



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/669,339	04/22/2010	Suresh Kumar Gupta	Q116768	3400
23373	7590	11/14/2011	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			11/14/2011	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):

USPTO@sughrue.com
sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	12/669,339	GUPTA 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 23 September 2011.
- 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) 1-6 is/are pending in the application.
5a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-5 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 _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

Art Unit: 1655

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5 in the reply filed on 09/23/2011 is acknowledged. The traversal is on the ground(s) that the international search authority did not issue a lack of unity and that there would not be a search burden. Applicants further argue that claim 1 is not obvious over Saida because Saida teaches a pet food comprising coenzyme Q10 and vitamin E for preventing cataracts in dogs and that the present application requires a synergistic blend of *F. vulgare*, *M. koeingii* and *Triphala* in equal parts. This is not found persuasive because the restriction requirement is based upon PCT rule 13.1 and 13.2, and whether unity exists between the inventions, not whether there is a search burden. The examination practices of the international search authority differ to the US examination practices. Despite the international search authority not issuing a restriction, does not make the application exempt from a restriction requirement when being examined at the USPTO. Furthermore, it should be noted that claim 1 is drawn to a composition for treating cataracts that appears to only require an extract of only one of the plant species, which coenzyme Q10 and vitamin E read on (please also see the 112, 2nd paragraph rejection below). Therefore, lack of unity is established based upon the teachings of Saida for the reasons set forth in the election/Restriction requirement mailed out on: 08/26/2011.

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

Claim 6 is 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. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/23/2011.

Claims 1-5 are currently under examination.

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.

Art Unit: 1655

Claim Objections

Claim 1 is objected to because of the following informalities: the term "cataract" in line 1 should be plural, the article is missing between "comprising" and "extract" in line 1, the phrase "selected from" is missing the group consisting of, which should appear after "selected from", and the term "Foeniculum" is misspelled. Appropriate correction is required.

Claims 2 and 3 are objected to because of the following informalities: the tables presented are not necessary. The claim should be written out as A composition comprising Foeniculum vulgare in an amount of 0.1 to 2.0% by weight... and should not contain tables. Appropriate correction is required.

Claim 3 is objected to because of the following informalities: the phrase "preferably comprises" is not appropriate. The phrase should read, wherein the composition comprises Foeniculum vulgare in an amount of 3% by weight... Appropriate correction is required.

Claim 4 is objected to because of the following informalities: The commas in many instances are incorrectly placed. They should occur right after the term followed by a space. In several instances, the incorrect tense is used. As an example, "cyclodextrin and their derivative" should read cyclodextrin and derivatives thereof. The phrase "selected from the group comprising...glycerol ,preservatives..." is not appropriate. The phrase should read, selected from the group consisting of:... glycerol, and preservatives... Appropriate correction is required.

Claim 4 is objected to because of the following informalities: the acronym "EDTA" should be written out next to the acronym, and either the full name or acronym should be in parenthesis. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: the phrase "wherein the composition is in the form of eye drop" is missing the article. Appropriate correction is required.

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 Unit: 1655

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 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an herbal composition for treating cataracts comprising an effective amount of an extract of herbs selected from *Foeniculum vulgare*, *Murraya koenigii* and *Triphala* does not reasonably provide enablement for a synergistic herbal composition useful against cataracts comprising an extract of herbs selected from *Foeniculum vulgare*, *Murraya koenigii* and *Triphala*. 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.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a synergistic herbal composition useful against cataracts comprising an extract of herbs selected from *Foeniculum vulgare*, *Murraya koenigii* and *Triphala* optionally along with a pharmaceutically acceptable excipient. The specification defines the terms 'synergistic' and

Art Unit: 1655

'synergistically effective' to mean a biological effect created from the application of two or more agents to produce a biological effect that is greater than the sum of the biological effects produced by the application of individual agents. Thus, the claims taken together with the specification imply that Applicants are claiming an herbal composition treating cataracts comprising amounts of extracts selected from a *Foeniculum vulgare*, *Murraya koenigii* and *Triphala* which, when combined, provide for a biological effect that is greater than sum of the biological effects produced by the application of the individual agents.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art is unpredictable with regard to synergistic results with respect to biological effects. The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522,526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730,734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soil*, 97 F.2d 623,624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488,496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work (see MPEP § 2164.04).

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

Art Unit: 1655

The specification has provided an examples wherein combinations of aqueous extracts of *Foeniculum vulgare*, *Murraya koenigii* and *Triphala* are tested for their effect on reducing galactose induced cataractogenesis in rats (see e.g. pages 9-13, Tables 1-5). However, none of the reductions of reducing opacity of the lens is achieved with the combinations of herbs is greater sum of the peak reductions achieved using those herbs individually (particularly when taking into account standard deviation). Therefore, the specification has not provided a means for evaluating all of the combinations of herbs as claimed in order to determine synergistically effective amounts for combinations of two or more herbs.

