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330 JOHN CA	RLYLE STREET		CLARK, AMY LYNN		
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			1655		
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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.

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

mail@krameramado.com

	Application No. 12/679,826	Applicant(s	
Office Action Summary	Examiner Amy L. Clark	Art Unit 1655	AIA (First Inventor to File) Status No
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	corresponder	nce address
A SHORTENED STATUTORY PERIOD FOR REPL' THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e. cause the application to become ABANDONE	nely filed the mailing date D (35 U.S.C. § 13	of this communication.
Status			
1) Responsive to communication(s) filed on <u>01/1.</u>			
A declaration(s)/affidavit(s) under 37 CFR 1.1			
·	action is non-final.		
3) An election was made by the applicant in resp	·		ing the interview on
 ; the restriction requirement and election Since this application is in condition for allowa closed in accordance with the practice under E 	nce except for formal matters, pro	secution as	
Disposition of Claims*			
5) Claim(s) 23-36,39-49,52-55,57-60,62 and 64 in 5a) Of the above claim(s) 42-44 and 52-55 is/a 6) Claim(s) is/are allowed. 7) Claim(s) 23-36,39-41,45-49,57-60,62 and 64 in 18 is/are objected to. 9) Claim(s) are subject to restriction and/o	re withdrawn from consideration. s/are rejected.		
* If any claims have been determined <u>allowable</u> , you may be e		annutian Uir	h
participating intellectual property office for the corresponding a		_	nway program at a
http://www.uspto.gov/patents/init_events/pph/index.jsp or send	• •		
Application Papers 10) The specification is objected to by the Examine 11) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct	er. epted or b) objected to by the drawing(s) be held in abeyance. See	Examiner. e 37 CFR 1.89	` /
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign Certified copies: a) All b) Some** c) None of the: 1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority documen application from the International Bureau	ts have been received. ts have been received in Applicat ority documents have been receiv	tion No	
** See the attached detailed Office action for a list of the certification and the certification of the certificat			
Attachment(s)	_		
 Notice of References Cited (PTO-892) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/Paper No(s)/Mail Date 	3) Interview Summary Paper No(s)/Mail D 4) Other:	•	

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

DETAILED ACTION

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicant's amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-36, 39-41, 45-49, 57-60, 62 and 64 are currently under examination.

Claim Rejections - 35 USC § 101

Claims 23-36, 39-41, 45-49, 57-60, 62 and 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (newly reapplied as necessitated by amendment). Based upon an analysis with respect to the claim as a whole, claims are determined to be directed toward a *judicial exception*. The rationale for this determination is explained below:

Effective December 16, 2014, subject matter eligibility determinations under 35 U.S.C. § 101 follow the procedure explained in the Federal Register notice titled **2014 Interim Guidance on Patent Subject Matter Eligibility** (79 FR 74618), which is found at: http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf. Applicants are kindly asked to review this guidance.

The statutory categories of invention under 35 U.S.C. 101 are processes, machines, manufactures, and compositions of matter. However, certain members of these categories constitute judicial exceptions, i.e., the courts have determined that these entities are not patentable subject matter. These judicial exceptions include abstract ideas, laws of nature, and natural phenomena. The Office released guidance on December 16, 2014 for the examination of claims reciting natural products under 35 U.S.C. 101 in light of the recent Supreme Court decisions in *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* (566 U.S. ____, 132 S. Ct. 1289, 101 USPQ2d 1961

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(2012)), Diamond v. Chakrabarty, 447 U.S. 303 (1980)) and Funk Brothers Seed Co. v. Kalo Inoculant Co. - 333 U.S. 127 (1948)). (inter alia).

