AMENDMENTS TO THE CLAIMS

A complete listing of the claims, including their current status identifier, is set forth below.

1. (Currently amended) A composition comprising a culture of [[An]] an isolated *Muscodor* strain, wherein the *Muscodor* strain is capable of ~~which~~:

(a) ~~produces~~ producing ~~a product comprising~~ at least one volatile organic compound selected from the group consisting of: 3-octanone, (-) aristolene, and acetic acid ester; and

(b) ~~produces a product~~ producing one or more products that possess[[es]] fungicidal, bactericidal, ~~and bacterial activity,~~ nematicidal, and~~/or~~ insecticidal activity, ~~or cell fraction, supernatant, extract, filtrate, compound, metabolite and/or volatile derived therefrom.~~

2. (Currently amended) The composition ~~isolated strain~~ according to claim 1, wherein said ~~culture~~ *Muscodor* strain produces a product that has at least about 1.5 fold more inhibitory effect on *Fusarium* growth than *Muscodor albus* strain CZ 620 (NRRL Accession No. B-30547).

3. (Currently amended) The ~~isolated culture~~ composition according to claim 2, wherein said ~~culture~~ *Muscodor* strain produces a product that has at least about 4 fold more of an effect on mortality on *Meloidogyne incognita* and *hapla* than *Muscodor albus* strain CZ 620 (NRRL Accession No. B-30547).

4. (Currently amended) The composition of claim 1, wherein the culture is [[A]] a substantially pure culture or whole cell broth ~~comprising the strain of claim 1~~.

5. (Currently amended) [[A]] The composition of claim 1, wherein the composition is a solid composition. ~~comprising (a) the substantially pure culture or whole cell broth~~

~~comprising and/or (b)a cell fraction, supernatant, compound, metabolite or volatile derived from the strain of claim 1.~~

6. (Currently amended) The ~~strain~~ composition of claim 1, wherein said *Muscodor* strain is ~~culture has at least one of the identifying characteristics of~~ *Muscodor albus* strain SA-13 (NRRL Accession No. B-50774).

7. (Currently amended) ~~A combination~~ The composition of claim 1, further comprising:

~~(a) a first substance selected from the group consisting of a pure culture, cell fraction, supernatant, metabolite or volatile derived from the culture of claim 1; and,~~

~~(b) at least one of (i) a second substance, wherein said second substance is a chemical or biological pesticide and (ii)~~ at least one of a carrier, diluent, surfactant, and adjuvant.

[[9.]] 8. (Currently amended) The composition ~~combination~~ according to claim [[8]] 1, further comprising a second substance, wherein said second substance is a chemical or biological pesticide. ~~wherein the combination is a composition.~~

[[10.]] 9. (Currently amended) The composition of claim 1, wherein the isolated *Muscodor* strain is further capable of producing ~~of claim 1 wherein the product of (a) also includes~~ at least one of Propanoic acid, 2-methyl-, methyl ester and Propanoic acid, 2-methyl-, ethyl ester.

[[11.]] 10. (Currently amended) A composition having pesticidal activity comprising:

Ethanol;
Propanol;
2-Butanone, 4-hydroxy-;
Ethyl Acetate;
Propanoic acid, ethyl ester;
1-Butanol, 3-methyl-;
1-Butanol, 2-methyl-;
Propanoic acid, 2-methyl-, ethyl ester;
Butanoic acid, 2-methyl-, methyl ester;
Butanoic acid, 2-methyl-, ethyl ester;
Propanoic acid, 2-methyl-,butyl ester;

1-Butanol, 3-methyl-, acetate;
Ethyl tiglate;
Phenylethyl Alcohol; and
Azulene, 1,2,3,5,6,7,8,8a-octahydro-1,4-dimethyl-7-(1-methylethenyl)-, [1S-(1.alpha.,7.alpha.,8a.beta.)]-[[.]];

at least one of: Propanoic acid, 2-methyl-, methyl ester; Acetic acid, 2-methylpropyl ester;; 1-Butanol, 2-methyl-, acetate; Propanoic acid, 2-methyl-, butyl ester; Benzene, methoxy-; 3-Octanone; Propanoic acid, 2-methyl-, 3-methylbutyl ester; Acetic acid, 2-phenylethyl ester; (-) Aristolene; Cyclohexane, 1-ethenyl-1-methyl-2,4-bis(1-methylethenyl)-; Azulene, 1,2,3,4,5,6,7,8-octahydro-1,4-dimethyl-7-(1-methylethenyl)-,(1S-(1.alpha.,4.alpha.,7.alpha.)]-; and Bicyclo[5.3.0]decane, 2-methylene-5-(1-methylvinyl)-8-methyl-;

and optionally at least one of a carrier, diluent, surfactant, and adjuvant.

