ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.L./

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	12477643
Filing Date	2009-06-03
First Named Inventor	GOKARAJU, et al.
Art Unit	1614
Examiner Name	Patricia LEITH
Attorney Docket Number	LIX 3022

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060040000	A	2011-02-23	Gokaraju et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	10072357	JP	A	1998-03-17	Lotte Co. Ltd.		☐

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	1	Savithramma et al., Ethnobotanical survey of plants used to treat asthman in Andhra Pradesh, India, Journal of Ethnopharmacology 113(2007) 54-61.	☐
	2	Ulbricht et al., Boswellia: An Evidence-Based Systematic Review by the Natural Standard Research Collaboration. Journal of Herbal Pharmacotherapy, Vol. 4(3) 2004	☐
	3	Arul et al., Mechanisms of the contractile effect of the alcoholic extract of Aegle marmelos Corr. on isolated guinea pig ileum and tracheal chain. Phytomedicine 11 (2004) 679-683.	☐
	4	Manthana Bhairava: Anandakandah-Edited with Tamil Translation by S.V. Radhakrishna Sastri, T.M.S.S.M. Libray, Tanjore, Madras, Edn 1st 1952 Pg 269. Formulation ID: RS 13/336E. Formulation Name: Udvartan Rasyan	☐
	5	Mohammad Najmul Ghani Kahn et al., Vol III (20th century AD), Nadeem Yunus Printer/Sheihk Mohd Basheer & Sons, Lahore, 1926 AD Pg 409. Formulation ID JA6/383A. Formulation Name Dawa Kundur.	☐
	6	Mohammad Asam Kahan et al., Vol I (19th centrury AD) Matba Nizami, Kanpur, 1896 AD Pg 334. Formulation ID: MH3/495H. Formulation Name: Dawa Baloot.	☐
	7	Mohammad Najmul Ghani Khan et al., (20th centrury AD), Munshi Nawal Kishore, Lucknow, (Second edition) 1928 AD Pg 37. Formulation ID: NA4/153. formulation Name: Afshara Barai Sual Wa Zeequnnaias.	☐
	8	Lankapatiravana et al., Edited and translation by Indradeva Tripathi, Krishnadas Academy, Varanasi, Edn, 1st 1995 Pg 117. Formulation ID: AK14/315B. Formulation Name: Nasika Rogahara Yoga-2.	☐
	9	Govt of India; Sahastrayoga - Tanslated by D.V. Panditarao: Central Council for Research in Ayurveda & Siddha, New Delhi, 1990 Pg 63. Formulation ID VS/2964. Formulation Name: Panalaveradikasayah.	☐
	10	Vangasena et al., Commentator Shaligram Vaisya. Edited Shankar lalji Jain et al., Bombay Edn. 1996 Pg 910. Formulation ID: AK11/4080. Formulation Name: Nirgundyadi Udvartna	☐
	11	Mohammad Azam Khuan et al., Vol I (19th century AD) Matba Nizami, Kanpur 1896 AD Pg 129-130. Formulation ID: MH3/72. Formulation Name: Adrak.	☐

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	12	Kali Dasa et al., with Hindi translation. Central Council for Reseaerch in ayrveda & Siddha, Gov't of India, New Delhi, Edn. 2005. Pg. 133. Formulation ID RS14/558. Formulation Name: Valli Palitahara Yoga.	☐
	13	Cudamani et al., Edited by Jivaramakalidasa Sastri, Part 4, Chaukhamba Publishers, Varanis, Edn 1st 1992 pg 286.	☐
	14	Bharata Bhaisajya Ratnaka. Vol III. B. Jain Publishers, New Delhi, Edn. 2nd Reprit, August 1999 Pg. 267. Formulation ID: RG/942. Formulation Name: Patoladikvathah(38)	☐
	15	Rasayoga Sagara, Vol. I, Krishandas Academy, Varansai Edn. Reprint, 1999. Pg 306. Formulation ID SJ/715B. Formulation Name: Kitimarirasah-2.	☐
	16	Wada et al., "Biocativities of Boswellia gum resin. AROMA RESEARCH (2006), 7(3), 234-241. CAS Abstract.	☐
	17	Sharma et al., "Phytochemical profile of Boswellia serrata;an overview". PHARMACOGNOSY REVIEWS (2007) 1(1), 137-142. CAS Absract.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Patricia Leith/	Date Considered	04/03/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Attorney Docket Number	LIX 3022