Applicants' claims 23, 26, 40, 41, 45, 46, 57 and 62 are directed toward an oral or parenteral dosage form for inhibiting or ameliorating adipogenesis in mammals, said herbal composition comprising: from 33% to 67% by weight of a Piper betle extract, wherein the Piper betle extract is obtained by extraction of Piper bet/e with a solvent selected from the group consisting of: a polar organic solvent selected from the group consisting of C3-C4 alcohols and C3-C6 ketones; and an effective amount of a Dolichos biflorus extract, wherein the Dolichos biflorus extract is obtained by extraction of Dolichos biflorus with a solvent selected from the group consisting of at least one polar organic solvent and a combination of a polar organic solvent and water; optionally in combination with at least one biologically acceptable excipient. Claims 27-32 and 34-36, 39 and 47-49 are drawn to an anti-adipogenic herbal composition for inhibiting or preventing or ameliorating disease conditions associated with adipogenesis in mammals, consisting essentially of comprising: an effective amount of a Piper betle extract, wherein the Piper betle extract is obtained by extraction of Piper betle with a solvent extraction of Piper betle with a solvent selected from the group consisting of: an alcoholic solvent containing 40% to 60% water, and optionally an effective amount of a Dolichos biflorus extract, wherein the Dolichos biflorus extract is obtained by extraction of Dolichos biflorus with a solvent selected from the group consisting of water, a polar organic solvent, and mixtures thereof; optionally in combination with at least one biologically acceptable excipient; wherein the said *Piper betle* extract further comprises one or more anti-adipogenic or anti-obesic agents selected from the group consisting of extracts of Commiphora mukul, Boerhavia diffusa, Tribulus terrestris, Zingiber officinale, and mixtures thereof; and optionally contains a bioenhancing agent or a bio-protecting agent. Claim 33 is drawn to the anti-adipogenic composition of 27, wherein said composition is in a pharmaceutically or nutraceutically suitable form for oral administration, said pharmaceutically or nutraceutically suitable form being selected from the group consisting of tablets, pills, granules, powders, emulsions, suspensions, syrups, and pellets. Claim 58 is drawn to an antiadipogenic herbal composition for inhibiting disease conditions associated with adipogenesis in mammals, comprising: an effective amount of a Piper betle extract, wherein the Piper betle extract is

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obtained by extraction of Piper betle with a solvent selected from the group consisting of: an alcoholic solvent containing 40% to 60% water, and C3-C6 ketones an effective amount of a Dolichos biflorus extract, wherein the Dolichos biflorus extract is obtained by extraction of Dolichos biflorus with water or a polar organic solvent or a mixture thereof; and an optional biologically acceptable excipient; wherein said Piper betle extract and said Dolichos biflorus extract are the only herbal ingredients present in said antiadipogenic herbal composition. Claim 59 is drawn to an anti-adipogenic herbal composition for inhibiting disease conditions associated with adipogenesis in mammals, consisting essentially of a first herbal component and an optional biologically acceptable excipient; said first herbal component comprising an effective amount of *Piper betle* extract obtained by extraction of *Piper betle* with at least one solvent selected from polar organic solvents to obtain a solution, and an effective amount of Dolichos biflorus extract obtained by extraction of Dolichos biflorus with at least one polar organic solvent or a combination of a polar organic solvent and water; wherein said first herbal component is prepared by a process consisting essentially of mixing said Piper betle extract and said Dolichos biflorus extract. Claim is drawn to an oral or parenteral dosage form, comprising: an amount of an anti-adipogenic herbal composition which is effective for inhibiting or ameliorating adipogenesis in mammals, said herbal composition comprising: from 33% to 67% by weight of a Piper betle extract, wherein the Piper betle extract is obtained by: extracting Piper betle with a solvent selected from the group consisting of at least one polar organic solvent and an aqueous alcohol containing 40% to 60% water to produce a Piper betel extract, filtering the Piper betel extract, and evaporating the filtered extract to dryness at 50-60°C; and an effective amount of a Dolichos biflorus extract, wherein the Dolichos biflorus extract is obtained by extraction of Dolichos biflorus with a solvent selected from the group consisting of water, a polar organic solvent and a combination of a polar organic solvent and water, and mixtures thereof; optionally in combination with at least one biologically acceptable excipient.

