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EXAMINER
PROSSER, ALISSA J

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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 *December 31, 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 16* 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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 16* 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 or send an inquiry to 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:

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) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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 December 31, 2014 is acknowledged.

Claims 1-7, 9-13 and 16 are pending.

Claims 8, 14 and 15 are cancelled.

Claim 1 is currently amended.

Claim 16 is new.

Claims 1-7, 9-13 and 16 as filed on December 31, 2014 are currently pending and under consideration.

This action is made **FINAL**.

Withdrawn Objections / Rejections

1. In view of the amendment of the specification, the objection to the specification is withdrawn.

2. In view of the cancellation of claim 15, the objection to claim 15 is withdrawn.

3. Upon further considerations, the rejection of claims 9-13 under 35 U.S.C. 101 is withdrawn.

4. Applicant's arguments and the Declaration of Suresh Patankar under 37 CFR 1.132 filed December 31, 2014 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.

Maintained Grounds of Rejection / New Ground of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 101

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

> 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 and 16 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 16 do not recite something significantly or markedly different than a judicial exception.

The rationale for this determination is explained below: as per the 2014 Interim Guidance on Patent Subject Matter Eligibility (Interim Eligibility Guidance) of December 16, 2014, nature-based products that (i) are naturally occurring or (ii) are not naturally occurring but have characteristics that are not markedly different from a naturally occurring counterpart fall within an exception (law of nature or natural phenomena). Compositions, or combinations of naturally occurring nature-based products, are not patent eligible under the Interim Eligibility Guidance even if the combination itself is not naturally occurring absent the presence of markedly different characteristics in structure, function and/or other properties. Non-limiting examples of markedly different characteristics include biological or pharmacological functions or activities; chemical and physical properties; phenotype; and structure and form. Likewise,

patents cannot issue for the mere use of a nature-based product that impose no meaningful limitation of the performance of a claimed method.

In the instant case, claims 1-7 and 16 are broadly drawn to an herbal composition comprising a 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 6 of the Nature-Based Products examples).

A copy of the Interim Eligibility Guidance is available as a Federal Register notice (79 FR 74618):

http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf

The announcement is also available at:

http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp

The announcement webpage also includes a link to claim examples that relate to nature based products to illustrate the markedly different characteristics analysis for determining when a nature-based product is directed to a judicial exception. A copy of these examples is directly available at:

http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf

Response to Arguments: Claim Rejections - 35 USC § 101

Applicant submits that the composition of claims 1 and 16 is drawn to plant material that has been subjected to a chemical reaction, namely combustion, and converted to ash prior to

extraction. Because the plant matter is materially changed, Applicant submits that the claimed composition is not simply a mixture of natural products and concludes the holding of *Funk Brothers* (Example D of the March 2014 Guidance, now superseded by Example 6 of the December 2014 Nature-Based Product examples) is not applicable to the current claims. Applicant further cites to Example 2 of the December 2014 Nature-Based Product examples which states that combination of naturally occurring pomelo juice with a preservative is not a "product of nature" exception because of the new preserving function conferred to the pomelo juice and to pages 8 and 9 of the Non-Final Rejection of July 1, 2014 describing the teachings of Patankar (2128/MUM/2006). Applicant concludes that because Patankar teach a synergistic herbal preparation comprising *Crataeva nurvala* and *Musa sapientum* (components (a) and (b) as instantly claimed), the mixtures as instantly claimed are markedly different from either component itself.

This is not found persuasive for the following reasons. Combustion of plant material is known to nature at least in the form of lightning induced fires. However, the updated Guidance clarifies that the markedly different analysis is to be performed in the context of the prior art to determine whether the claims amount to significantly more than a nature based exception. In view of the prior art of record and in particular the traditional knowledge resources filed by a third party on March 24, 2014, burning these plant materials for medicinal purposes is routine and conventional since 1000 years. Therefore, burning is not a marked difference that adds significantly more to confer patent eligibility to the instant claims. The holdings of *Funk Brothers* (Example 6) remain relevant because there is no indication that the claimed mixtures have any characteristics that are different from the individual components. Applicant's citation

to Patankar and Example 2 of the Nature-Based Product examples and suggestion that the synergism taught by Patankar confers a new function to the instantly claimed mixture is acknowledged but is ultimately unpersuasive because the instantly claimed mixture is different from that of Patankar (although the instantly claimed mixture encompasses the mixture of Patankar) and because Patankar clearly teach the function of the mixture is the same as the function of the individual components, that is, they are both individually and in combination known as treatments for kidney stones. No new function is suggested to be present. Likewise, Applicant has provided no evidence to suggest that the additional components of the instantly claimed mixture impart a new function to the composition. Therefore, the rejection under 35 USC 101 is properly maintained and made again.