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

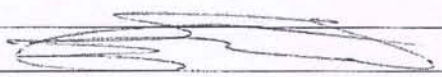
☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2011-08-23
Name/Print	Arlir M. Amado	Registration Number	51,399

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/477,643	06/03/2009	Ganga Raju Gokaraju	LIX 3022	7867

30868 7590 01/03/2012

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1725 DUKE STREET
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ALEXANDRIA, VA 22314

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
01/03/2012	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):

mail@krameramado.com

Office Action Summary	Application No.	Applicant(s)	
	12/477,643	GOKARAJU ET AL.	
	Examiner	Art Unit	
	PATRICIA A. LEITH	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 *09 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) *1-32* is/are pending in the application.

5a) Of the above claim(s) *19-31* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-18 and 32* 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 *6/3/2009* 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: _____.

DETAILED ACTION

Claims 1-32 are pending in this US Patent Application.

Claims 19-31 remain withdrawn from examination at this time as being directed toward a non-elected Invention.

Claims 1-18 and 32 were examined on their merits.

Applicants' arguments pertaining to the Double Patenting rejection as well as the prior art rejections were found persuasive in light of Applicants' amendments to the Independent claims which newly recite that the *A. marmelos* extract is from the fruit of the plant. It is noted however that Applicants indicated that the Examiner asserted that if the claims were limited to the fruit of this plant the claims would be patentable. To clarify the record, the Examiner indicated that such an amendment would overcome the prior art of record, and not necessarily that the claims would be patentable. Additionally, while the previous rejections have been removed, new rejections follow.

Claim Rejections - 35 USC § 112

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

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16, 17, 18 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 32 have been amended to recite wherein the A. marmelos extract is a fruit extract. However, the only disclosure of a fruit extract of this plant is an alcoholic extract of the fruit. There is no general disclosure of an extract of A. marmelos, which, as claimed, is broad enough to read on any extract of *A. marmelos* fruit which was not originally disclosed. It is the opinion of the Examiner that a representative number of types of extracts which could be obtained from *A. marmelos* (a myriad of potential extracts could potentially be extracted from the fruit of this plant) is not disclosed and coupled with the fact that there is no general disclosure of A. marmelos fruits disclosed explicitly or implicitly, that Applicants were not in possession of this embodiment at the time the Invention was made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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.

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 1-12, 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ponnapalli et al. (US 2005/0220913 A1) and Visvabharati, C, 2000, as evidenced by Sailer et al. – ACETYL-11-KETO-BETA-BOSWELLIC ACID (AKBA): STRUCUTRE REQURIEMENTS FOR BINDING AND 5-LIPOXYGNEASE INHIBITORY ACTIVITY; Br. J. Pharmacol., 1996, February, 117(4) Abstract.*

It is first noted that the phrase 'enriched Boswellia extract containing from 10% to 99% by weight of [AKBA]' as recited by claim 1 is broad enough to read on a composition comprising 99% of AKBA and 1% of water (or any other type of solvent). It is noted however, that the amount of AKBA in the composition is undefined by the claim and therefore, the amount of AKBA in the claim may be present in any amount so long as the AKBA is present in the Boswellia extract between 10 and 99%. A composition comprising 99% AKBA and 1% of water is essentially the same as a composition comprising essentially 100% of AKBA.

In the rejection which follows, the Examiner has reasoned why one of ordinary skill in the art would be motivated to use AKBA alone or AKBA as it is present in a Boswellia extract in combination with AM for treating skin proliferative disorders such as psoriasis and eczema.

Majeed et al. discloses a composition comprising boswellic acid compounds such as acetyl- 11-keto-β-boswellic acid (AKBA, the same compound as claimed for evidence, see Sailer et al. – ACETYL-11-KETO-BETA-BOSWELLIC ACID (AKBA): STRUCUTRE REQURIEMENTS FOR BINDING AND 5-LIPOXYGNEASE INHIBITORY ACTIVITY; Br. J. Pharmacol., 1996, February, 117(4) Abstract) or Boswellia seratta extracts containing AKBA for treating dermatological conditions such as psoriasis (see entire Pre-Grant Publication including [0001]-[0003]).

