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| 14/002,940  | 09/03/2013  | Suresh Balkrishna Patankar | GNA 3046            | 6909             |
| 30868 7590 07/01/2014<br><b>KRAMER &amp; AMADO, P.C.</b><br><b>330 JOHN CARLYLE STREET</b><br><b>3RD FLOOR</b><br><b>ALEXANDRIA, VA 22314</b> |             |                            |                     |                  |
|   |             |                            | EXAMINER            |                  |
|   |             |                            | PROSSER, ALISSA J   |                  |
|   |             |                            | ART UNIT            | PAPER NUMBER     |
|   |             |                            | 1619                |                  |
|   |             |                            | NOTIFICATION DATE   | DELIVERY MODE    |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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

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

mail@krameramado.com

## Office Action Summary

Application No.  
14/002,940

Applicant(s)  
PATANKAR, SURESH  
BALKRISHNA

Examiner  
ALISSA PROSSER

Art Unit  
1619

AIA (First Inventor to File)  
Status  
No

-- 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 MONTHS 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 April 25, 2014.  
 A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on \_\_\_\_\_.
- 2a)  This action is FINAL. 2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims\*

- 5)  Claim(s) 1-7,9-13 and 15 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 1-7,9-13 and 15 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the Patent Prosecution Highway program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

### 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).

### Priority under 35 U.S.C. § 119

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

#### Certified copies:

- a)  All b)  Some\*\* c)  None of the:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 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)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
Paper No(s)/Mail Date March 24, 2014
- 3)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 4)  Other: \_\_\_\_\_

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

#### **DETAILED ACTION**

Applicant's Request for Reconsideration dated April 25, 2014 is acknowledged.

Claims 1-7, 9-13 and 15 are pending.

Claims 8 and 14 are cancelled.

Claims 1, 3, 9, 10 and 12 are amended.

Claim 15 is new.

Claims 1-7, 9-13 and 15 as filed on April 25, 2014 are pending and under consideration.

This action is made **NONFINAL**.

#### ***Withdrawn Objections / Rejections***

1. The objections to claims 1 and 3 are withdrawn in view of the amendments to claims 1 and 3.
2. The rejections of claims 3, 4, 9 and 11-13 under 35 USC 112(b) are withdrawn in view of Applicant's arguments and the amendments to claims 9, 10 and 11.
3. Applicant's arguments have been fully considered. Rejections and/or objections not reiterated from **previous** office actions are hereby withdrawn. The following rejections and/or objections are **either** reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***37 CFR 1.121 – Manner of Making Amendments***

With regard to claim 1, the Examiner notes as per MPEP § 714 II C (B) all claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by strike-through (for deleted matter) or underlining (for added matter). In the instant case, the spelling of *Achyranthes* was changed without markings to indicate such a change. It is presumed that this oversight represents an inadvertent, automatic spell-check error.

***Information Disclosure Statement / Third-Party Submission under 37 CFR 1.290***

The information disclosure statement (IDS) submitted by Dr. Archana Sharma on March 24, 2014 has been entered was considered. The involvement of a third party in filing a submission under 37 CFR 1.290 ends with the filing of the submission as per MPEP § 1134.01 V. MPEP § 1134.01 VI B states that neither the Examiner nor the Applicant is required to comment or otherwise respond to the substance of the third party filing, however, Applicant may consider more clearly delineating aspects of the instant invention that represent improvements over what is known and conventional in the interest of compact prosecution because the documents filed by a third party demonstrate that combinations of *Hordeum vulgare* with cow urine extract (document 1), with *Musa sapientum* and *Achyranthes aspera* (document 2) and with *Crataeva nurvala* (document 3) for the treatment of urinary calculus are long known.

