a LCDR3 domain having an amino acid sequence selected from SEQ ID NOs: 16, 112, 128, 144, 160 and 176.

5. (currently amended) The isolated antibody of claim 4, or an antigen-binding fragment thereof ~~that specifically binds toxin A of *Clostridium difficile*~~, wherein the antibody comprises:

(a) a HCDR1 domain having an amino acid sequence of SEQ ID NO: 148;

(b) a HCDR2 domain having an amino acid sequence of SEQ ID NO: 150;

(c) a HCDR3 domain having an amino acid sequence of SEQ ID NO: 152;

(d) a LCDR1 domain having an amino acid sequence of SEQ ID NO: 156;

(e) a LCDR2 domain having an amino acid sequence of SEQ ID NO: 158; and

(f) a LCDR3 domain having an amino acid sequence of SEQ ID NO: 160.

6-14. (cancelled)

15. (original) A pharmaceutical composition comprising one or more antibodies of claim 1 and a pharmaceutically acceptable carrier or diluent.

16. (currently amended) The pharmaceutical composition of claim 15, wherein the composition <u>further</u> comprises at least one antibody, or an antigen-binding fragment thereof that binds specifically to ~~toxin A of *Clostridium difficile* and at least one antibody, or an antigen-binding fragment thereof that binds specifically to~~ toxin B of *Clostridium difficile*, wherein:

~~a) the antibody or antigen-binding fragment thereof that binds specifically to toxin A comprises the three heavy chain complementarity determining regions (HCDR1, HCDR2 and HCDR3) contained within any one of the heavy chain variable region (HCVR) amino acid sequences selected from the group consisting of SEQ ID NOs: 2, 98, 114, 130, 146 and 162; and the three light chain complementarity determining regions (LCDR1, LCDR2 and LCDR3) contained within any one of the light chain variable region (LCVR) amino acid sequences selected from the group consisting of SEQ ID NOs: 10, 106, 122, 138, 154 and 170; and wherein~~

~~b)~~ the antibody or antigen-binding fragment thereof that binds specifically to toxin B comprises the three heavy chain CDRs (HCDR1, HCDR2 and HCDR3) contained within any one of the HCVR amino acid sequences selected from the group consisting of SEQ ID NOs: 178, 194, 210, 226, 242, 258, 274, 290, 306, 322, 338 and 354; and the three light chain CDRs (LCDR1, LCDR2 and LCDR3) contained within any one of the LCVR amino acid sequences selected from the group consisting of SEQ ID NOs: 186, 202, 218, 234, 250, 266, 282, 298, 314, 330, 346 and 362.

17. (original) The pharmaceutical composition of claim 16, wherein the antibody or an antigen-binding fragment thereof that specifically binds toxin A of *Clostridium difficile* comprises a HCVR/LCVR amino acid sequence pair of SEQ ID NO: 146/154, and wherein the antibody or an antigen-binding fragment thereof that specifically binds toxin B of *Clostridium difficile* comprises a HCVR/LCVR amino acid sequence pair of SEQ ID NO: 274/282.

18. (original) The pharmaceutical composition of claim 16, comprising:

a) an isolated first antibody, or antigen-binding fragment thereof that specifically binds toxin A of *Clostridium difficile*, comprising a HCDR1 having the amino acid sequence of SEQ ID NO: 148, a HCDR2 having the amino acid sequence of SEQ ID NO: 150, a HCDR3 having the amino acid sequence of SEQ ID NO: 152, a LCDR1 having the amino acid sequence of SEQ ID NO: 156, a LCDR2 having the amino acid sequence of SEQ ID NO: 158, a LCDR3 having the amino acid sequence of SEQ ID NO: 160;

b) an isolated second antibody, or antigen-binding fragment thereof that specifically binds toxin B of *Clostridium difficile*, comprising a HCDR1 having the amino acid sequence of SEQ ID NO: 276, a HCDR2 having the amino acid sequence of SEQ ID NO: 278, a HCDR3 having the amino acid sequence of SEQ ID NO: 280, a LCDR1 having the amino acid sequence of SEQ ID NO: 284, a LCDR2 having the amino acid sequence of SEQ ID NO: 286, a LCDR3 having the amino acid sequence of SEQ ID NO: 288; and

c) a pharmaceutically acceptable carrier or diluent.

19. (currently amended) The pharmaceutical composition of claim 16 [[15]], wherein the antibodies contained within the composition are effective at neutralizing toxins A and B from a hypervirulent strain of *Clostridium difficile*.

20. (original) The pharmaceutical composition of claim 19, wherein the hypervirulent strain of *Clostridium difficile* is a BI/NAP1/027 strain.

21. (original) The pharmaceutical composition of claim 20, wherein the BI/NAP1/027 strain is selected from VA5, VA17, 6336 and 6443.