Majeed et al. report:

> Boswellic acids inhibit 5-lipoxygenase…the enzyme which catalyzes conversion of arachidonic acid to inflammatory leukotrienes [and] inhibit the enzyme human leukocyte elastase (HLE) which catalyzes connective tissue break down… ([0008]).
>
> Inflammatory leukotrienes have been implicated in the pathogenesis and pathophysiology of psoriasis. In lesional skin from psoriasis and eczema patients, leukotriene B4 was found to increase by approximately 6.6-fold. [0009]

Majeed et al. indicate formulating the Boswellia extracts containing boswellic acids, including AKBA, or AKBA into conventional dosage forms such as tablets, capsules, powders [0062], creams or lotions [0063] with conventional carriers such as Vitamin E (antioxidant), PEG-100, ascorbyl palmitate and dimethicone (*inter alia*). A lotion is a liquid. Drops of this lotion for administration would be considered 'liquid drops' absent any specific definition for 'liquid drops' in the specification.

Majeed et al. propose the use of 50-500 mg of AKBA into their compositions (see, e.g., claim 7). Additionally, Majeed et al. teach an exemplary formulation which comprises 4 types of boswellic acids (including AKBA) along with a carrier (Table 1 of Example 1). Majeed et al. make clear that Boswellia seratta extracts containing these boswellic acids as-listed in this table were a preferred embodiment (Boswellin being a trademarked product containing all 4 boswellic acids, see, e.g., [0062] and claims 3 and 6. Taking the formulation of Table 1 into consideration, the mixtures of boswellic acids may be said to be an 'extract' of Boswellia. Here, the boswellic acids alone constitute 168 mg and AKBA is present at 32 mg or approximately 19% of the Boswellia extract which falls within Applicants' claimed range of 10-99%.

It is again noted that the use of AKBA alone was indeed considered by Majeed et al. and that such a composition which would be considered an extract of Boswellia comprising 100% of AKBA would be essentially the same as an extract of Boswellia containing 99% water and 1% AKBA. One of ordinary skill in the art would see little or no difference between such a composition and the addition or subtraction of such a small amount of water would not be expected to materially affect the composition. Hence, it is the opinion of the Examiner that an extract of Boswellia containing 99% AKBA and an extract of Boswellia containing

100% AKBA would be so similar that no discernable differences could be established.

Majeed et al. did not teach the incorporation of *Aegle marmelos* extract into to their composition.

Ponnapalli et al. report that imperatorin, extractable from *Aegle marmelos* (bael)is an iNOS inhibitor and an anti-inflammatory agent (see entire US Pre-grant Publication, including [0004]. Although Ponnapalli et al. teach that ethylenedichloride is a more economical choice of solvent, Ponnapalli et al. indicate that ethanol and methanol will also extract this compound from bael fruit ([0018]-[0021]).

Additionally, *Aegle marmelos* and *Boswellia seratta* (which intrinsically possesses boswellic acids such as AKBA) are present in a single formulation in traditional Indian medicine for treatment of dermatitis and eczema (see Visvabharati, C, 2000, TKDL translation). Hence, the presence of both of these plants was found advantageous in traditional Indian medicine for treatment of skin conditions such as eczema.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

In the Instant case, it was known in the art that all of *Boswellia serrata* extract containing boswellic acids such as AKBA, AKBA alone and a water extract of AM leaves possessed anti-inflammatory properties. AKBA was a known anti-inflammatory touted for use in treating proliferative skin conditions such as psoriasis, AM was known for possessing anti-inflammatory activity and is present in an Indian traditional formulation containing only one other herbal ingredient for treating dermatitis or eczema. Additionally, to reiterate from above, Majeed et al. report:

> Boswellic acids inhibit 5-lipoxygenase…the enzyme which catalyzes conversion of arachidonic acid to inflammatory leukotrienes [and] inhibit the enzyme human leukocyte elastase (HLE) which catalyzes connective tissue break down… ([0008]).
>
> Inflammatory leukotrienes have been implicated in the pathogenesis and pathophysiology of psoriasis. In lesional skin from psoriasis and eczema patients, leukotriene B4 was found to increase by approximately 6.6-fold. [0009]