[[12.]] 11. (Currently amended) The composition according to claim [[11]] 10, wherein said composition ~~artificial mixture~~ comprises

Ethanol;
Propanol;
2-Butanone, 4-hydroxy-;
Ethyl Acetate;
Propanoic acid, 2-methyl-, methyl ester;
Propanoic acid, ethyl ester;
1-Butanol, 3-methyl-;
1-Butanol, 2-methyl-;
Propanoic acid, 2-methyl-, ethyl ester;
Acetic acid, 2-methylpropyl ester;
Butanoic acid, 2-methyl-, methyl ester;
Butanoic acid, 2-methyl-, ethyl ester;
Propanoic acid, 2-methyl-,butyl ester;
1-Butanol, 3-methyl-, acetate;
1-Butanol, 2-methyl-, acetate;
Propanoic acid, 2-methyl-, butyl ester;
Benzene, methoxy-;
Ethyl tiglate;
3-Octanone;
Propanoic acid, 2-methyl-, 3-methylbutyl ester;
Phenylethyl Alcohol;
Acetic acid, 2-phenylethyl ester;
(-)Aristolene;

Cyclohexane, 1-ethenyl-1-methyl-2,4-bis(1-methylethenyl)-;
Azulene, 1,2,3,4,5,6,7,8-octahydro-1,4-dimethyl-7-(1-methylethenyl)-,(1S-(1.alpha.,4.alpha.,7.alpha.)]-;
Bicyclo[5.3.0]decane, 2-methylene-5-(1-methylvinyl)-8-methyl-; and,
Azulene, 1,2,3,5,6,7,8,8a-octahydro-1,4-dimethyl-7-(1-methylethenyl)-, [1S-(1.alpha.,7.alpha.,8a.beta.)]-.

[[13.]] 12. (Currently amended) A method for modulating pest infestation and/or phytopathogenic infection in a plant in need thereof comprising applying to the plant and/or seeds thereof and/or substrate used for growing said plant an effective amount of the composition of claim [[5]] 1.

[[14.]] 13. (Currently amended) A method for modulating pest infestation and/or phytopathogenic infection in a plant in need thereof comprising applying to the plant and/or seeds thereof and/or substrate used for growing said plant an effective amount of the composition of claim [[11]] 10.

[[15.]] 14. (Currently amended) The method according to claim [[13]] 12, wherein said pest is an insect pest, fungus, bacteria, or nematode.

[[16.]] 15. (Currently amended) The method according to claim [[15]] 12, wherein said pest is an insect pest, wherein said insect pest is *Spodoptera exigua*.

[[17.]] 16. (Currently amended) The method according to claim [[15]] 12, wherein said pest is a nematode, wherein said nematode ~~and said nematode~~ is *M. incognita* or *M. hapla*.

[[18.]] 17. (Currently amended) The method according to claim [[13]] 12, wherein said phytopathogenic infection results from fungus infection, wherein said fungus is a member of the *Botrytis* spp., *Sclerotinia* spp., *Sclerotium* spp., *Macrophomina* spp., *Verticillium* spp., *Fusarium* spp., *Rhizoctonia* spp., or *Pythium* spp.

[[19.]] 18. The method according to claim [[13]] 12, wherein said phytopathogenic

infection results from bacterial infection, wherein said bacteria is a member of the *Pectobacterium* spp., *Pseudomonas* spp., *Xanthomas* spp., or *Calvibacter* spp.

20-22. (Canceled)

23. (Original) An artificial mixture having fungicidal and nematicidal activity, the mixture comprising: ethanol; ethyl acetate; 1-Propanol,2-methyl; 1-Butanol, 3-methyl; 1-Butanol, 2-methyl; and, at least one of: Propanoic acid, 2-methyl-, methyl ester and Propanoic acid, 2-methyl-, ethyl ester and optionally at least one of a carrier, diluent, surfactant, and adjuvant.

24. (Original) The artificial mixture of claim 23, wherein the mixture comprises: ethanol; ethyl acetate; 1-Propanol, 2-methyl; Propanoic acid, 2-methyl-, methyl ester; 1-Butanol, 3-methyl; 1-Butanol, 2-methyl; and Propanoic acid, 2-methyl-, ethyl ester, and optionally at least one of a carrier, diluent, surfactant, and adjuvant.