The product obtained via the product-by-process (PBP) set forth in claims 23, 27, 58 and 64 results in a product found in nature absent evidence to the contrary. Although the product obtained by the PBP limitations found in claims 23, 27, 58 and 64, respectively, will produce a composition which is separated from its natural source, isolation of a natural product or group of natural products does not



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transform the claims into an exemption of the judicial exception because the products are naturally-occurring; i.e., they are found in nature. Similarly, in *Association for Molecular Pathology v. Myriad*, 569 U. S. _____ (2013) it was determined that excised DNA, although separated from its natural source, was naturally-occurring and non-patentable subject matter.

It is noted that a change in the ratio or amount of a naturally-derived extract/compound ('effective amount of an isolated anti-microbial adhesion inhibitory fraction from cranberry to inhibit the adhesions of bacteria to cells...') does not transform the claims into an exemption of the 'judicial exception' because amounts/ratios/percentages do not set forth a 'markedly different' structure as compared to the naturally-occurring product (see; e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

Discovering a new property of a naturally-occurring ingredient does not render the naturally-occurring ingredient patentable under this statute. Thus, while Applicants have discovered that the claimed composition, comprising Piper betle extract, wherein the Piper betle extract is obtained by extraction of Piper betle with a solvent selected from the group consisting of: a polar organic solvent selected from the group consisting of C3-C4 alcohols and C3-C6 ketones; and an effective amount of a Dolichos biflorus extract, wherein the Dolichos biflorus extract is obtained by extraction of Dolichos biflorus with a solvent selected from the group consisting of at least one polar organic solvent and a combination of a polar organic solvent and water, is anti-adipogenic this property is an inherent property of the naturally-occurring compound itself; i.e., Applicants did not manipulate the chemical structure of the naturally-occurring product to achieve such a result; rather, the result manifested from the innate capabilities of the naturally-occurring product itself. The claims do not comprise any other ingredient other than the naturally-derived extract component, such as a non-naturally occurring ingredient which may alter the Invention to such an extent that the Examiner could determine that the Invention is 'markedly different' from the product which occurs naturally. Therefore, the claims do not recite something significantly different than a judicial exception and are thus deemed patent ineligible subject matter.

Claim Rejections - 35 USC § 103

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Claims 23-36, 39-41, 45-49, 57-60, 62 and 64 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lak¾m=vil¢sarasa (X1), in view of Medoroge Pathya (U2), Punarnav¢dikv¢tha (V2) and Vanga Shodhana (W2) (newly applied as necessitated by amendment).

Lak¾mevil¢sarasa teaches a composition for treating obesity comprising Piper betle leaves,

Tribulus terrestris and sulphur (which reads on an extract of each plant in claim 60), wherein the

composition can be orally administered and can be in the form of an alcoholic extract, alcoholic

preparation of sweet expressed juice and in the form of a pill or bolus.

Lak¾mevilosarasa does not expressly teach Piper bette leaves obtained by extraction with 40-60% ethanol and the product-by-process steps as claimed. However, it should be noted that in Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Lak¾m¤vil¢sarasa does not teach Dolichos biflorus, Commiphora mukul, Piper nigrum or Zingiber officinale.

Mediorogie Pathya teaches a dietary composition for treating obesity comprising Dolichos biflorus.

Commiphora mukul, Piper migrum and Zingiber officinale, fermented drug distillate containing alcohol and

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water. Pathya further teaches that the composition further comprises honey (which reads on at least one biologically acceptable excipient).

Lak¾m¤vil¢sarasa does not teach Boerhaavia diffusa.

Punarnav¢dikv¢tha teaches a therapeutic compound formula consisting of Boerhaavia diffusa for treating obesity.

Lak¾m ¤vil¢sarasa does not teach Dolichos biflorus leaf.

Vanga Shodhana teaches a therapeutic single/compound formulation consisting of Dolichos biflorus leaf for use in various formulations.

Please note that with regards to the language "consisting essentially of" that Applicant has included the language "comprising". Since Applicant has opened the claim language, the language is construed as open claim language. Furthermore, MPEP 2111.03 states, "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)".