Hence, one of ordinary skill would have readily recognized the advantages for combining AKBA with an extract of AM fruit containing

imperatorin for treatment of skin proliferative disorders such as psoriasis or skin disorders such as eczema/dermatitis. One would have had a reasonable expectation of such because each of these components is anti-inflammatory. Those of ordinary skill would have recognized the advantage of adding an additional anti-inflammatory agent to treat skin conditions such as psoriasis and/or eczema or to treat various other inflammatory conditions. Further, both Boswellia and AM (bael) fruit are both Indian traditional medicines known to be used together for treating skin disorders. Those of ordinary skill in this art would have been motivated to combine Indian traditional medicines and/or extracts thereof for their additive effect.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the amounts of constituents as claimed may not specifically be taught by the prior art, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of claimed components because both AKBA and AM extracts were art-recognized result-effective variables having pharmacological effect. Hence, adjusting the concentrations of these claimed ingredients within a pharmaceutical formulation for treating a dermatological condition such as psoriasis or eczema would have been routinely determined and optimized in the pharmaceutical art.

It is noted that claim 11, although providing a percentage of an additional ingredient does not positively recite that the ingredient is necessarily present. Because claim 1 makes it clear that any herbal extracts besides a Boswellia extract containing AKBA and AM are optional, it is taken that the herbal components of these claims are also optional and are not required. If Applicants wish for these additional herbals to necessarily be present in the composition, it is suggested that the claim language be changed to 'wherein the second extract is present in the composition and is in a percentage.... '.

Although Majeed et al. did not *per se* discuss formulating their boswellic acid composition into, e.g., a beverage as required for claim 8, they none-the-less taught oral administration and further taught formulating the composition into powders (*Id.*). It would be clear to one of ordinary skill that a powder could be formulated into a beverage by adding the powder to water or any other beverage in order to carry the pharmaceutical for oral delivery. Hence, this aspect of claim 8 is rendered obvious by Majeed et al.; such a medicament, in the form of a beverage would have been considered a predictable variation of the teachings of the prior art.

Claims 1-12, 15, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ponnapalli et al. (US

2005/0220913 A1), Visvabharati, C, 2000, TKDL translation and Wu et al. (US 6,274,177)

The teachings of Majeed et al., Ponapalli et al. and Visvabharati were discussed above. These references did not specifically discuss the incorporation of *Zingiber officinale* into their pharmaceutical formulation.

Wu et al. teach that extracts of *Zingiber officinale* (ginger) possess anti-inflammatory properties (see entire reference including the Abstract), Wu et al. postulating that its success in treating arthritis and 'muscular discomforts' are due to inhibition of prostanoid synthesis as well as products of 5-lipoxygnase (e.g., leukotrienes) (see columns 1-2, in particular, col. 1, line 66- col 2, line 21). Ginger's ability to inhibit inflammation have been verified through positive outcome of carrageenan-induced rat paw edema (Id.).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well- established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claims 1-12, 14, 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ponnapalli et al. (US 2005/0220913 A1), Visvabharati, C, 2000, TKDL translation, (Jan, 2008) and Balunas et al. (US 2009/0181110 A1).

The teachings of Majeed et al. Ponnapalli et al. and Visvabharati were discussed above. Neither reference taught the incorporation of *Garcinia mangostana* or whereby the 'second extract' was an alcoholic or hydroalcholic extract.

Alcoholic extracts of *C. Mangosteen* were known for possessing anti-inflammatory properties (Balunas et al., [0031] and the claims, particularly claims 1 and

13). Hence, similar to the reasoning set forth in light of *In re Kerkhoven* and/or *In re Sussman* above, the ordinary artisan would have found the combination of elements obvious and predictable based upon their similar biochemical properties. One of ordinary skill in the art would have had a reasonable expectation of success in combining the claimed elements in order to provide a composition with enhanced anti-inflammatory properties.

Claims 1-12, 15, 17, 18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ponnapalli et al. (US 2005/0220913 A1), Visvabharati, C, 2000, TKDL translation and Ishida et al. (JP 2005298429 A).

The teachings of Majeed et al. Ponnapalli et al. and Visvabharati were discussed above. These references did not teach the incorporation of a third extract such as *Piper longum*.

Ishida et al. teach that *Piper longum* extract possesses antiinflammatory properties (see English Abstract).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well- established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claims 1-18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ponnapalli et al. (US 2005/0220913 A1), Visvabharati, C, 2000, TKDL translation, Wu et al. (US 6,274,177), Balunas et al. (US 2009/0181110 A1) and Ishida et al. (JP 2005298429 A).