25. (Original) A method for modulating pest infestation and/or phytopathogenic infection in a plant in need thereof comprising applying to the plant and/or seeds thereof and/or substrate used for growing said plant an amount of the artificial mixture of claim 17 effective to modulate pest infestation and/or phytopathogenic infection.

26. (Original) A method for modulating pest infestation and/or phytopathogenic infection in a plant in need thereof comprising applying to the plant and/or seeds thereof and/or substrate used for growing said plant an amount of the artificial mixture of claim 23 effective to modulate pest infestation and/or phytopathogenic infection.

27. (New) The composition of claim 5, wherein the solid composition is a dried grain grown with the culture of the *Muscodor* strain.

28. (New) The composition of claim 27, wherein the dried grain is selected from barley, corn, rye, rice, and wheat.

29. (New) The composition of claim 1, wherein the culture is a solid culture.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
[redacted]	03/15/2013	[redacted]	[redacted]	5689

117607 7590 04/01/2014

[redacted]

EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1653	

NOTIFICATION DATE	DELIVERY MODE
04/01/2014	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):

[redacted]

Office Action Summary	Application No. [redacted]	Applicant(s) [redacted]
	Examiner SHERIDAN MACAULEY	Art Unit 1653 / 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 *10 October, 2013*.

☐ 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) *1-19 and 23-29* is/are pending in the application.

5a) Of the above claim(s) *10-19 and 23-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-9,27 and 29* 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 *15 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 _____.

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

4) ☐ Other: _____.

9. The invention appears to employ a specific strain of fungi to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at pp. 60-61 that *Muscodor albus* strain SA-13 was deposited at NRRL under Budapest Treaty conditions on August 31, 2012.

10. For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. See MPEP 2403.

11. Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

12. Therefore, the claims do not comply with the requirements of 35 USC 112(a).

Claim Rejections - 35 USC § 101

13. 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.**

14. Claims 1-9, 27 and 29 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, claims 1-9 do not recite something significantly different than a judicial exception. The rationale for this determination is explained below.

15. Claims 1-9, 27 and 29 are directed to a composition of matter and recite a judicial exception (a natural product). The claims as a whole do not recite something significantly different from a natural product for the following reasons:

16. The March 4, 2014 USPTO guidance memorandum titled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)* implements a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of recent court decisions including *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. _, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. _, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

17. In order to answer the question, "Does the claim as a whole recite something *significantly different* than the judicial exception(s)?", the following factors are analyzed. On balance, if the totality of the relevant factors weighs toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected.

Factors that weigh <u>toward</u> eligibility (significantly different):

a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.
b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).

d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).
f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.
h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.
i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).
j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.
k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.

18. Regarding claims 1-6, 9 and 29, with respect to factors weighing towards eligibility, factor (a) is not satisfied. These claims recite a product that appears to be a natural product that is not markedly different in structure from naturally occurring products. Note that the claims recite a strain of *Muscodor albus*, specifically *Muscodor albus* strain SA-13, which is a naturally occurring strain, as discussed at p. 24 of the specification. Thus, the claimed fungal strain is not markedly different from what exists in nature. Factors (b) through (f) are not relevant because the claims do not include any elements in addition to the natural product. Note that claims 2, 3, 6 and 9 recite further

characteristics of the strain and thus do not include any elements in addition to the natural product. Claims 4, 5 and 29 recite basic properties of a fungal culture and thus also do not include any elements in addition to the natural product.

19. With respect to factors weighing against eligibility, factor (g) is satisfied because the claimed fungal strain is not markedly different from a naturally occurring fungal strain. Factors (h) through (l) are not relevant, because the claims do not include any elements in addition to the natural product.

20. In sum, when the relevant factors are analyzed, they weight against a significant difference. Accordingly, claims 1-6, 9 and 29 do not qualify as eligible subject matter.

21. Regarding claims 7, 8 and 27, with respect to factors weighing towards eligibility, factor (a) is not satisfied. The claim recites a product (a fungal strain) that appears to be a natural product that is not markedly different in structure from naturally occurring products. Each of the claims recites that the composition comprising the natural product also comprises an additional component. Claim 7 recites that the composition additionally comprises a carrier, claim 8 recites that the composition additionally comprises a chemical or biological pesticide, and claim 27 recites that the composition additionally comprises a dried grain. However, these limitations also read on a natural product, such as starch (a carrier), oxygen (a chemical pesticide), or a dried grain. Thus, factors (b) through (f) are not relevant because the claims do not include any elements in addition to the natural products, i.e., there is nothing in the claim other than the natural products.