22. (withdrawn) A method for treating a patient suffering from a *Clostridium difficile*-associated condition or disease, or for treating at least one symptom or complication associated with the condition or disease, or for preventing the development of a *Clostridium difficile*-associated condition or disease in a patient at risk thereof, the method comprising administering to the patient an effective amount of the pharmaceutical composition of claim 15, wherein the *Clostridium difficile*-associated condition or disease is either prevented, or lessened in severity and/or duration, or at least one symptom or complication associated with the condition or disease is prevented, or ameliorated, or that the frequency and/or duration of, or the severity of recurrences, or relapses with *Clostridium difficile* is reduced.

23. (withdrawn) The method of claim 22, wherein the at least one symptom or complication associated with the *Clostridium difficile*-associated condition or disease is selected from the group consisting of anorexia, abdominal pain, abdominal bloating, diarrhea with or without bleeding, dehydration, malnutrition, pseudomembranous colitis, complete or segmental colonic resection, fever and systemic infection (sepsis), death, relapse of the *Clostridium difficile* condition or disease, and rejection of a transplanted tissue or organ.

24. (withdrawn) The method of claim 22, wherein the patient at risk of developing a *Clostridium difficile*-associated condition or disease is selected from the group consisting of an elderly patient (≥ 65 years old), a patient who is immunocompromised due to underlying illness or due to administration of immunosuppressive therapeutics, a patient who has some underlying medical condition that may pre-dispose them to acquiring a *Clostridium difficile* infection, a patient hospitalized for an extended period of time (at least one week), a patient who has been treated for an extended period of time(≥ 14 days) with broad spectrum antibiotics, a cancer patient, a transplant patient, and a patient on therapy with agents such as but not limited to a proton pump inhibitor, or histamine H2 receptor inhibitor that are used for treatment of gastrointestinal diseases or conditions to reduce or treat gastric acidity, gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, or heartburn.

25. (withdrawn) The method of claim 24, wherein the cancer patient is undergoing treatment with an anti-cancer drug, or undergoing radiotherapy to treat a cancer.

26. (withdrawn) The method of claim 24, wherein the transplant patient is a patient receiving a hematopoietic stem cell transplant, or a solid tissue or organ transplant.

27. (withdrawn) The method of claim 26, wherein the transplant patient is being treated with an immunosuppressive drug, or any transplant rejection drug, or who is undergoing treatment with a drug regimen to prevent tissue or organ graft rejection following the transplant.

28. (withdrawn) The method of claim 22, wherein the pharmaceutical composition is administered to the patient in combination with a second therapeutic agent.

29. (withdrawn) The method of claim 28, wherein the second therapeutic agent is selected from the group consisting of a toxoid, a *Clostridium difficile* vaccine, an antibiotic, another different antibody to *Clostridium difficile* toxin A and/or B, and any other palliative therapy useful for ameliorating at least one symptom associated with a *Clostridium difficile*-associated condition or disease.

30. (withdrawn) The method of claim 29, wherein the at least one symptom or complication associated with the *Clostridium difficile*-associated condition or disease is selected from the group consisting of anorexia, abdominal pain, abdominal bloating, diarrhea with or without bleeding, dehydration, malnutrition, pseudomembranous colitis, complete or segmental colonic resection, fever and systemic infection (sepsis), death, relapse of the *Clostridium difficile* condition or disease, and rejection of a transplanted tissue or organ.

31. (original) An isolated antibody that interacts with, or binds to, an epitope within amino acid residues 468-863 of the carboxy terminal receptor binding domain of toxin A produced by *Clostridium difficile*, or an antigen binding fragment thereof, wherein the carboxy terminal receptor binding domain of toxin A comprises the amino acid sequence of SEQ ID NO: 375.

25. (withdrawn) The method of claim 24, wherein the cancer patient is undergoing treatment with an anti-cancer drug, or undergoing radiotherapy to treat a cancer.

26. (withdrawn) The method of claim 24, wherein the transplant patient is a patient receiving a hematopoietic stem cell transplant, or a solid tissue or organ transplant.

27. (withdrawn) The method of claim 26, wherein the transplant patient is being treated with an immunosuppressive drug, or any transplant rejection drug, or who is undergoing treatment with a drug regimen to prevent tissue or organ graft rejection following the transplant.

28. (withdrawn) The method of claim 22, wherein the pharmaceutical composition is administered to the patient in combination with a second therapeutic agent.

29. (withdrawn) The method of claim 28, wherein the second therapeutic agent is selected from the group consisting of a toxoid, a *Clostridium difficile* vaccine, an antibiotic, another different antibody to *Clostridium difficile* toxin A and/or B, and any other palliative therapy useful for ameliorating at least one symptom associated with a *Clostridium difficile*-associated condition or disease.