(8) The quantity of experimentation necessary:

Considering the high unpredictability and the lack of guidance provided in the specification with regard to determining synergistically effective amounts of herbs in the instantly claimed composition, one of ordinary skill in the art would be burdened with undue experimentation to determine all of the amounts and combinations in order to determine which amounts of the instantly claimed herbs would be synergistic.

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 1-5 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.

Claim 1 is rendered vague and indefinite by the phrase "a synergistic herbal composition" because it is unclear as to what amount (e.g., amount range, proportion, and/or ratio) of each claimed ingredient actually defines a synergistic amount with respect to the other ingredients so as to provide a combined synergistically effective amount of the overall composition. Accordingly, the metes and bounds of this phrase (e.g., the synergistically effective amounts of each ingredient with respect to the others) are not clearly nor adequately delineated with respect to the synergistic amounts of the individual components. Please note that synergism is an unpredictable phenomenon which is highly dependent

Art Unit: 1655

upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the independent claim language itself. While Applicant has recited the weight % (although the recited weight percentages are not related to a determined parameter of mass or volume) of each of the claimed ingredients in claims 2 and 3, the Office notes that as drafted claim 1 reads on a composition comprising *Foeniculum vulgare*, *Murraya koenigii* or *Triphala*. As drafted, claim 1 would appear to not read on a synergistic herbal composition, since synergism is generally defined by the enhanced overall activity of more than one ingredient when combined together as compared to the overall activity of each of the ingredients alone.

The metes and bounds of claim 1 are rendered uncertain by the phrase "comprising an extract of herbs selected from *Foeniculum vulgare*, *Murraya koenigii* and *Triphala*" because it is unclear whether the extract is a solvent extract, and if it is a solvent extract, what type of solvent (non-polar, polar, alcoholic, aqueous, hot water) and what part of the plant is extracted, or if Applicants are claiming specific compounds extracted from one of more of the plants. Also, it is unclear if Applicants are claiming that the extract must contain extracts from all of the instantly claimed plants, or only one of them, and if the extract is a combination of these plants or individual extracts. 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.

The metes and bounds of claims 2 and 3 are rendered uncertain by the tables provided because it is unclear whether Applicants are claiming that these are additional herbs that are present in addition to the extract or if these are the herbs that are extracted. A table in the claims is unclear in these cases and should be replaced by claim language. Further, the claim language needs to further define what Applicants mean by "herbs". 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.

Regarding claim 4, the phrase "such as" in lines 3, 4, 6 and 8-10 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Art Unit: 1655

Claim 4 contains the trademark/trade name "Cremophore RH 40". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, it is unclear what the trademark/trade name is used to identify/describe, therefore, the identification/description is indefinite.

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 negated 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 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jivantayadi Ghrta (U), in view of Kan Kumari Patru (V).

Jivantayadi Ghrta teaches a composition for treating cataracts comprising water, *Foeniculum vulgare* in an amount of 12 grams, triphala in an amount of 12 grams (triphala contains: *Terminalia chebula* in an amount of 4 grams, *Terminalia bellirica* in an amount of 4 grams and *Emblica officianalis*

Art Unit: 1655

(Phyllanthus emblica) in an amount of 4 grams (which comes to 12 grams total)) (which reads on a water extract of Foeniculum vulgare and triphala, since adding the herbs to water would provide a water extract. Further, Jivantayadi Ghrta teaches the method of extracting the herbs in water) and rock salt/Indian rock salt (which is synonymous with sodium chloride, and reads on the limitations of claim 4, wherein the pharmaceutically acceptable excipient is an osmolarity adjusting agent). Jivantayadi Ghrta further teaches that the composition can be combined with milk. Please note that although Jivantayadi Ghrta teaches the composition can be taken internally, internal compositions would be considered to be safe to apply topically. Therefore, the formulation could be topically applied.

Kan Kumari Patru teaches a composition for treating cataracts comprising *Murraya koenigii* in an amount of 1 part, *Phyllanthus emblica* (*Emblica officianlis*) in an amount of 1 part and *Terminalia chebula* in an amount of 1 part. Kan Kumari Patru further teaches that the composition is prepared as a liquid drug by first combining with aloe, processing and grinding the herbs (which reads on an extract). Kan Kumari Patru further teaches that the composition is formulated as a pasty application (which reads on cream and ointments, as claimed in claim 5) and ground with human milk for external application around the eye.