22. With respect to factors weighing against eligibility, factor (g) is satisfied because the claimed fungal strain and the additional elements are not markedly different from naturally occurring products. Factors (h) through (l) are not relevant, because the claims do not include any elements in addition to the natural products.

23. In sum, when the relevant factors are analyzed, they weight against a significant difference. Accordingly, claims 7, 8 and 27 do not qualify as eligible subject matter.

24. Therefore, the claimed invention is not directed to patent eligible subject matter.

Claim Rejections - 35 USC § 103

25. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

In the Claims

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

1. (Currently Amended) A peptide that increases the level of estrogen *in vitro* or *in vivo*, wherein the peptide is ~~selected from the group consisting of:~~

~~a)~~ an isolated or substantially pure polypeptide obtainable from *Dioscorea* sp., wherein the polypeptide has an apparent molecular weight of about 32.5 kDA by chromatography, wherein the first twenty-one consecutive amino acids at the N-terminal of the polypeptide consists of SEQ ID NO:1~~;~~

~~b) a fragment of said polypeptide, wherein said fragment exhibits estrogen increasing activity; and~~

~~c) a variant having at least 85% sequence identity with said polypeptide, wherein said variant exhibits estrogen increasing activity~~.

2. (Original) A peptide according to claim 1, wherein the peptide increases the level of progesterone *in vitro* or *in vivo*.

3. (Canceled).

4. (Currently Amended) A peptide according to claim 1, wherein the polypeptide originates from *Dioscorea* ~~*Discorea*~~ *Opposita*.

5. (Original) A peptide according to claim 1, which is recombinantly-produced.

6. (Original) A peptide according to claim 1, wherein the peptide has higher activity after incubation at pH 1 than after incubation at pH 0.1 or at pH 2, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

[redacted]

7. (Original) A peptide according to claim 6, wherein the peptide has activity after incubation at pH 0.1, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

8. (Original) A peptide according to claim 1, wherein the peptide has higher activity after incubation at 80°C than after incubation at 60°C or at 100°C, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

9. (Original) A peptide according to claim 8, wherein the peptide has activity after incubation at 100°C, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

10. – 20. (Canceled).

[redacted]

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
[redacted]	08/17/2012	[redacted]	[redacted]	6857

23557 7590 06/06/2014

[redacted]

EXAMINER
NOAKES, SUZANNE MARIE

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/06/2014	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):

[redacted]

Office Action Summary	Application No. [redacted]	Applicant(s) [redacted]
	Examiner SUZANNE M. NOAKES	Art Unit 1656 / 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 *04/25/2014*.

☐ 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) *1,2 and 4-9* 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) *1,2 and 4-9* 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 _____ 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 _____.

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

4) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The amendments and response filed 25 April 2014 are acknowledged. Claims 3, and 10-20 are canceled. Thus, claims 1, 2 and 4-9 are pending and subject to examination on the merits.

Withdrawal of Previous Rejections

2. The rejection of claims 1-9 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, written description is withdrawn in view of the amendments to the claims.

3. The indicated allowability of claim 1(a) is withdrawn upon further consideration for the reasons indicated in the rejection below.

Claim Rejections - 35 USC § 101

4. 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.

5. Claims 1, 2 and 4-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because based upon an analysis with respect to the claims as a whole, said claim(s) do not recite something significantly different than a judicial exception. That is, said claims are determined to be drawn to a

naturally occurring polypeptide which is a product of nature that is not markedly or substantially different from that which exists in naturally.

The claims are drawn to a peptide that increases the level of estrogen *in vivo* or *in vitro* wherein said peptide is a substantially pure or isolated polypeptide from the species *Dioscorea*, said polypeptide has a MW of 32.5 kDa (ascertained by chromatography) and a N-terminus of SEQ ID NO: 1.

Thus, the claims are considered to be drawn to the judicial exception of a natural product and thus the claims are analyzed as whole in order to determine if they recite something which includes elements that add significantly more to the natural product than the mere isolation or discovery of the natural product itself.

Upon review of the instant claims, the claimed peptides/polypeptides are deemed to solely encompass natural products that exist in nature and which have not been altered in any way so that they are markedly or substantially different. That is, for example, the polypeptide comprising SEQ ID NO: 1 has not been altered in any way which would impart something markedly different from the natural polypeptide comprising SEQ ID NO: 1. As such, the claims are not subject matter which is eligible under the current standards for patentability of 35 U.S.C. § 101.

