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EXAMINER

NEAGU, IRINA

ART UNIT	PAPER NUMBER
1627	

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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.

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

### **DETAILED ACTION**

Applicant's amendment of 29 August, 2013, in which claims 1, 11, 12, 13, 14, 16 and 18 have been amended and claims 4-10 and 15 have been cancelled, is acknowledged.

Claims 1- 3, 11-14 and 16-20 are pending in the instant application.

Claims 14 and 16-20 are withdrawn, as being drawn to a non-elected invention.

Claims 1-3 and 11-13 are being examined herein.

### ***Priority***

The instant application is a National Stage entry of International Application No. PCT/US2010/31430, filed on 16 April 2010, which claims priority from U.S. Provisional Application No. 61/170,234, filed on 17 April 2009. A certified copy of the priority document has been submitted on 14 October 2011.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 14 October 2011, 29 March 2013 and 18 September 2013, are acknowledged and considered.

With regards to the non-patent literature documents listed on page 2 of the IDS of 29 March, 2013, the examiner requests the Applicant to indicate the year /date for each of the cited entries, in order for the references to be considered.

### ***Election/Restrictions***

Applicant's election with traverse of Group 1, drawn to a method of inducing a reward response in a subject with a composition comprising an extract from *Mucuna pruriens* and an extract from *Nelumbo nucifera*, in the reply of 29 August 2013, is acknowledged. Claims 14 and

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16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **with** traverse.

Applicants' election of nuciferine, as the species of an aporphine alkaloid for initial examination, in the reply of 29 August 2013, is acknowledged. Claims 1-3 and 11-13 read on the elected species.

Applicant has amended the claims to recite a composition comprising an extract from *Mucuna pruriens* and an extract from *Nelumbo nucifera*. The examiner acknowledges Applicant's election with traverse on the basis that the newly amended claims share the technical feature which is an extract from *Mucuna pruriens* and *Nelumbo nucifera*, which is not in the prior art.

The examiner disagrees with Applicant's assertion that such a combined extract is not known in the prior art. The examiner emphasizes that each of the two extracts, namely the extract from *Mucuna pruriens* and the extract from *Nelumbo nucifera*, has long been known in traditional medicine to have satiating properties; thus, the combination of the two is expected to have similar satiating properties. As such, the combination of extracts from *Mucuna pruriens* and *Nelumbo nucifera* is rendered obvious by the prior art, and is not a special technical feature. Therefore, unity of invention is not present.

Based on the response presented above, the requirement for restriction/election is maintained and is herein made FINAL.

Claims 1-3 and 11-13 have been examined to the extent they read on the elected species: nuciferine as the aporphine alkaloid, and the following rejections and objections are made below.

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***Objection to the Specification***

The Specification is objected to due to the following informality: in the amendment to the Specification, submitted on 14 October 2011, on line 2, the text "PCT/US2006/031430" should read --PCT/US2010/031430--.

***Objection to the Drawings***

The drawings, submitted on 14 October 2011, are objected to due to the following informality: in Figure 2, the structure of L-phenyl alanine is incorrect. Appropriate correction is required.

***Claims Objections***

Claim 3 is objected to due to the following informality: the text "The method of claim 3" should read --The method of claim 1-- or --The method of claim 2--. Appropriate correction is required.

Claims 14 and 16-20, while currently withdrawn, are objected to because of the following informality: The withdrawn claims are objected to for being presented in a non-compliant form. Specifically, the status identifier states the claim is "(Original)" or "(Currently amended)", but the claims are withdrawn because of the election made by the Applicant on 29 August 2013. As such, claims 14 and 16-20 should be identified as "(Withdrawn)" until such time as examiner rejoins the claims for examination. Appropriate correction is required. See MPEP 714(C).

***Claim Rejections - 35 USC § 112***

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.

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Claims 1 and 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a method of inducing a reward response in a subject, and claim 2 is drawn to the method of claim 1, wherein the said response stimulates a desired state of being in the subject. The specification defines a reward response as a "positive, self-reinforcing response to a pleasurable act, [...] (which) may be difficult to quantify" (Specification, page 1, [0003], lines 11-13). Based on the definition provided in the Specification, it is the examiner's position that such as "reward response" is a relative term, and, consequently, a method of inducing such a reward response is indefinite. Furthermore, the term "a desired state of being in a subject" in claim 2 is a relative term which renders the claim indefinite. The term "a desired state of being in a subject" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention

Appropriate correction is required.

For the purpose of compact prosecution, the examiner interprets the language of claims 1 and 2 to mean a method of stimulating in a subject a feeling of having already eaten (or a method of reducing a subject's desire to eat); based on this interpretation, the following rejections are made below.

#### ***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:

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(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 negated by the manner in which the invention was made.

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 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.

Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uccatadyamodakah (In *Vangasena*; Shankar et al., Eds.; Bombay, India, 1996; p. 236; cited as Exhibit 1 in the IDS of 29 March 2013) and Nilakamala Kanda Gunah (Kaiyadeva, Nilakamala Kanda Gunah. In *Kaiyadevanighantau*; Sharma et al., Eds.; Varanasi, India, 1979; p. 268-269; cited as Exhibit 3 in the IDS of 29 March 2013), in view of Van Der Glessen et al. (US 2006/0165822, published 27 July 2006, cited in the IDS of 14 October 2011) and Mukherjee et al. (J. Pharm. Pharmacol. 2009, 61, 407-422, cited in PTO-892).

Uccatadyamodakah (In *Vangasena*; Shankar et al., Eds.; Bombay, India, 1996; p. 236; cited as Exhibit 1 in the IDS of 29 March 2013) teaches a method of stimulating in a subject a feeling of satiation with a therapeutic formulation comprising *Mucuna pruriens* (seeds), in an amount of 192 g, the seeds being dried and grounded in a mortar, with the addition of other ingredients and of water to make a soft paste, the formulation being administered as bolus like

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sweet pills in an amount of 48 grams (which reads on a therapeutically effective amount).

Uccatadyamodakah teaches the administration is oral, in the evening, on empty stomach (before the subject eats a meal, as in claim 11).

Uccatadyamodakah does not teach a method of stimulating of feeling of having already eaten with a combination of an extract from *Mucuna pruriens* and *Nelumbo nucifera*.

Uccatadyamodakah does not specifically teach administration of the composition 90 minutes before the subject eats a meal, as in instant claim 11.

Nilakamala Kanda Gunah (Kaiyadeva, Nilakamala Kanda Gunah. In *Kaiyadevanighantau*; Sharma et al., Eds.; Varanasi, India, 1979; p. 268-269; cited as Exhibit 3 in the IDS of 29 March 2013) teaches a method of stimulating in a subject a feeling of satiation with a therapeutic formulation comprising *Nelumbo Nucifera*.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an extract of *Mucuna pruriens* and an extract of *Nelumbo nucifera*, in a therapeutic formulation used to stimulate a feeling of having already eaten, and administer said formulation 90 minutes before the subject eats a meal.

Even though Uccatadyamodakah does not specifically teach that an extract of *Mucuna pruriens* contains L-Dopa, the L-Dopa content is an inherent property of the seeds of *Mucuna pruriens*, known at the time the invention was made, as evidenced by Van Der Glessen et al. (US 2006/0165822, published 27 July 2006, cited in the IDS of 14 October 2011, see Abstract, [0016], *Mucuna pruriens* used either as seed powder or as extract, also [0022]).



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Similarly, even though Nilakamala Kanda Gunah does not specifically teach that an extract of *Nelumbo nucifera* contains an aporphine alkaloid such as nuciferine, the nuciferine content is an inherent property of the *Nelumbo nucifera* seed extract, known at the time the invention was made, as evidenced by Mukherjee et al. (J. Pharm. Pharmacol. 2009, 61, 407-422, cited in PTO-892, see page 409, left column, lines 7 and 9, and page 410, Figure 1, bottom left structure).

The person of ordinary skill in the art at the time the invention was made would have been motivated to combine an extract of *Mucuna pruriens* and an extract of *Nelumbo nucifera* and use the combination in a method of stimulating in a subject a feeling of satiation, because *Mucuna pruriens* (seeds or extract) and *Nelumbo nucifera* were each known to be inducing a feeling of satiation in a subject, as taught by Uccatadyamodakah and Nilakamala Kanda Gunah. Therefore, one of ordinary skill in the art would have reasonably expected that combining extracts from seeds of *Mucuna pruriens* and *Nelumbo nucifera*, known to be useful for the same purpose, will result in an appetite-suppressing composition. Since all composition components herein are known to be useful as inducing satiation, it is considered *prima facie* obvious to combine them into a single composition useful for the same purpose. At least additive effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the combination of extracts of *Mucuna pruriens* and *Nelumbo nucifera* 90 minutes before the subject eats a meal. The person of ordinary skill in the art would have been motivated to administer the composition before the subject eats a meal, because compositions comprising *Mucuna pruriens* were known to be administered orally on an

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empty stomach, as taught by Uccatadyamodakah. Varying the time before the composition is administered to the subject with the aim of improving the therapeutic effect of the composition is considered routine for the skilled artisan.