***New Grounds of Rejection: Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:



Art Unit: 1619

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1-7, 9-13 and 15 are rejected under 35 U.S.C. 101 because the claimed inventions are not directed to patent eligible subject matter.** Based upon an analysis with respect to the claim(s) as a whole, claim(s) 1-7, 9-13 and 15 do not recite something significantly or markedly different than a judicial exception. The rationale for this determination is explained below: as per the PTO memorandum of March 4, 2014 entitled "2014 Procedure for Subject Matter Eligibility and Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products," claims reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products may be patent eligible only when drawn to subject matter that reflects a significant difference from what exists in nature. In the instant case, claims 1-7 and 15 are broadly drawn to an herbal composition comprising a mixture of plant extracts and claims 8-13 are broadly drawn to a method of administering said mixture of plant extracts. Because extracts are natural products that do not significantly or markedly differ from a natural product, the instant claims are not drawn to patent eligible subject matter. Likewise, combinations of natural products are not patent eligible under the new guidelines even if the combination itself is not naturally occurring (see Example D "Composition claim reciting multiple natural products" of the memorandum). Patent eligibility requires that claimed products be both non-naturally occurring and markedly different from naturally occurring products. Patents cannot issue for the discovery of phenomena of nature, e.g., the discovery of latent physical properties inherent to a natural product, or for mere use of a natural product that imposes no meaningful limitation of the performance of a claimed method. In the instant case,

Art Unit: 1619

the dependent claims similarly fail to encompass something markedly different than a judicial exception.

A copy of the memorandum is available at:

[http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf)

The announcement is available at:

<http://www.uspto.gov/patents/announce/myriad-mayo.jsp>

### *Specification*

The disclosure is objected to because of the following informalities:

- a. Page 4, 2<sup>nd</sup> paragraph: "An another object" could be simplified to "Another object".
- b. Pages 4, 5, 6, 8, 12, 16, 17, 18, 19: the content of the final paragraphs of these pages does not naturally flow into the first paragraphs on the following pages. The issue is also present in the corresponding WIPO document WO 2012/127498. Applicant is respectfully requested to double-check the page turns of the instant specification for inadvertently omitted content, perhaps due to differences in international paper sizes/margins, and make corrections as appropriate.
- c. Whole document: *Achyranthes* appears to be consistently misspelled.

Appropriate correction is required.

Art Unit: 1619

***Claim Objections***

Claim 15 is objected to because of the following informalities: *Achyranthes* appears to be misspelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 112(a)***

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

(a) IN GENERAL. 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 or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 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 1-7, 9-13 and 15 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), 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 or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Independent claims 9 and 10 are drawn to a method of treatment comprising administering the herbal composition according to claim 1. The composition of claim 1 recites upper ranges of about 55 wt% of the four required components. There is nothing in the specification as filed to lead one of ordinary skill in the art to choose an upper range of 55 wt%. At least the capsule formulation on page 11 provides support for weight percentages in general,

as the formulation of page 11 is consistent with the embodiment (percentages) recited in the first paragraph of page 7.

The composition of claim 15 recites upper ranges of 100 wt% of the four required components. There is nothing in the specification as filed to lead one of ordinary skill in the art to choose an upper range of 100 wt%. The specification as filed provides support for amounts of about 15 to 85 % on page 7.

***Response to Arguments: Claim Rejections - 35 USC § 112(a)***

Applicant submits that the claimed ranges of 15 to 55 wt% for each of the required four components do not represent new matter because a person of ordinary skill in the art would understand the mathematical necessity thereof.

This is not found persuasive in view of the language of the statute as summarized supra. Applicant is required at the time of filing to submit a written description of the invention in full, clear, concise and exact terms and shall set forth the best mode for carrying out the invention. Because the instant claim limitations are not supported by the instant specification, they constitute new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 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.



