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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/121,416	03/29/2011	Chie Suzuki	378262US99PCT	8980

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
02/02/2012	ELECTRONIC

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

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

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

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	13/121,416	SUZUKI ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- 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 _____.

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) 1-24 is/are pending in the application.

5a) Of the above claim(s) 1-6 and 10-13 is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) 7-9 and 14-24 is/are rejected.

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

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

Application Papers

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

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 06/27/2011;08/30/2011.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 01/24/2012 with the amendment of claims 8 and 9 and newly added claims 14-24.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement (IDS) submitted on 06/27/2011 and 08/30/2011 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group II, claims 7-9 (and newly added claims 14-24) in the reply filed on 01/18/2012 is acknowledged. The traversal is on the ground(s) that no adequate reason has been provided to support the conclusion of patentable distinctness between the groups and that there does not appear to be a lack of unity or burden for examining the inventions together. This is not found persuasive because claim 1, at least, is anticipated or obvious over Tyman (A*) because Tyman clearly teaches the instantly claimed bloat therapeutic agent. Therefore, the special technical feature is lacking. The restriction was made under PCT Rules 13.1 and 13.2, and, thus, examination burden is not

considered. Since the inventions lack unity, the restriction is deemed proper and is maintained for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-9 and 14-24 are currently being examined on the merits.

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 7-9 and 14-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating bloating and flatulence in a ruminant suffering from bloating and flatulence comprising administering to said ruminant cashew nut shell liquid, wherein the cashew nut shell liquid is first heated, and wherein the cashew nut shell liquid comprises anacardic acid, cardanol, cardol, does not reasonably provide enablement for a method for bloat therapy, comprising administering cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol to a ruminant suffering from bloat nor is the specification enabling for treating bloat caused by *Streptococcus bovis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention and Breadth of the Claims: The claims are drawn to a method for bloat therapy, comprising administering cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid,

cardanol, or anacardic acid and cardanol to a ruminant suffering from bloat and for treating bloat caused by *Streptococcus bovis*. The specification describes that the bloat therapeutic agent of the present invention can prevent a relapse of bloat and that the agent of the present invention has both a defoaming effect and a sterilizing/suppressing effect against S. bovis.

The nature of the invention is complex and the claims are broad in that cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol can be administered for treating and preventing bloat and that the cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol can sterilize/suppress *Streptococcus bovis*. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes administering cashew nut shell liquid, wherein the cashew nut shell liquid is first heated, and wherein the cashew nut shell liquid comprises anacardic acid, cardanol, cardol to a bull.

However, no working examples are provided with regard to administering cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol to a ruminant suffering from bloat or to a ruminant suffering from *Streptococcus bovis* infection.

Please note that preventing a relapse of bloat is impossible and that Applicant has not provided any evidence that the cashew nut shell liquid has a defoaming effect and is capable of sterilizing/suppressing *Streptococcus bovis*.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. "Streptococcus Group D Infections Treatment and Management" (U) teaches that S. bovis is treated with intravenous penicillin G or ceftriaxone or with a combination of penicillin or ceftriaxone and gentamicin, in uncomplicated cases.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to use cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol for treating bloat in ruminants or for sterilizing/suppressing *Streptococcus*

bovis. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 7-9 and 14-24 are not considered to be fully enabled by the instant specification.

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

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claim 7 are rendered uncertain by the phrase "a method for bloat therapy, comprising administering cashew nut shell liquid, heated cashew nut shell liquid, anacardic acid, cardanol, or anacardic acid and cardanol to a ruminant suffering from bloat" because it is unclear if Applicant is claiming administering a combination of ingredients or individual ingredients. For example, is Applicant claiming that the cashew nut shell liquid contains the ingredients or that all of the ingredients are being administered or that only one of the ingredients are being administered or that a combination of ingredients can be administered? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that the art rejection below is based upon what Applicant is enabled for and that no art rejection has been made for claims drawn to treating bloat caused by *Streptococcus bovis*, since Applicant is not enabled for this limitation (See above 112, 1st paragraph rejection).

Claim Rejections - 35 USC § 103

The following is a quotation of 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.

This application currently names joint inventors. In considering patentability of the claims under 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 were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Vaayu Mel Puchu Thylam" (V).

"Vaayu Mel Puchu Thylam" teaches that a composition comprising cashew nut shell oil that has been heated to boiling can be administered for treating gaseous/flatulence (which reads on bloat/bloating). "Vaayu Mel Puchu Thylam" further teaches that the cashew nut shell oil is administered in an amount of 350 grams.

Although "Vaayu Mel Puchu Thylam" does not teach that the cashew nut shell liquid contains anacardic acid, cardanol, or anacardic acid and cardanol, the claimed compounds are inherent to the cashew nut shell liquid taught by "Vaayu Mel Puchu Thylam" because the cashew nut shell oil and heated cashew nut shell oil taught by "Vaayu Mel Puchu Thylam" is one and the same as disclosed in the instantly claimed invention of Applicant. Thus, anacardic acid, cardanol, or anacardic acid and cardanol are inherent to the cashew nut shell oil taught by "Vaayu Mel Puchu Thylam".

It would have been obvious to modify the method taught by "Vaayu Mel Puchu Thylam" by administering cashew nut shell oil that has been heated to a ruminant because at the time the invention

was made, it was known that cashew nut shell oil that has been heated could be administered for treating gas/flatulence as clearly taught by "Vaayu Mel Puchu Thylam".

Thus, an artisan of ordinary skill would reasonably expect that administering cashew nut shell oil that had been heated would be effective in a ruminant, since it was known that cashew nut shell oil that has been heated can be administered to a human for treating gas/flatulence and it would be expected that a composition that is safe for humans could safely be administered to a ruminant. This reasonable expectation of success would motivate the artisan to administer cashew nut shell oil that has been heated to a ruminant based upon the teachings of "Vaayu Mel Puchu Thylam".

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a safe and effective concentration of cashew nut shell oil that has been heated to treat bloat in a ruminant animal. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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 obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would

have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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

Claims 7-9 and 14-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 26 and 29 of copending Application No. 12/663598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods in both applications are drawn to a method of treating bloating in ruminants by administering cashew nut shell oil and its components.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. 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.

/Amy L Clark/
Primary Examiner, Art Unit 1655

Notice of References Cited	Application/Control No. 13/121,416	Applicant(s)/Patent Under Reexamination SUZUKI ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	"Streptococcus Group D Infections Treatment & Management" by Sinave et al, Eds. Internet Date: 2012-01-12 [Retrieved from the Internet on: 2012-01-29]. Retrieved from the Internet: <URL: http://emedicine.medscape.com/article/229209-treatment>.
	V	"Vaayu Mel Puchu Thylam" from Anuboga Vaithiya Navaneetham,Pub:Palani Thandayuthapani Devasthanam publications , Directorate of Indian systems of Medicine, Chennai.(1975) by Abdulla Sahib. Page 36.
	W	
	X	

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