It naturally follows that the whole of the claims are properly rejected under 35 USC 103(a) using the above-cited references for the same reasons the individual claims were rejected using the respective references. Hence, the reasons set forth above in each individual rejection of the claims applies to this rejection equally.

Pertaining to all of the rejections instituted herein under 35 USC 103(a), the Supreme court has acknowledged:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*this reference is placed merely to relay an inherent/intrinsic property and is not used in the basis for rejection *per se*.

Conclusion

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).

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 PATRICIA A. LEITH whose telephone number is (571)272-0968. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm.

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.

PATRICIA A LEITH
Primary Examiner
Art Unit 1655

/PATRICIA A LEITH/
Primary Examiner, Art Unit 1655
December 23, 2011

Notice of References Cited	Application/Control No. 12/477,643	Applicant(s)/Patent Under Reexamination GOKARAJU ET AL.	
	Examiner PATRICIA A. LEITH	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-2005/0220913	10-2005	Ponnapalli et al.	424/777
	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	
	V	
	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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/477,643	06/03/2009	Ganga Raju Gokaraju	LIX 3022	7867

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
08/29/2011	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):

mail@krameramado.com

Office Action Summary	Application No.	Applicant(s)	
	12/477,643	GOKARAJU ET AL.	
	Examiner	Art Unit	
	PATRICIA A. LEITH	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 *13 July 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) *1-32* is/are pending in the application.

5a) Of the above claim(s) *19-31* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-18 and 32* 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 *6/3/2009* 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 *3/16/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending in this US Patent Application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-18 and 32 in the reply filed on 7/13/2011 is acknowledged. The traversal is on the ground(s) that Claim 21 (Group III) is not independent of claim 1 because claim 21 is dependent 'from claim 1'. This is not found persuasive because claim 21 is an independent claim and not a dependent claim and is properly restrictable for the suitable reasons set forth in the original requirement for Restriction.

Applicant argues that the Examiner has failed to establish a burden of search and argues that the composition of Group I also contains ginger extracts and could be classified in Class 424 756 and each contain boswellic acids which could be classified in class 424, subclass 725. However, Applicant is respectfully not recognizing that Group I are composition claims and Group II are method claims. The Examiner set forth ample reason why these Groups are distinct and Applicant has not provided sufficient reason to persuade the Examiner otherwise. While the Inventions could be classified together, they do not overlap completely and may also be classified separately.

Additionally, separate classification was not the only reason given to support a burden of search. The Examiner specifically stated that the inventions have acquired a separate status in the art due to their recognized divergent subject matter and the inventions require a different field of search (e.g., searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

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

Claims 19-31 are hereby withdrawn from examination at this time as being directed toward a non-elected Invention.

Claims 1-18 and 32 were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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

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

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

Claims 1-4, 6-18 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-50, of copending Application No. 12/610,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of said

'502 application 'render obvious' the Instantly claimed invention for the following reasons:

Claims 21-50 of '502 teach a composition comprising extracts of *Boswellia serrata* including AKBA, *Piper longum, glycyrrhiza glabra, Aegle marmelos* and *Zingiber officinale*. Claim 30 specifically teaches the addition of a carrier ingredient and claim 25 specifically adds ingredients such as It is noted that every claim including additional extracts states 'or mixture thereof' hence teaching the incorporation of all of the claimed extracts. The use of alcohol as an extraction solvent would have been an obvious variation of the claims of the '502 application because the specification of '502 specifically teaches that alcohol is a suitable solvent for plant extraction [0068]. Although ethanol is not expressly recited by the specification of '502, ethanol would have been a suitable choice in extraction alcohol considering that ethanol and methanol are both well-known alcoholic solvents used in the plant extraction art.

Although the claims of '502 do not specifically teach the amounts of constituents as claimed, , it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the amounts of constituents as claimed may not specifically be taught by the claims of '502, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal

concentrations of claimed components because all of the components were art-recognized result-effective variables having pharmacological effect. Hence, adjusting the concentrations of these claimed ingredients within a pharmaceutical formulation would have been routinely determined and optimized in the pharmaceutical art.

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

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.