Art Unit: 1619

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 pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 5-7, 9-13 and 15 are rejected under pre-AIA 35 U.S.C. 103(a) as being**

**unpatentable over Patankar (2128/MUM/2006, published August 15, 2008) in view of The**

**Tribune online article by Vatsyayan "The stone-breaker," January 23, 2002, the Ayurveda**

**Sanjeevani online blog entry "Some hints to control kidney stones or stones related to**

**urinary tract," January 4, 2007 as evidenced by Natarajan et al. "Growth of some urinary**

**crystals and studies on inhibitors and promoters. II. X-ray studies and inhibitory or**

**promotory role of some substances," *Crystal Research and Technology* 32(4):553-559, 1997**

**and Vagabhata "Astanga Hrdaya," published 1998, IDS reference filed March 24, 2014.**

In the last paragraph of page 5 Patankar teaches a synergistic herbal preparation for the treatment of kidney stones (renal calculi) which gives significant results in the elimination of kidney stones with least side effects. While it is possible for the active ingredients to be administered alone it is preferable to present them as pharmaceutical formulations suitable for human use, **as required by instant claim 11**. Typically, 15 to 85% of both the active ingredients are included in the formulation. The formulations include those suitable for oral, nasal, topical (including buccal and sublingual), vaginal or parenteral and rectal administration,

Art Unit: 1619

**as required by instant claims 7 and 13.** The formulations may be conveniently presented in unit dosage form.

The first paragraph of page 6 lists formulations suitable for oral administration inclusive of capsules, cachets or tablets; powder or granules; solution or suspension; emulsion; bolus, electuary or paste, **as required by instant claims 5, 6 and 12.** The carrier constitutes one or more accessory ingredients (pharmaceutically acceptable additive), **as required by instant claim 4.**

The herbal composition comprises A) a homogenized powdered mixture of i) Varun extract prepared from the barks of at least one of Varun *Crataeva nurvala* Buch-Ham and *Crataeva magna* and ii) banana stem extract prepared from at least one of *Musa paradisiaca* and *Musa sapientum*, B) ash salt of banana root and C) a pharmaceutically acceptable carrier (abstract). Typically the proportion of 'A' and 'B' are on an equal weight basis (abstract).

The banana stem extract is prepared from the rhizome (root), stem (core part), leaves, inflorescence and fruits (page 4, 2<sup>nd</sup> paragraph). Use of aqueous banana stem extract as a useful agent is known (page 4, last paragraph).

A clinical study (method of treating a subject in need thereof) randomly assigned patients with kidney **stones of size 1.5 to 2 cm either the trial drug/s or placebo** (comprising administering the herbal composition) (paragraph bridging pages 6 and 7). Efficacy was evaluated on the basis of sonographic image of the calculi and pain index to confirm stone clearance. Example 6 on page 8 shows that either Varun alone or Banana Stem extract alone are comparable in terms of treating renal calculi, but the combination of Varun and Banana is better.

Art Unit: 1619

Patankar does not teach the herbal composition to comprise an extract from flowers, leaves, seeds, roots and fruits of *Achyranthes aspera* in an amount of about 15 to 55 wt%, at least 15 wt%; and an extract from (ash of) burnt seeds of *Hordeum vulgare* in an amount of about 15 to 55 wt%, at least 15 wt% as required by claims 1, 9, 10 and 15.

These deficiencies are made up for in the teachings of Vatsyayan, Ayurveda Sanjeevani and Vagabhata.

Vatsyayan teaches apamarga (*Achyranthes aspera*) is a drug of choice for urinary afflictions like calculus because of its diuretic and alkalizer properties (page 6, 2<sup>nd</sup> to last paragraph). Ayurvedic texts describe the use of apamarga kshara (ash of whole dried plant) to gain the maximum benefits (page 6, last paragraph). To treat small urinary stones, apamarga kshara is considered the foremost ayurvedic medicine (page 7, 2<sup>nd</sup> paragraph).

Ayurveda Sanjeevani teaches barley water (extract of seed) is a very good medicine for kidney stones (page 2). Juice extracted from the stem of banana plant is the best medicine (page 3). As evidenced by Table 2 on page 557 of Natarajan, the botanical name for barley is *Hordeum vulgare* which is known as a good inhibitor of calcium oxalate monohydrate (COM) crystals, the sole or major component of kidney stones (Natarajan, page 553).