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It would have been obvious to modify the composition taught by Lak¾m¤vil¢sarasa by combining an alcohol extract of Piper betle leaves, Tribulus terrestris and sulphur, with an extract of Dolichos biflorus plant (including leaves), Commiphora mukul extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum extract and Zingiber officinale extract and honey because at the time the invention was made, it was known that Piper betle leaf alcohol extract, sulphur, Dolichos biflorus plant (including leaves) alcohol and aqueous extract, Commiphora mukul extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum, Zingiber officinale extract and honey are effective ingredients for treating obesity that could be combined with food and orally consumed and could also be administered as a bolus, as clearly taught by the above references.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. Based on the disclosure by these references that Piper betle leaf alcohol extract, sulphur, Dolichos biflorus plant (including leaves) alcohol and aqueous extract, Commiphora mukul extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum, Zingiber officinale extract and honey could be orally consumed and provided as a bolus for treating obesity, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Thus, an artisan of ordinary skill would reasonably expect that combining Piper betle leaf alcohol extract, sulphur, Dolichos biflorus plant (including leaves) alcohol and aqueous extract, Commiphora mukul extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum, Zingiber officinale extract and honey would provide an even more effective antioxidant formulation for oral administration. This reasonable expectation of success would motivate the artisan to Piper betle leaf alcohol extract, sulphur, Dolichos biflorus plant (including leaves) alcohol and aqueous extract, Commiphora mukul

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extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum, Zingiber officinale extract and honeyto provide an even more effective antioxidant formulation for combination with food for oral consumption based upon the teachings of the above references.

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 concentration of Piper bettle leaf alcohol extract, sulphur, Dolichos biflorus plant (including leaves) alcohol and aqueous extract, Commiphora mukul extract, Boerhaavia diffusa extract, Tribulus terrestris extract, Piper nigrum, Zingiber officinale extract and honey to provide an even more effective composition for treating obesity and to modify the ratio of water to alcohol used as the extraction solvent. 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.

Response to Arguments

Applicant's arguments have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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

Application/Control No. Applicant(s)/Patent Under Reexamination 12/679,826 GOKARAJU ET AL. Notice of References Cited Art Unit Examiner Page 1 of 2 Amy L. Clark 1655 **U.S. PATENT DOCUMENTS** Document Number Date Name Classification Country Code-Number-Kind Code MM-YYYY Α US-US-В US-С US-D US-Ε US-US-G US-Н USļ US-US-Κ US-L US-Μ FOREIGN PATENT DOCUMENTS Document Number Date Country Name Classification Country Code-Number-Kind Code MM-YYYY Ν 0 Р Q R S Τ **NON-PATENT DOCUMENTS** Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) U ٧ W

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.

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(X1) Lak¾m¤vil¢sarasa. From: Bhai¾ajya Ratn¢vala - Edited by Rajeshvaradutta Shastri, Translated by Ambikaduttashastri:

Chaukhamba Sanskrit Sansthan, Varanasi, Edn. 14th, 2001. [This book contains backr eferences from 1000 B.C.to 18th

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	Α	US-			
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

_		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	(U2) Medoroge Pathya. From: Basavar¢jeyam-Chaukhambha Sanskrit Pratisthan, Delhi; Edn. 1st Reprint ;2005 [Time of origin 15th century] prior art Page 275. Retrieved from TKDL on 28-04-2015.
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A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)

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Search Notes



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GOKARAJU ET AL.

Applicant(s)/Patent Under Reexamination

Examiner

AMY L CLARK

Art Unit

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US CLASSIFICATION SEARCHED							
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SEARCH NOTES							
Search Notes	Date	Examiner					
EAST-See Search Notes	4/26/2015	ALC					
All Inventors Names Searched in PALM	4/26/2015	ALC					
Google and TKDL website Search for all of the ingredients plus their synonyms	4/26/2015	ALC					

INTERFERENCE SEARCH							
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