Claim 15 is 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 15 states 'wherein said second extract is an ethanol or hydroalcohol extract' however, claim 1 states that the second extract is AM and optionally *Zingiber officinale* or *Garcina mangostana* or both. Hence, claim 15 lacks clear antecedent basis and it is not apparently evident which extract Applicants are refering to. Hence, the lack of antecedent basis in the present case leads to confusion and thus

indefiniteness. In order to overcome this rejection, it is suggested that claim 15 be amended to recite specifically which second extract is an alcohol or hydroalcoholic extract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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.

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 1-12, 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ghangale et al, (Jan, 2008) and Visvabharati, C, 2000, TKDL translation, as evidenced by Sailer et al. – ACETYL-11-KETO-BETA-BOSWELLIC ACID (AKBA): STRUCUTRE REQURIEMENTS FOR BINDING AND 5-LIPOXYGNEASE INHIBITORY ACTIVITY; Br. J. Pharmacol., 1996, February, 117(4) Abstract.*

It is first noted that the phrase 'enriched Boswellia extract containing from 10% to 99% by weight of [AKBA]' as recited by claim 1 is broad enough to read on a composition comprising 99% of AKBA and 1% of water (or any other type of solvent). It is noted however, that the amount of AKBA in the composition is undefined by the claim and therefore, the amount of AKBA in the claim may be present in any amount so long as the AKBA is present in the Boswellia extract between 10 and 99%. A composition comprising 99% AKBA and 1% of water is essentially the same as a composition comprising essentially 100% of AKBA.

In the rejection which follows, the Examiner has reasoned why one of ordinary skill in the art would be motivated to use AKBA alone or AKBA as it is present in a

Boswellia extract in combination with AM for treating skin proliferative disorders such as psoriasis and eczema.

Majeed et al. discloses a composition comprising boswellic acid compounds such as acetyl- 11-keto-β-boswellic acid (AKBA, the same compound as claimed for evidence, see Sailer et al. – ACETYL-11-KETO-BETA-BOSWELLIC ACID (AKBA): STRUCUTRE REQURIEMENTS FOR BINDING AND 5-LIPOXYGNEASE INHIBITORY ACTIVITY; Br. J. Pharmacol., 1996, February, 117(4) Abstract) or Boswellia seratta extracts containing AKBA for treating dermatological conditions such as psoriasis (see entire Pre-Grant Publication including [0001]-[0003]).

Majeed et al. report:

> Boswellic acids inhibit 5-lipoxygenase...the enzyme which catalyzes conversion of arachidonic acid to inflammatory leukotrienes [and] inhibit the enzyme human leukocyte elastase (HLE) which catalyzes connective tissue break down... ([0008]).
>
> Inflammatory leukotrienes have been implicated in the pathogenesis and pathophysiology of psoriasis. In lesional skin from psoriasis and eczema patients, leukotriene B4 was found to increase by approximately 6.6-fold. [0009]

Majeed et al. indicate formulating the Boswellia extracts containing boswellic acids, including AKBA, or AKBA into conventional dosage forms such as tablets, capsules, powders [0062], creams or lotions [0063] with conventional carriers such as Vitamin E (antioxidant), PEG-100, ascorbyl palmitate and dimethicone (*inter alia*). A lotion is a liquid. Drops of this lotion for administration

would be considered 'liquid drops' absent any specific definition for 'liquid drops' in the specification.

Majeed et al. propose the use of 50-500 mg of AKBA into their compositions (see, e.g., claim 7). Additionally, Majeed et al. teach an exemplary formulation which comprises 4 types of boswellic acids (including AKBA) along with a carrier (Table 1 of Example 1). Majeed et al. make clear that Boswellia seratta extracts containing these boswellic acids as-listed in this table were a preferred embodiment (Boswellin being a trademarked product containing all 4 boswellic acids, see, e.g., [0062] and claims 3 and 6. Taking the formulation of Table 1 into consideration, the mixtures of boswellic acids may be said to be an 'extract' of Boswellia. Here, the boswellic acids alone constitute 168 mg and AKBA is present at 32 mg or approximately 19% of the Boswellia extract which falls within Applicants' claimed range of 10-99%.