30. (withdrawn) The method of claim 29, wherein the at least one symptom or complication associated with the *Clostridium difficile*-associated condition or disease is selected from the group consisting of anorexia, abdominal pain, abdominal bloating, diarrhea with or without bleeding, dehydration, malnutrition, pseudomembranous colitis, complete or segmental colonic resection, fever and systemic infection (sepsis), death, relapse of the *Clostridium difficile* condition or disease, and rejection of a transplanted tissue or organ.

31. (original) An isolated antibody that interacts with, or binds to, an epitope within amino acid residues 468-863 of the carboxy terminal receptor binding domain of toxin A produced by *Clostridium difficile*, or an antigen binding fragment thereof, wherein the carboxy terminal receptor binding domain of toxin A comprises the amino acid sequence of SEQ ID NO: 375.

32. (original) An isolated antibody that interacts with or binds to an epitope within the carboxy terminal receptor binding domain of toxin A produced by *Clostridium difficile*, or an antigen binding fragment thereof, wherein the epitope is selected from the group consisting of residues 468-488 of SEQ ID NO: 375, residues 510-530 of SEQ ID NO: 375, residues 602-610 of SEQ ID NO: 375, residues 644-703 of SEQ ID NO: 375, residues 724-794 of SEQ ID NO: 375, residues 799-814 of SEQ ID NO: 375 and residues 858-863 of SEQ ID NO: 375.

33. (original) The isolated antibody of claim 32, comprising the HCVR/LCVR amino acid sequence pair of SEQ ID NOs: 146/154.

34. (original) A pharmaceutical composition comprising the isolated antibody of claim 32 and a second isolated antibody that interacts with, or binds to toxin B of *Clostridium difficile* and a pharmaceutically acceptable carrier or diluent.

35. (original) The pharmaceutical composition of claim 34, wherein the second antibody that interacts with or binds to toxin B of *Clostridium difficile* comprises the HCVR/LCVR amino acid sequence pair of SEQ ID NOs: 274/282.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/782,444	03/01/2013	Anne Gurnett-Bander	017283.0124/7150A-US	4231

122585 7590 06/04/2014

Regeneron Pharmaceuticals, Inc.
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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
06/04/2014	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):

PatentDocket@BHFS.com

Office Action Summary	Application No. 13/782,444	Applicant(s) GURNETT-BANDER ET AL.	
	Examiner ROBERT A. ZEMAN	Art Unit 1645	AIA (First Inventor to File) Status No

-- 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 MONTHS 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 *06 February 2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *1-5 and 15-35* is/are pending in the application.

5a) Of the above claim(s) *16-30,34 and 35* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,15 and 31-33* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *13 March 2013* 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).

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).

Certified copies:

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)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *9-6-2013*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It should be noted that the cited occurrences of improper use are only exemplary and Applicant should review the entire specification to correct any other improper use of trademarks.

Claim Objections

Claims 1, 3-4 and 31-32 are objected to for reciting language drawn to non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 15 and 31-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a naturally-occurring antibodies or fragment thereof, whether isolated or not, that is not patent-eligible pursuant to the Supreme court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, – U. S. – (June 13, 2013). Given that the claimed antibodies are not structurally or functionally different than naturally occurring antibodies raised against the same antigen (Toxin A of *Clostridium difficile*).

end of 101-rejection

Amendments to the Claims:

This listing of claims will replace all prior versions/listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A vaccine for protecting a mammal against infection by an influenza C virus ~~infection by an isolated strain of influenza C virus~~, comprising an acceptable carrier, [[and]] an immunologically effective amount of inactivated C/swine/Oklahoma/1334/2011, and an oil in water adjuvant. ~~of killed cells of said isolated strain of influenza C virus capable of infecting a mammal.~~

2. (Original) The vaccine of claim 1, wherein the isolated strain of influenza C virus was isolated from a pig.

3. (Original) The vaccine of claim 2, wherein said isolated strain of influenza C virus is capable of infecting a ferret.

4. (Original) The vaccine of claim 2, wherein said vaccine protects pigs against infection by said isolated strain of influenza C virus.

5. (Currently Amended) The vaccine of claim 1, wherein the oil in water adjuvant is present in an amount of about 10%.~~a cDNA library produced from said isolated strain of influenza C virus has less than about 85% homology with the genome of a strain of human influenza C virus.~~

6. (Currently Amended) The vaccine of claim 1 or 5, wherein the adjuvant is TRIGEN.~~a cDNA library produced from said isolated strain of influenza C virus has less than about 50% homology with the genome of a strain of human influenza C virus.~~

7-12. (Cancelled)

13. (Withdrawn) A method of determining the presence of the porcine influenza C virus of claim 9 in at least one sample, comprising the steps of:
(a) amplifying one or more segments of at least one nucleic acid from the sample using at least one purified oligonucleotide primer pair that comprises forward and reverse primers, wherein the forward primer comprises SEQ ID NO: 1 and the reverse primer comprises SEQ ID NO: 2 to produce at least one amplification product; and
(b) detecting the amplification product, thereby determining the presence of the porcine influenza C virus in the sample.

