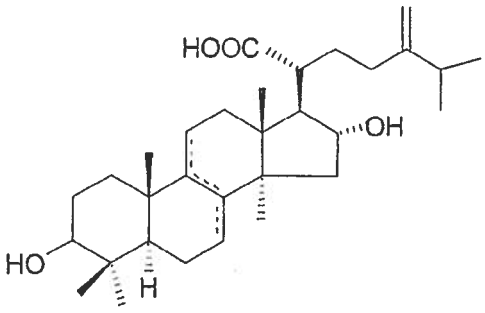
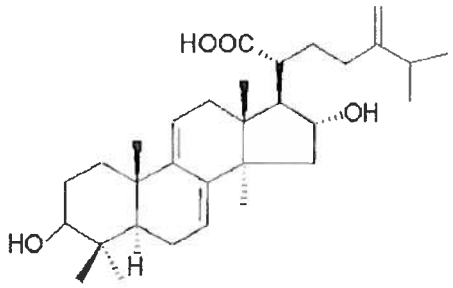
IN THE CLAIMS:

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.

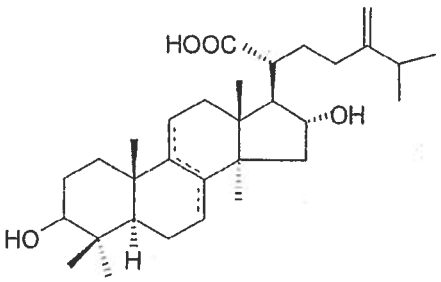
14. (Previously presented) The method of claim 13, wherein the extraction in step a) is carried out by using 95% ethanol.

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).

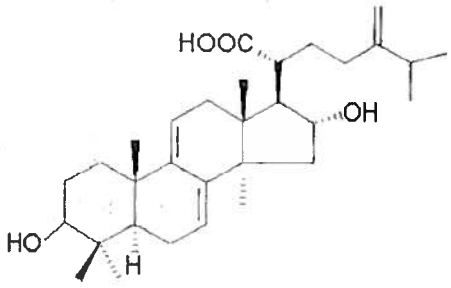
16. (Previously presented) The method of claim 13, wherein the low polarity eluent is a mixed solvent containing dichloromethane and methanol in a volumetric ratio of 96.5:3.5.

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

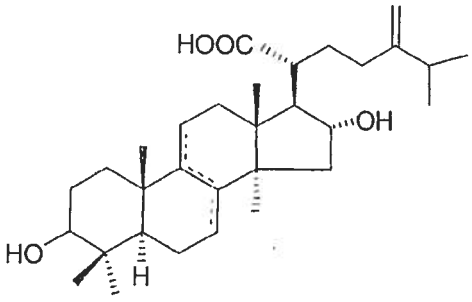
18. (Previously presented) The method of claim 11, wherein the composition contains an isolated lanostane selected from the group consisting of



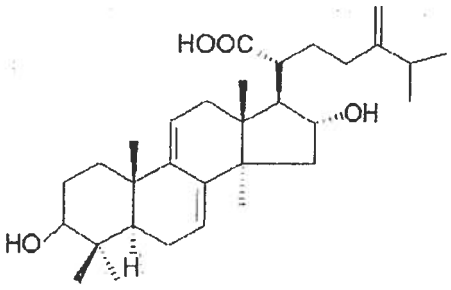
and



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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14/069,989	11/01/2013	Hang-Ching Lin	218040-0005D2	5453

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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):

docket@c-m.com
USPTOMail@c-m.com

Office Action Summary	Application No. 14/069,989	Applicant(s) LIN ET AL.	
	Examiner Susan Hoffman	Art Unit 1655	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 *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.