It is again noted that the use of AKBA alone was indeed considered by Majeed et al. and that such a composition which would be considered an extract of Boswellia comprising 100% of AKBA would be essentially the same as an extract of Boswellia containing 99% water and 1% AKBA. One of ordinary skill in the art would see little or no difference between such a composition and the addition or subtraction of such a small amount of water would not be expected to materially affect the composition. Hence, it is the opinion of the Examiner that an

extract of Boswellia containing 99% AKBA and an extract of Boswellia containing 100% AKBA would be so similar that no discernable differences could be established.

Majeed et al. did not teach the incorporation of *Aegle marmelos* extract into to their composition.

Aegle marmelos leaf water extract has been shown to possess significant anti-inflammatory activity (see Ghangale et AL, (Jan, 2008) Abstract, the full reference has been ordered).

Additionally, *Aegle marmelos* and *Boswellia seratta* (which intrinsically possesses boswellic acids such as AKBA) are present in a single formulation in traditional Indian medicine for treatment of dermatitis and eczema (see Visvabharati, C, 2000, TKDL translation). Hence, the presence of both of these plants was found advantageous in traditional Indian medicine for treatment of skin conditions such as eczema.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from

their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

In the Instant case, it was known in the art that all of *Boswellia serrata* extract containing boswellic acids such as AKBA, AKBA alone and a water extract of AM leaves possessed anti-inflammatory properties. AKBA was a known anti-inflammatory touted for use in treating proliferative skin conditions such as psoriasis, AM was known for possessing anti-inflammatory activity and is present in an Indian traditional formulation containing only one other herbal ingredient for treating dermatitis or eczema. Additionally, to reiterate from above, Majeed et al. report:

> Boswellic acids inhibit 5-lipoxygenase...the enzyme which catalyzes conversion of arachidonic acid to inflammatory leukotrienes [and] inhibit the enzyme human leukocyte elastase (HLE) which catalyzes connective tissue break down... ([0008]).
>
> Inflammatory leukotrienes have been implicated in the pathogenesis and pathophysiology of psoriasis. In lesional skin from psoriasis and eczema patients, leukotriene B4 was found to increase by approximately 6.6-fold. [0009]

Hence, one of ordinary skill would have readily recognized the advantages for combining AKBA with an extract of AM for treatment of skin proliferative disorders such as psoriasis or skin disorders such as eczema/dermatitis. One would have had a reasonable expectation of such because of their past use together to treat dermatological conditions and further

because both were known anti-inflammatory agents, AKBA being a recognized 5-lipoxygenase/leukotriene inhibitors whereby leukotriene B4 has been linked to psoriasis as well as eczema. Hence, the advantageous nature of combining these ingredients was, in the opinion of the Examiner, easily recognized by those of ordinary skill in the art wishing to combine naturally-derived medicines for dermatological treatment.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the amounts of constituents as claimed may not specifically be taught by the prior art, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of claimed components because both AKBA and AM extracts were art-recognized result-effective variables having pharmacological effect. Hence, adjusting the concentrations of these claimed ingredients within a pharmaceutical formulation for treating a dermatological condition such as psoriasis or eczema would have been routinely determined and optimized in the pharmaceutical art.

It is noted that claim 11, although providing a percentage of an additional ingredient does not positively recite that the ingredient is necessarily present. Because claim 1 makes it clear that any herbal extracts besides a Boswellia extract containing AKBA and

AM are optional, it is taken that the herbal components of these claims are also optional and are not required. If Applicants wish for these additional herbals to necessarily be present in the composition, it is suggested that the claim language be changed to 'wherein the second extract is present in the composition and is in a percentage.... '.

Although Majeed et al. did not per se discuss formulation of their boswellic acid composition into, e.g., a beverage as required for claim 8, they none-the-less taught oral administration and further taught formulating the composition into powders (Id.). It would be clear to one of ordinary skill that a powder could be formulated into a beverage by adding the powder to water or any other beverage in order to carry the pharmaceutical for oral delivery. Hence, this aspect of claim 8 is rendered obvious by Majeed et al.; such a medicament, in the form of a beverage would have been considered a predictable variation of the teachings of the prior art.

Pertaining to claim 15 which states that the second extract is an ethanol or hydroalcohol extract: While the prior art teaches a water extract of AM possesses anti-inflammatory properties, it is the opinion of the Examiner that a water extract of AM and the extract of Instant claim 15 pertaining to a hydroalcoholic extract are so similar that differences between the products could not be construed. The reason being: a 'hydroalcoholic extract' is very broad and may read on an extraction carried out with essentially entirely water and a trace amount of alcohol. Such a composition would be, in the opinion of the Examiner, the same as a water extract.