Applicants are referred to http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf, and specifically to Examples A-E.

Conclusion

6. No claim is allowed. This is a Non-Final Office action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for 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 (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.

/SUZANNE M NOAKES/
Primary Examiner, Art Unit 1656
03 June 2014

AMENDMENTS TO THE CLAIMS

1-73 (Cancelled)

74. (New) A pharmaceutical product comprising an allergen extract or an allergoid thereof, which comprises at least one extract of mite bodies selected from the following groups a)-b):

a) An extract of Der p mite bodies, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der p mite bodies,

b) An extract of Der f mite bodies, wherein the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 70% v/v Der f mite bodies,

and at least one extract of mite faecal particles selected from the following groups c)-d):

c) An extract of Der p faecal particles, wherein the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der p faecal particles,

d) An extract of Der f faecal particles, wherein the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der f faecal particles.

75. (New) The pharmaceutical product according to claim 74 comprising an extract of Der p mite bodies and an extract of Der p faecal particles.

76. (New) The pharmaceutical product according to claim 74 comprising an extract of Der f mite bodies and an extract of Der f faecal particles.

77. (New) The pharmaceutical product according to claim 74 comprising an extract of Der p mite bodies, an extract of Der p faecal particles, an extract of Der f mite bodies and an extract of Der f 2 faecal particles.

78. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p mite bodies; and/or the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 95% v/v Der f mite bodies; and/or the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p faecal particles; and/or the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der f faecal particles.

79. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one Der p mite body fraction or combined Der p mite body fractions and where extraction of said fraction(s) of mite bodies results in an extract comprising by weight equal amounts of group 1 and group 2 allergen or more group 2 allergen than group 1 allergen and/or the extract of Der f mite bodies is prepared from one Der f mite body fraction or more combined Der f mite body fractions and where extraction of said fraction(s) of mite bodies results in an extract comprising by weight equal amounts by weight of group 1 and group 2 allergen or more group 2 allergen than group 1 allergen.

80. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p mite bodies; the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 95% v/v Der f mite bodies; the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p faecal particles; the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der f faecal particles.

81. (New) The pharmaceutical product according to claim 74, wherein the pharmaceutical product is a sublingual tablet.

82. (New) The pharmaceutical product according to claim 81, wherein the sublingual tablet is a fast dissolving sublingual tablet.

83. (New) A mite body fraction comprising more than 70% v/v mite bodies.

84. (New) The mite body fraction according to claim 83, wherein the mite bodies are Der p mite bodies or Der f mite bodies.

85. (New) A mite faecal particle fraction comprising more than 70% v/v faecal particles.

86. (New) The mite faecal particle fraction according to claim 85, wherein the faecal particles is Der p faecal particles or Der f faecal particles.

87. (New) A method for the manufacture of a mite allergen allergen extract (I) or allergoids thereof for a pharmaceutical product according to claim 74, said allergen extract (I) having a predetermined and controlled amount by weight of allergens selected from Der f 1, Der f 2, Der p 1 and Der p 2 allergens and comprising the following steps:

a) Fractions of Der p mite bodies and/or fractions of Der p mite faecal particles are isolated from Der p cultures of mites, and/or fractions of Der f mite bodies and/or fractions of Der f mite faecal particles are isolated from Der f mite cultures;

b) Optionally combining several fractions of Der p mite bodies, optionally combining several fractions of Der p mite faecal particles, optionally combining several fractions of Der f mite bodies and optionally combining several fractions of Der f mite faecal particles;

c) Extracting allergens from mite body faction(s) obtained in a step a) or a step b) as above and/or extraction of allergens from mite faecal particle fraction(s) obtained in a step a) or a step b) as above; and thereafter

d) Measuring the concentration (w/v) of group 1 and group 2 allergen in mite allergen extracts obtained in a step c) as above; and optionally

c) Mixing one or more extract(s) of mite bodies with one or more extract(s) of faecal particles as obtained in a step c) as above to obtain a mixture of allergen extracts (I) with a predetermined amount by weight of group 1 to group 2 allergen and optionally

f) Converting the extract (I) to an allergoid thereof.

88. (New) The method according to claim 87, wherein one or more extract(s) of mite bodies and one or more extract(s) of faecal particles is mixed to obtain a mixture of allergen extracts (I).

89. (New) The method according to claim 87, wherein the mixture of mite allergen extract (I) comprises extract(s) of Der p mite bodies, extract(s) of Der p faecal particles, extract(s) of Der f mite bodies and extract(s) of Der f 2 faecal particles.