Vagabhata teach a treatment for urinary calculus prepared as a kshar (ash) of equal parts *Sesamum indicum*, *Achyranthes aspera*, *Musa paradisiaca*, *Butea monosperma* and *Hordeum vulgare*.

Patankar, Vatsyayan, Ayurveda Sanjeevani and Vagabhata are analogous inventions in the field of herbal ayurvedic treatments for urinary afflictions like kidney stones.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the herbal composition of Patankar comprising on an equal weight basis, typically 15 to 85%, of Varun extract prepared from the barks or at least one of Varun *Crataeva nurvala* Buch-Ham and *Crataeva magna* and banana stem extract prepared from the rhizome (root), stem (core part), leaves, inflorescence and fruits from at least one of *Musa paradisiaca* and *Musa sapientum* with the inclusion of apamarga (*Achyranthes aspera*) as taught by Vatsyayan and barley (*Hordeum vulgare*) as taught by Ayurveda Sanjeevani. One would be motivated to do so because Vatsyayan teaches apamarga is the drug of choice for urinary afflictions like calculus because of its diuretic and alkalizer properties and apamarga kshara (ash of whole dried) is considered the foremost ayurvedic medicine with maximum benefits. In addition, Ayurveda Sanjeevani teaches the juice of the banana which is already included in the composition of Patankar is the best medicine for kidney stones and that barley water is also a very good medicine. As evidenced by Natarajan, barley or *Hordeum vulgare* is known as a good inhibitor of calcium oxalate monohydrate crystals. There would be a reasonable expectation of success because Patankar have shown that while the Varun alone or Banana Stem extract alone are comparable in terms of treating renal calculi, the combination of Varun and Banana is better. One of ordinary skill in the art would therefore be imbued with the reasonable expectation that the combination of herbal remedies would be better than a single, known remedy. One of ordinary skill in the art would combine these ingredients on an equal weight basis according to the teachings of Patankar. It would take nothing more than routine experimentation to determine

Art Unit: 1619

a composition that optimizes the treatment efficacy of the herbal mixture. It is *prima facie* obvious to optimize a result effective variable. See MPEP § 2144.05 II.

It would have been obvious to one of ordinary skill in the art to include barley (*Hordeum vulgare*) as a kshar (ash) as taught by Vagabhata because Vatsyayan teaches Ayurvedic texts describe the use of apamarga kshara (ash of whole dried plant) to gain the maximum benefits (page 6, last paragraph). One of ordinary skill in the art would be imbued with the reasonable expectation that the kshar of barley would similarly yield maximum benefits, absent evidence to the contrary.

Also, “[i]t 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). One would be imbued with the reasonable expectation that combining the anticalculus herb apamarga or apamarga kshara as taught by Vatsyayan and the anticalculus barley kshar of Ayurveda Sanjeevani and Vagabhata with the anticalculus herbal blend comprising varun and banana extract as taught by Patankar would result in a third composition also capable of anticalculus, as each herbal composition is individually taught to have this property.

**Claims 2-4 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Patankar (2128/MUM/2006, published August 15, 2008) in view of The Tribune online article by Vatsyayan “The stone-breaker,” January 23, 2002, the Ayurveda Sanjeevani**

Art Unit: 1619

online blog entry **"Some hints to control kidney stones or stones related to urinary tract,"** January 4, 2007 as evidenced by Natarajan et al. **"Growth of some urinary crystals and studies on inhibitors and promoters. II. X-ray studies and inhibitory or promotery role of some substances,"** *Crystal Research and Technology* 32(4):553-559, 1997 and Vagabhata **"Astanga Hrdaya,"** published 1998, IDS reference filed March 24, 2014 as applied to claim **1, 5-7, 9-13 and 15 above, and further in view of Khanuja et al. (U.S. 6,896,907,** published May 24, 2005).

The teachings of Patankar, Vatsyayan, Ayurveda Sanjeevani and Vagabhata have been described supra.