As such, claims 1-3 and 11 are rejected as *prima facie* obvious.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uccatadyamodakah (In *Vangasena*; Shankar et al., Eds.; Bombay, India, 1996; p. 236; cited as Exhibit 1 in the IDS of 29 March 2013) and Nilakamala Kanda Gunah (Kaiyadeva, Nilakamala Kanda Gunah. In *Kaiyadevanighantau*; Sharma et al., Eds.; Varanasi, India, 1979; p. 268-269; cited as Exhibit 3 in the IDS of 29 March 2013), as applied to claims 1-3 and 11 above, in further view of Jones (US 6,224,873 of 1 May 2001, cited in PTO-892), Maletto et al. (US 2006/0078627, published 13 April 2006, cited in PTO-892) and Chinery (US 2004/0077556, published 22 April 2004, cited in the IDS of 14 October 2011).

Uccatadyamodakah and Nilakamala Kanda Gunah are as above.

Jones (US 6,224,873) teaches a method of weight control/loss by regulation of appetite using compositions comprising *Citrus aurantium* (Examples 2, 3, 5, columns 17-18, subjects completed a daily appetite and satiety rating questionnaire). Jones teaches (column 16, last paragraph) that the Citrus material, either in the form of an extract or as the natural material, may be given in combination with other herbs that possess beneficial effects for humans, particularly in respect to weight loss.

Maletto et al. (US 2006/0078627) teaches (page 2, [0025], [0027]) a method of reducing hunger with a composition comprising *Griffonia simplicifolia*. Maletto teaches that *Griffonia*

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*Simplicifolia* is a natural source of 5-hydroxytryptophan, which is a precursor to serotonin ([0027]). Maletto teaches that serotonin is one of the most important brain neurotransmitters involved in appetite suppression; it has been established that increased serotonin levels decrease appetite.

Chinery (US 2004/0077556) teaches a method for promoting weight loss in mammals with a nutritional supplement composition comprising *Camellia sinensis* ([0006]). Chinery teaches that green tea extract, *Camellia sinensis*, contains epigallocatechin gallate (EGCG), which suppresses appetite ([0006]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add an extract from *Citrus aurantium* and an extract from *Griffonia simplicifolia* to a combination of extracts of *Mucuna pruriens* and *Nelumbo nucifera*, in a therapeutic formulation used to stimulate a feeling of having already eaten.

The person of ordinary skill in the art at the time the invention was made would have been motivated to to add an extract from *Citrus aurantium* and an extract from *Griffonia simplicifolia* to a combination of extracts of *Mucuna pruriens* and *Nelumbo nucifera* and use the combination in a method of stimulating in a subject a feeling of satiation, because extracts of *Citrus aurantium* were known to suppress appetite and induce weight loss, as taught by Jones, and extracts of *Griffonia Simplicifolia* were known to reduce hunger, as taught by Maletto. The person of ordinary skill in the art would have been further motivated to add such extracts together because Jones teaches that *Citrus aurantium*, either in the form of an extract or as the natural material, may be given in combination with other herbs that possess beneficial effects for humans, particularly in respect to weight loss.

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Similarly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add an extract from *Camellia sinensis* to a combination of extracts of *Mucuna pruriens* and *Nelumbo nucifera*, in a therapeutic formulation used to stimulate a feeling of having already eaten. The person of ordinary skill in the art at the time the invention was made would have been motivated to add an extract from *Camellia sinensis* to a combination of extracts of *Mucuna pruriens* and *Nelumbo nucifera* and use the combination in a method of stimulating in a subject a feeling of satiation, because extracts of *Camellia sinensis* were known to suppress appetite and promote weight loss, as taught by Chinery.

Therefore, one of ordinary skill in the art would have reasonably expected that combining extracts from *Citrus aurantium*, *Griffonia simplicifolia*, *Mucuna pruriens* and *Nelumbo nucifera*, or combining extracts from *Camellia sinensis*, *Mucuna pruriens* and *Nelumbo nucifera*, known to be useful for the same purpose, will result in an appetite-suppressing composition. Since all composition components herein are known to be useful as inducing satiation, it is considered *prima facie* obvious to combine them into a single composition useful for the same purpose. At least additive effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

As such, claims 12 and 13 are rejected as *prima facie* obvious.

### ***Conclusion***

Claims 1-3 and 11-13 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRINA NEAGU whose telephone number is (571)270-5908. The examiner can normally be reached on Monday-Thursday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENIVASAN PADMANABHAN can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/IRINA NEAGU/  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627

<b>Search Notes</b>  	<b>Application/Control No.</b> 13264586	<b>Applicant(s)/Patent Under Reexamination</b> JONES, DENNIS
	<b>Examiner</b> IRINA NEAGU	<b>Art Unit</b> 1627

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SEARCH NOTES		
Search Notes	Date	Examiner
EAST inventor search, assignee search, word/term search	10 October 2013	IN
<u>Traditional Knowledge Digital Library (TKDL) search</u>	10 October 2013	IN

INTERFERENCE SEARCH			
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