It would have been obvious to modify the composition used in the method taught by Jivantayadi Ghrta by combining *Foeniculum vulgare* and triphala with *Murraya koenigii* because at the time the invention was made, it was known that *Foeniculum vulgare*, triphala and *Murraya koenigii* were all useful ingredients that could be applied administered for treating cataracts as clearly taught by Jivantayadi Ghrta and Kan Kumari Patru.

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 *Foeniculum vulgare*, triphala and *Murraya koenigii* were all useful ingredients that could be applied administered for treating cataracts, 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

Art Unit: 1655

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 *Foeniculum vulgare*, triphala and *Murraya koenigii* would provide an even more effective composition for treating cataracts, since these ingredients were well known to be useful for treating cataracts. This reasonable expectation of success would motivate the artisan to use *Foeniculum vulgare*, triphala and *Murraya koenigii* in a composition for treating cataracts based upon the teachings of Jivantayadi Ghrta and Kan Kumari Patru.

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 *Foeniculum vulgare*, triphala and *Murraya koenigii* and to pick and choose what type of composition formulation would be most useful, safe and effective for application to the eye area for treating cataracts. 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.

Conclusion

No claims are allowed.

Art Unit: 1655

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. 12/669,339	Applicant(s)/Patent Under Reexamination GUPTA 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	Jivantayadi Ghrta. From : A%4c-ga H"daya - (commentary by Arunadutta) edited by Bhisagacarya Harisastrri Paradakara vaidya : Chaukhamba Orientalia, Varanasi, edn. 8th, 1998. [Time of origin 5th century], page 483. [Retrieved from the Internet on: 2011-11-07]. Retrieved from TKDL website: <URL: http://www.tkd.l.res.in/ >.			
V	Kan Kumari Patru. From: Abdulla Sahib. Anuboga Vaithya Navaneetham, Part - 10, Ed: Mohammad Abdullah Shahib, Pub: Thamarai Noolagam, Chennai. (Edn:2 nd , 2002) page 137. [Retrieved from the Internet on: 2011-11-07]. Retrieved from TKDL website: <URL: http://www.tkd.l.res.in/ >.			
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.

Search Notes 	Application/Control No. 12669339	Applicant(s)/Patent Under Reexamination GUPTA ET AL.
	Examiner AMY L CLARK	Art Unit 1655

SEARCHED			
Class	Subclass	Date	Examiner
NONE	NONE		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST-See Search Notes	11/7/2011	ALC
All Inventors Names Searched in PALM	11/7/2011	ALC
Google/TKDL search for terms including: Foeniculum vulgare, Murraya koenigii and Triphala	11/7/2011	ALC

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
NONE	NONE		

--	--



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/669,339	04/22/2010	Suresh Kumar Gupta	Q116768	3400
23373	7590	04/20/2012	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			04/20/2012	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):

USPTO@sughrue.com
sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM

Office Action Summary

Application No.

12/669,339

Applicant(s)

GUPTA ET AL.

Examiner

Amy L. Clark

Art Unit

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 14 February 2012.
- 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) 1,3,4 and 6-13 is/are pending in the application.
 - 5a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1,3,4 and 8-13 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 _____.
- 4) Interview Summary (PTO-413)
 - Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Art Unit: 1655

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 02/14/2012 with the amendment of claims 1, 3, 4 and withdrawn claim 6, the cancellation of claims 2 and 5, and newly added claims 7-13.

Election/Restrictions

The election/restriction requirement is maintained for the reasons of record.

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 1, 3, 4 and 8-13 are currently under examination.

Claim Rejections - 35 USC § 112

Claims 1, 3, 4 and 8-13 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 (newly applied as necessitated by amendment).

The metes and bounds of claim 1 are rendered uncertain by the phrase "comprising a mixture of an extract of herbs selected from the group consisting of *Foeniculum vulgare*, *Murraya koenigii* and *Triphala*" because it is unclear whether the extract is a solvent extract, and if it is a solvent extract, what type of solvent (non-polar, polar, alcoholic, aqueous, hot water) and what part of the plant is extracted, or if Applicants are claiming specific compounds extracted from one of more of the plants. Also, it is unclear if Applicants are claiming that the extract must contain extracts from all of the instantly claimed plants, or only one of them, and if the extract is a combination of these plants or individual extracts. The lack of

Art Unit: 1655

clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of claim 1 are rendered uncertain by the phrase "comprising a mixture of an extract of herbs selected from the group consisting of *Foeniculum vulgare*, *Murraya koenigii* and *Triphala* optionally along with a pharmaceutically acceptable carrier" because it is unclear whether the extract is a solvent extract, and if it is a solvent extract, what type of solvent (non-polar, polar, alcoholic, aqueous, hot water) and what part of the plant is extracted, or if Applicants are claiming specific compounds extracted from one or more of the plants. Also, it is unclear if Applicants are claiming that the extract must contain extracts from all of the instantly claimed plants, or only one of them, and if the extract is a combination of these plants or individual extracts. Finally, it is unclear what the optional ingredient is. Is it the mixture of herbs or the pharmaceutically acceptable excipient? 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.