Patankar teaches suitable carriers constitute one or more accessory ingredients (pharmaceutically acceptable additives), **as required by instant claim 4.**

They do not teach cow urine extract as required by claim 2.

They do not teach wherein said cow urine extract is present in an amount of 15 to 85 % of the total composition as required by claim 3.

These deficiencies are made up for in the teachings of Khanuja.

Khanuja teach cow urine distillate (extract) as activity enhancer and availability facilitator for bioactive molecules including anti-infective and anti-cancer agents (abstract), **as required by instant claim 2.** In Ayurveda cow urine is suggested for improving general health (column 1, lines 27-28).

Patankar, Vatsyayan, Ayurveda Sanjeevani, Vagabhata and Khanuja are analogous inventions in the field of herbal ayurvedic treatments for urinary afflictions like kidney stones and for improving health.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the herbal composition of Patankar in view of Vatsyayan, Ayurveda Sanjeevani and Vagabhata with the inclusion of cow urine distillate (extract) as taught by Khanuja because Khanuja teach cow urine is known to Ayurvedic medicine for improving general health and cow urine extract has been shown to enhance the bioavailability of other drugs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the cow urine extract of Khanuja in the herbal composition of Patankar in view of Vatsyayan, Ayurveda Sanjeevani and Vagabhata on an equal weight basis, typically 15 to 85%, according to the teachings of Patankar. It would take nothing more than routine experimentation to determine the amount of cow urine distillate is required to enhance the bioavailability of the herbal composition of Patankar in view of Vatsyayan, Ayurveda Sanjeevani and Vagabhata. It is prima facie obvious to optimize a result-effective variable as per MPEP § 2144.05.

***Response to Arguments: Claim Rejections - 35 USC § 103***

Applicant's arguments have been fully considered.

Applicant submits that none of the cited references teach an extract of an ash from barley as instantly claimed.

The rejection has been updated to teach this new limitation.

Applicant submits that the comparative data on page 19 of the instant specification demonstrate that the claimed composition is superior to that of the Varun extract and banana kshar alone as taught by the primary reference.

This is not found persuasive because the referenced data is not commensurate in scope with the instant claims. Nor does the proffered data directly compare to the primary reference to Patankar at least because Herbmed (as taught by the primary reference) comprises equal amounts of Varun extract and banana kshar while Herbmed plus (the subject of the instant application) contains 50% Varun extract and 15% banana kshar (page 18 of the instant specification).

Applicant submits that synergism is unpredictable and that the comparative data of the instant specification could not have been foreseen.

This is not found persuasive because there is no evidence of synergism in the proffered data of the instant specification or in the primary reference to Patankar. However, the Examiner agrees that the use of the word synergism in the previous rejection was a poor choice of words and the rejection has been updated to use more accurate verbiage. The primary reference to Patankar merely states that the combination of Varun and Banana is better than either Varun alone or Banana Stem extract alone. Likewise, the data within the Table of page 19 merely shows the singular Herbmed plus composition is better than the singular Herbmed composition. **That a blend of ingredients is "better" is exactly what is taught by Patankar. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). See MPEP § 716.02(c) II.**



Applicant submits that there is no motivation to combine Khanuja in order to teach cow urine extract because Khanuja concerns anti-infective and anti-cancer agents.

This is not found persuasive because Khanuja teach in Ayurveda cow urine is suggested for improving general health and is known as an activity enhancer and availability facilitator for bioactive molecules.

Applicant has not provided unexpected properties or results for the claimed compositions that are commensurate in scope with the instantly claimed compositions and as such, the claims remain *prima facie* obvious over the combined teachings of the prior art.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALISSA PROSSER whose telephone number is (571)272-5164. The examiner can normally be reached on M - F, 9 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DAVID BLANCHARD can be reached on (571)272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 14/002,940  
Art Unit: 1619

Page 17

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.

/ALISSA PROSSER/  
Examiner, Art Unit 1619

/HELENA POPA/  
Primary Examiner, Art Unit 1633