14. (Withdrawn) The method of claim 13, wherein (b) comprises determining the amount of said porcine influenza C virus in the sample.

15. (Withdrawn) The method of claim 13, wherein (b) comprises reverse transcription real time polymerase chain reaction.

16. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 4.

17. (Withdrawn) The isolated nucleic acid of claim 16, encoding the protein of SEQ ID NO: 5.

18. (Withdrawn) The isolated nucleic acid of claim 17, wherein said protein has at least a 71% homology with influenza C virus polymerase 2.

19. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 6.

20. (Withdrawn) The isolated nucleic acid of claim 19, encoding the protein of SEQ ID NO: 7.

21. (Withdrawn) The isolated nucleic acid of claim 20, wherein said protein has at least an 85% homology with influenza C virus polymerase subunit PB 1.

22. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 8.

23. (Withdrawn) The isolated nucleic acid of claim 22, encoding the protein of SEQ ID NO: 9.

24. (Withdrawn) The isolated nucleic acid of claim 23, wherein said protein has at least a 66% homology with influenza C virus polymerase 3.

25. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 10.

26. (Withdrawn) The isolated nucleic acid of claim 25, encoding the protein of SEQ ID NO: 11.

27. (Withdrawn) The isolated nucleic acid of claim 26, wherein said protein has at least a 66% homology with influenza C virus hemagglutinin esterase.

28. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 12.

29. (Withdrawn) The isolated nucleic acid of claim 28, encoding the protein of SEQ ID NO: 13.

30. (Withdrawn) The isolated nucleic acid of claim 29, wherein said protein has at least a 59% homology with influenza C virus nucleoprotein.

31. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 14.

32. (Withdrawn) The isolated nucleic acid of claim 31, encoding the protein of SEQ ID NO: 15.

33. (Withdrawn) The isolated nucleic acid of claim 32, wherein said protein has at least a 58% homology with influenza C virus unspliced product of M gene.

34. (Withdrawn) An isolated nucleic acid comprising SEQ ID NO: 16.

35. (Withdrawn) The isolated nucleic acid of claim 34, encoding the protein of SEQ ID NO: 17.

36. (Withdrawn) The isolated nucleic acid of claim 35, wherein said protein has at least a 48% homology with influenza C virus nonstructural protein 1.

37. (Withdrawn) The isolated nucleic acid of claim 34, encoding the protein of SEQ ID N0:18.

38. (Withdrawn) The isolated nucleic acid of claim 37, wherein said protein has at least a 48% homology with influenza C virus nonstructural protein 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/385,004	01/27/2012	Randy R. Simonson	MER 31671.20	5872

33928 7590 07/07/2014
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3239 SATELLITE BLVD. 3RD FLOOR
DULUTH, GA 30096

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
07/07/2014	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):

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lisa.alburquerque@merial.com
docket.ip@merial.com

Office Action Summary	Application No. 13/385,004	Applicant(s) SIMONSON ET AL.	
	Examiner MYRON HILL	Art Unit 1648	AIA (First Inventor to File) Status No

-- 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 *4/1/14*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *1-6 and 13-38* is/are pending in the application.

5a) Of the above claim(s) *13-38* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-6* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *8/23/12* 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).

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).

Certified copies:

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)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☒ Other: *Notice to Comply*.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

New Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) 1-5 do not recite something significantly different from a judicial exception. The rationale for this determination is explained below:

The claimed invention is directed to non-statutory subject matter because the claimed invention is directed to natural products of virus, oil, and eater, whether isolated or not, that is not patent-eligible pursuant to the Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, Inc., -- U.S. -- (June 13, 2013) and office policy based on the decision.

Funk Bros. Seed Co. v. Kalo Co. (333 US 127 - Supreme Court 1948) concluded that the combination of natural products is not patentable.

TRIGEN is a proprietary adjuvant and the formulation is not disclosed. The oil in water is in addition to the virus. There is no disclosure of a particular structure not found in nature, for example an oil in water emulsion containing a virus.

Virus can become inactivated in nature by exposure to the elements. In considering the additional factors against patentability include inactivated virus is routinely used in the art with adjuvant and there does not appear to be a transformation of the product from natural state.

Rejections Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims require a virus, C/swine/Oklahoma/1334/2011. This requires a specific virus to make and use the genome used in the specification. The specification fails to disclose that the virus is publically available.

For the reasons discussed above, it is apparent that the virus specifically recited in the claims is required to practice the claimed invention. As a required element, the virus must be known and readily available to the public or obtainable by repeatable method set forth in the specification, or otherwise readily available to the public. If not