Claims 1-12, 15, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ghangale et al, (Jan, 2008), Wu et al. (US 6,274,177) and Visvabharati, C, 2000, TKDL translation.

The teachings of Majeed et al. were discussed above. Majeed et al. did not specifically discuss the incorporation of *Zingiber officinale* into their pharmaceutical formulation.

Wu et al. teach that extracts of *Zingiber officinale* (ginger) possess anti-inflammatory properties (see entire reference including the Abstract), Wu et al. postulating that its success in treating arthritis and 'muscular discomforts' are due to inhibition of prostanoid synthesis as well as products of 5-lipoxygnase (e.g., leukotrienes) (see columns 1-2, in particular, col. 1, line 66- col 2, line 21). Ginger's ability to inhibit inflammation have been verified through positive outcome of carrageenan-induced rat paw edema (Id.).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846,

850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well- established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claims 1-12, 14, 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ghangale et AL, Visvabharati, C, 2000, TKDL translation, (Jan, 2008) and Balunas et al. (US 2009/0181110 A1).

The teachings of Majeed et al. and Ghangale et al. were discussed above. Neither reference taught the incorporation of *Garcinia mangostana* or whereby the 'second extract' was an alcoholic or hydroalcholic extract.

It is noted, as set forth in the rejection placed over claim 15 under 35 USC 112 Second paragraph, that it is unknown which 'second extract' is alcoholic or hydroalcoholic. Thus, for the purposes of examination, the claim was examined as if any of the 'second extracts' could be alcoholic or hydroalcoholic.

Alcoholic extracts of C. Mangosteen were known for possessing anti-inflammatory properties. Balunas et al. for example, claim a composition taught ts anti-inflammatory properties prior to Applicants' Invention.

Claims 1-12, 15, 17, 18 a nd 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ghangale et AL (Jan, 2008), Visvabharati, C, 2000, TKDL translation and Ishida et al. (JP 2005298429 A).

The teachings of Majeed et al. and Ghangale et al. were discussed above. These references did not teach the incorporation of a third extract such as Piper longum.

Ishida et al. teach that *Piper longum* extract possesses antiinflammatory properties (see English Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well- established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claims 1-18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US 2005/0123559) in view of Ghangale et al (Jan, 2008), Visvabharati, C, 2000, TKDL translation, Wu et al. (US 6,274,177), Balunas et al. (US 2009/0181110 A1) and Ishida et al. (JP 2005298429 A).

It naturally follows that the whole of the claims are properly rejected under 35 USC 103(a) using the above-cited references for the same reasons the individual claims were rejected using the respective references. Hence, the reasons set forth above in each individual rejection of the claims applies to this rejection equally.

Pertaining to all of the rejections instituted herein under 35 USC 103(a), the Supreme court has acknowledged:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*this reference is placed merely to relay an inherent/intrinsic property and is not used in the basis for rejection *per se*.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA A. LEITH whose telephone number is (571)272-0968. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm.

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.

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Primary Examiner
Art Unit 1655

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Primary Examiner, Art Unit 1655
August 21, 2011

Notice of References Cited	Application/Control No. 12/477,643	Applicant(s)/Patent Under Reexamination GOKARAJU ET AL.	
	Examiner PATRICIA A. LEITH	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-2005/0123559	06-2005	Majeed et al.	424/195.18
*	B	US-2009/0181110	07-2009	Balunas et al.	424/725
*	C	US-6,274,177	08-2001	Wu et al.	424/756
	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	2005298429 A	10-2005	JP	Ishida et al.	English Abstract
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ghangale et al. EVALUATION OF AEGLE MARMELOS (BAEL) FOR ANTI-INFLAMMATORY ACTIVITY IN RATS; Journal of Bombay Veterinary College; January 2008, Volume 16, Issue 1, one page Abstract.
	V	Visvabharati, C. 2000, TKDL Translation, 2 pages.
	W	Sailer et al. – ACETYL-11-KETO-BETA-BOSWELLIC ACID (AKBA): STRUCUTRE REQURIEMENTS FOR BINDING AND 5-LIPOXYGNEASE INHIBITORY ACTIVITY; Br. J. Pharmacol., 1996, February, 117(4) Abstract)
	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.