90. (New) The method according to claim 87, wherein the pharmaceutical product is a fast dissolving sublingual tablet.

91. (New) A method for treatment and/or prevention of allergy and allergic asthma caused by house dust mites which method comprises administering to a patient in need of such treatment an effective amount of a pharmaceutical product of claim 74.

[redacted]

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
[redacted]	04/22/2013	[redacted]	[redacted]	2518

826 7590 06/19/2014

[redacted]

EXAMINER
ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/19/2014	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):

[redacted]

Office Action Summary	Application No. [redacted]	Applicant(s) [redacted]	
	Examiner NORA ROONEY	Art Unit 1644	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 *05/08/2014*.

☐ 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) *74-91* is/are pending in the application.

5a) Of the above claim(s) *83-91* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *74-82* 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 *12/03/2012* 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 *12/03/2012*.

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

4) ☐ Other: _____.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

2. Claims 74-91 are pending.

3. Applicant's election of Group I, claims 74-82 without traverse in the reply filed on 03/10/2014 is acknowledged.

4. Claims 83-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/10/2014.

4. Claims 74-82 are currently under consideration as they read on a pharmaceutical product comprising mite body and fecal particle extracts.

5. Applicant's IDS document filed on 12/03/2012 has been considered.

Double Patenting

6. Claims 74-82 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11, 13-15 and 17-29 of copending Application No. 13/314,024. Although the claims at issue are not identical, they are not patentably distinct from each other because claims 1-11, 13-15 and 17-29 in Application 13/314,024 are directed to method of manufacturing and using the instant allergen extracts of instant claims 74-82.

The reference teachings anticipate the claimed invention.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Rejections - 35 USC § 101

7. 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.

8. Claims 74-82 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claims 74-82 do not recite something significantly different than a judicial exception. The rationale for this determination is explained below:

Claims 74-82 are directed to naturally occurring products, which are a judicial exception for patent-eligibility under 35 U.S.C. 101 in light of the recent court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

See *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (*Guidance*). The Guidance implements a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of these recent court decisions.

The pharmaceutical products recited in the claims are not markedly different from naturally occurring products. The "markedly different" inquiry focuses on the structural characteristics of the product and not how it was made. It is noted that new laboratory or

engineering techniques are not required and the extent of effort required to make product is not relevant to the inquiry. The examiner gives the claim its broadest reasonable interpretation in light of the specification. Based on the plain and ordinary meaning of Der p and Der f extracts of mite bodies and fecal particles in the art in light of the specification, naturally occurring extracts and allergens are encompassed. The combination of the two naturally occurring extract or allergen products in a single composition does not make them eligible. A marked difference requires a product to be both (1) non-naturally occurring and (2) markedly different in structure. As such, the claimed pharmaceutical products are ineligible.

As such, claims 74-82 are not directed to patent eligible subject matter.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

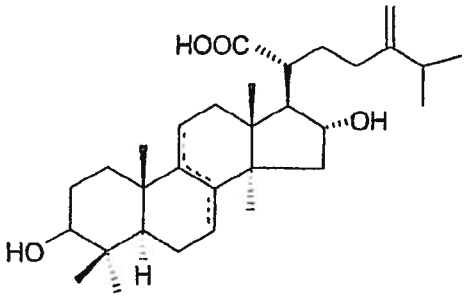
10. Claims 74-76 and 78-80 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2010/0024048 (PTO-892; Reference A) and corresponding U.S. Patent 8,312,841 (PTO-892; Reference B).

U.S. Patent Application Publication 2010/0024048 and U.S. Patent 8,312,841 teaches preparing Dermatophagoides pteronyssinus and Dermatophagoides farinae allergenic extracts used in allergy formulations for use in vivo or in vitro. The reference teaches extracts of whole cultures, where allergens from both the mites and mite fecal particles are obtained. The reference

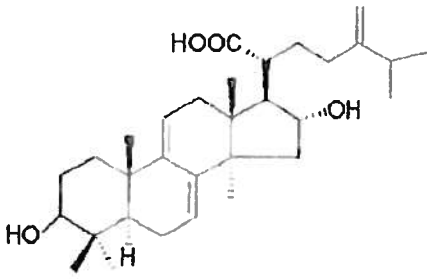
IN THE CLAIMS:

1-10. (Canceled)

11. (Currently amended) A method of enhancing immunity of an individual comprising administering to the individual a ~~therapeutically effective amount of~~ a composition that contains a lanostane, the composition being substantially devoid of secolanostane, wherein the lanostane is



or



and wherein the amount of the composition administered to the individual is effective for increasing in the individual, as compared with a control, growth of spleen cells or the serum level of an immunoglobulin selected from the group consisting of IgG, IgM, and IgA.