The metes and bounds of claim 3 are rendered uncertain by the table provided because it is unclear whether Applicants are claiming that these are additional herbs that are present in addition to the extract or if these are the herbs that are extracted. A table in the claims is unclear in these cases and should be replaced by claim language. Further, the claim language needs to further define what Applicants mean by "herbs". 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.

Claim Rejections - 35 USC § 103

Claims 1, 3 and 4 and newly added claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohl Barae Nuzool-al-Maa (W), in view of Srinivas et al. (N, abstract only), *Triphalagh tam* (X) (newly applied as necessitated by amendment).

Kohl Barae Nuzool-al-Maa teaches a therapeutic composition for ocular administration for treating cataracts comprising an extract of *Foeniculum vulgare*.

Art Unit: 1655

Srinivas teaches extracted hydrophilic and lipophilic antioxidants from curry leaves (which reads on an extract of *Murraya koenigii*) for treating cataracts.

Triphalagh^{am} teaches a therapeutic composition for treating cataracts comprising extracts of *Terminalia chebula*, *Terminalia bellirica* and *Phyllanthus emblica* in equal parts for medicinal application to the eye, eye irrigation with special drops or unctuous irrigation of the eye.

Please note that claim 1 does not require a pharmaceutically acceptable excipient, since it is an optional ingredient. Therefore, the limitations of claims 8-13 are met, since these ingredients are optional and not required in the composition.

It would have been obvious to modify the composition taught by Kohl Barae Nuzool-al-Maa by combining an extract of *Foeniculum vulgare* with an extract of curry leaves and extracts of *Terminalia chebula*, *Terminalia bellirica* and *Phyllanthus emblica* because at the time the invention was made, it was known that *Foeniculum vulgare*, an extract of curry leaves and extracts of *Terminalia chebula*, *Terminalia bellirica* and *Phyllanthus emblica* were all useful ingredients that could be applied to eyes for treating cataracts 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 an extract of *Foeniculum vulgare* with an extract of curry leaves and extracts of *Terminalia chebula*, *Terminalia bellirica* and *Phyllanthus emblica* are useful ingredients for treating cataracts by administering the composition to eyes, 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 an extract of *Foeniculum vulgare* with an extract of curry leaves and extracts of *Terminalia chebula*, *Terminalia bellirica*

Art Unit: 1655

and Phyllanthus emblica would provide an even more effective ocular composition for treating cataracts. This reasonable expectation of success would motivate the artisan to use an extract of Foeniculum vulgare with an extract of curry leaves and extracts of Terminalia chebula, Terminalia bellirica and Phyllanthus emblica to treat cataracts 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 an extract of Foeniculum vulgare with an extract of curry leaves and extracts of Terminalia chebula, Terminalia bellirica and Phyllanthus emblica to provide a more effective composition for treating cataracts. 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 with respect to claims 1, 3 and 4 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).

Art Unit: 1655

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

Notice of References Cited	Application/Control No. 12/669,339	Applicant(s)/Patent Under Reexamination GUPTA 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 IN 2004CH00029 A	12-2005	India	Srinivas et al.	
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	"Kohl Barae Nuzool-al-Maa" in Kitaab-al-Haawi-fil-Tibb, Vol.II (9th century AD), Dayerah-al-Ma'aarif Usmania, Hyderabad, 1976 AD, page 311.
X	"Triphalagh"tam" in Nigha' uratnckara ³ - Edited and Marathi Translation by GRS Datar, BAS Tamankar, KS Mahabal, VV Patel; Part-3, Vishnu Vasudev Godbole, Bombay, Edn. 1868, page 1480.

*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.

Search Notes 	Application/Control No. 12669339	Applicant(s)/Patent Under Reexamination GUPTA ET AL.
	Examiner AMY L CLARK	Art Unit 1655

SEARCHED			
Class	Subclass	Date	Examiner
NONE	NONE		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST/STN-See Search Notes	4/17/2012	ALC
All Inventors Names Searched in PALM	4/17/2012	ALC
Google/TKDL search for terms including: Foeniculam vulgare, Murraya koenigii and Triphala	4/17/2012	ALC

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
NONE	NONE		

--	--