12. (Previously presented) The method of claim 11, wherein the composition is a *Poria* extract, the *Poria* extract has a chromatographic value Rf, not less than 0.1 in accordance with a thin layer chromatography, which is developed by a mixed solvent of dichloromethane:methanol = 96:4 and is detected by an ultraviolet lamp and iodine vapor.

13. (Previously presented) The method of claim 12, wherein the *Poria* extract is prepared by a method comprising the following steps:

a) extracting metabolites, fermentation products or sclerotium of *Poria cocos* (Schw) Wolf by water, methanol, ethanol, or a mixed solvent thereof;

b) concentrating the resulting liquid extract from step a);

c) introducing the resulting concentrated substance from step b) into a silica gel column;

d) eluting the silica gel column with an eluent having a low polarity, and collecting the resulting eluate;

e) concentrating the eluate to form a concentrated eluate, wherein said eluent having a low polarity is so selected such that the concentrated eluate has a chromatographic value, Rf, not less than 0.1 in accordance with a thin layer chromatography, which is developed by a mixed solvent of dichloromethane:methanol = 96:4 and is detected by an ultraviolet lamp and iodine vapor.

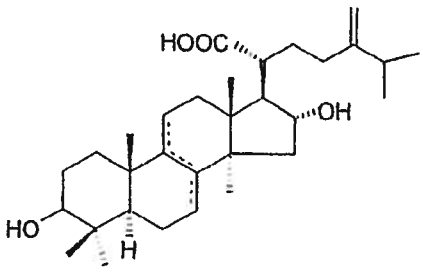
14. (Previously presented) The method of claim 13, wherein the extraction in step a) is carried out by using 95% ethanol.

15. (Previously presented) The method of claim 13, wherein the concentrated substance resulted from step b) is further extracted with a two-phase solvent containing methanol and n-hexane in a volumetric ratio of 1:1, a methanol layer is separated from the two-phase solvent extraction mixture, and the methanol layer is concentrated to form a concentrate, which is used as a feed to the silica gel column in step c).

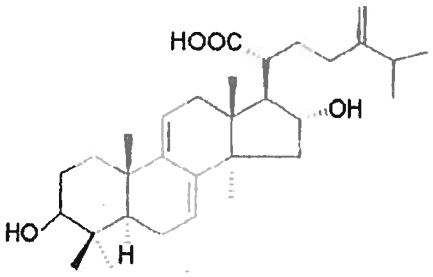
16. (Previously presented) The method of claim 13, wherein the low polarity eluent is a mixed solvent containing dichloromethane and methanol in a volumetric ratio of 96.5:3.5.

17. (Previously presented) The method of claim 12, wherein the *Poria* extract contains 5-60% of the lanostane.

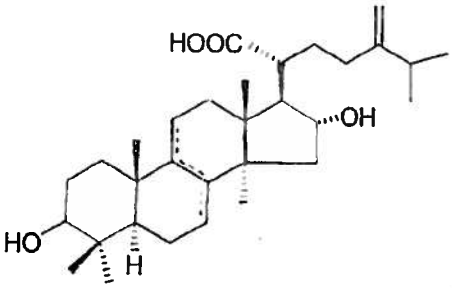
18. (Previously presented) The method of claim 11, wherein the composition contains an isolated lanostane selected from the group consisting of



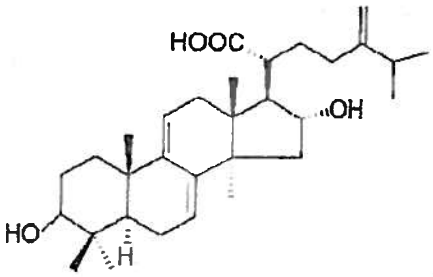
and



19. (Previously presented) The method of claim 18, wherein the isolated lanostane is



20. (Previously presented) The method of claim 18, wherein the isolated lanostane is



21. (Canceled)

22. (New) The method of claim 11, wherein the amount administered is effective for increasing both growth of spleen cells and the serum level of an immunoglobulin.

23. (New) The method of claim 11, wherein 2.5 to 20 mg/kg/day of the lanostane is administered.

24. (New) The method of claim 23, wherein 5 to 20 mg/kg/day of the lanostane is administered.

25. (New) The method of claim 23, wherein 2.5, 5, 10, or 20 mg/kg/day of the lanostane is administered.

26. (New) The method of claim 12, wherein 10-80 mg/kg/day of the composition is administered.

27. (New) The method of claim 26, wherein 10, 40, or 80 mg/kg/day of the composition is administered.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
[redacted]	11/01/2013	[redacted]	[redacted]	5453

24267 7590 08/19/2014

[redacted]

EXAMINER
HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
08/19/2014	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):

[redacted]

Office Action Summary	Application No. [redacted]	Applicant(s) [redacted]
	Examiner Susan Hoffman	Art Unit 1655
		AIA (First Inventor to File) Status No

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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 *8/4/14*.

☐ 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) *11-20 and 22-27* 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) *11-20 and 22-27* 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 _____ 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 _____.

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

4) ☐ Other: _____.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

2. The amendment filed August 4, 2014 has been received and entered. The text of those sections of Title 35, U.S. Code. not included in this action can be found in a prior Office action. Any rejection set forth in a previous Office action that is not specifically set forth below is withdrawn.

3. Claims 11-20 and 22-27 are pending.

Claim Rejections - 35 USC § 101

4. Claims 11-20 and 22-27 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that "Present claims 11-20 require administration of an amount of a composition containing K2 or K4 that is effective for increasing growth of spleen cells or the serum level of IgG, IgM, or IgA in the individual. Like claim 3 in the example discussed above [in the guidance memorandum], factors b, c, d, and weigh toward patent eligibility of the claims." However, in claim 3 of Example IIIB in the guidance memorandum relates to treating a colon cancer patient. Thus, claim 3 in Example IIIB is limited to specific patient subset; however, applicant's current claims are drawn to increasing the growth of spleen cells or increasing the serum levels of IgG, IgM, or IgA. All individuals have spleen cells and serum levels of IgG, IgM, or IgA; thus, the individual treated in applicant's claims can

be any individual. Therefore, applicant's method is not limited to a specific patient population like the colon cancer patient of Example IIIB. Consequently, applicant's claimed method reads on administering the natural products to any individual.

Applicant also argues that "Factor [b]) is satisfied as the claims are meaningfully limited to administering an amount of the composition that is effective for increasing growth of spleen cells or the serum level of IgG, IgM, or IgA in the individual." However, as discussed above, the claims encompass any administration of the claimed natural products to any individual. As discussed in Example G in the guidance memorandum, a step of only administering a natural product is not considered to place a meaningful limit on the scope of the claim. Applicant's method substantially forecloses others from any administration of the natural products. Furthermore, applicant argues that "Factor d) is satisfied as the claims recite more than a general instruction to use the composition." However, as discussed above, the claims encompass any administration of the claimed natural products to any individual. As discussed in Example G in the guidance memorandum, a step of exposing/administering a patient to a natural product is "no more than a general instruction to apply or use the natural" product. Applicant also argues that "Factor f) is satisfied as it was not well known or routine to use the composition to enhance immunity of a subject, much less by administering an amount effective for increasing growth of spleen cells or the serum level of IgG, IgM, or IgA." However, as discussed above, the claims encompass any administration of the claimed natural products to any individual. Administering the claimed natural products is well-understood and conventional in the art.

In regards to new claims 23-27, since the individual treated in the method encompasses any individual, claims 23-27 would preclude the use of the natural products in these broadly

claimed amounts. Therefore, new claims 23-27 are also not considered to be drawn to patent eligible subject matter.

Double Patenting

5. Claims 11-20 and 22-27 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 8,658,629 (Lin) for the reasons set forth in the previous Office action.

Applicant has requested that this rejection be held in abeyance until allowable subject matter is indicated. The request is noted. The rejection is currently still considered valid at this time for the reasons set forth in the previous Office action.

6. Claims 11-20 and 22-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-13, 16, and 17 of copending Application No. 12/854,037 for the reasons set forth in the previous Office action.

Applicant has requested that this rejection be held in abeyance until allowable subject matter is indicated. The request is noted. The rejection is currently still considered valid at this time for the reasons set forth in the previous Office action.

7. Claims 11-20 and 22-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-21 of copending Application No. 12/415,205 for the reasons set forth in the previous Office action.

Applicant has requested that this rejection be held in abeyance until allowable subject matter is indicated. The request is noted. The rejection is currently still considered valid at this time for the reasons set forth in the previous Office action.