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.

The composition of claim 1 recites about 15 to 50% of component (a) and at least about 15% of components (b), (c) and (d), respectively, wherein the percentages are based on the combined weight of (a), (b), (c) and (d). There is nothing in the specification as filed to lead one of ordinary skill in the art to choose an upper range from 85 to 100 wt% as is implied as the upper end of the range of at least about 15%. 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 specification as filed provides support for amounts of about 15 to 85%. The extension of the numerical ranges to 100% constitutes new matter.

The composition of claim 16 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 cites the Herbmed plus composition on page 18 which describes a 500 mg capsule which contains Varun extract, Banana kshar, Yav kshar, Aghada kshar in proportions of 50%, 15%, 20%, 15%, respectively, along with Gomutrakashar 300 mg as providing support for the instantly claimed ranges and Applicant submits that the recited range of about 15% for each of four components, based on their weight, is adequately disclosed.

This is not found persuasive because neither the specification nor the claims as originally filed disclose the broad ranges as instantly claimed. 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 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 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 16 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 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.**

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, **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, 2nd 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.

Patankar does not teach ash of banana to comprise the stem and yam; the composition to comprise an extract from ash of burnt flowers, leaves, seeds, roots and fruits of *Achyranthes aspera* in an amount of at least about 15 wt%; and an extract from ash of burnt seeds of *Hordeum vulgare* in an amount of at least about 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, 2nd 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, 2nd 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 component B) ash salt of banana root of Patankar to include ash salt of rhizome, stem (core part), leaves, inflorescence and fruits because Patankar teach these are the parts of the banana used as therapeutic ingredients.

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* and ash salt of banana root 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. The 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 that routine experimentation to determine 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 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 and 132 Declaration of Suresh Patankar

Applicant's arguments and the Declaration of Suresh have been fully considered but they are not persuasive.

Applicant submits the instant specification at page 19 provides data regarding the treatment of patients with renal/ureteric stone with Herbmed, the prior art composition of Patankar, and Herbmed plus, the composition of the instant claims. The comparative data demonstrate superior clearance rates and reduced pain. The Declaration of Suresh Patankar provides additional comparative data as prescribed by MPEP § 716.02(e). Accordingly, Applicant submits that these data are sufficient to rebut *prima facie* obviousness.

For convenience, the data at page 19 are reproduced as follows:

	N	Complete clearance	Average duration of clearance	Average pain score	Average hematuria score
Group Herbmed plus	108	98 (90.7%)	8.7 weeks	0.45	0.06
Group Herbmed	54	31 (57.4%)	10.4 weeks	1.15	0.35

In exploratory trial on 10 patients of Renal stone for the Capsule of Herbmed plus 500 mg with Gomutra kshar 150 mg given together for twice a day for total 90 day around 6 patients showed a significant reduction in stone size of this treatment group.

As noted in the Non-Final rejection of July 1, 2014, these data are not commensurate in scope with the instant claims. The specification at page 18 defines the composition as follows:

Group 1- (Herbmed)

There were 54 patients in group-1 these patients were administered HERBMED in the form of capsule 500 mg which contains Varun extract and banana kshar 250 mg each.

Group 2- (Herbmed plus)

There were 108 patients in group-2 these patients were administered HERBMED PLUS in the form of capsule of 500 mg which contains Varun extract, Banana kshar, Yav kshar, Aghada kshar in proportion of 50%, 15%, 20%, 15% respectively, along with Gomutrakshar 300 mg.

It is not immediately clear that Herbmed as described supra in fact refers to the composition of Patankar because Patankar teach 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. It is not clear that the Herbmed as described supra comprises component A)

ii) of Patankar. However, assuming that Herbmed is the product of Patankar, which seems a reasonable assumption give the instant Applicant is in fact Patankar, several questions need be addressed. Are the differences in properties unexpected? Any differences between the claimed invention and the prior art may be expected to result in some differences in properties as elaborated in MPEP § 716.02. And as per § 716.02(d), [w]hether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens,* 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). The Herbmed plus composition as described supra is but one embodiment of instant claim 3. Applicant either needs to demonstrate that the superior clearance rates and reduced pain described above occurs across the full scope of claims 1 and 16 or Applicant should consider narrowing amendments to bring the claims into conformance with the proffered data.

For convenience, the data of the Declaration are reproduced as follows:

Details	Calcium mg/dl	Oxalate mg/dl	Citrate mg/dl	Magnesium mg/dl
Group I (N)	1.27 ± 0.18	0.40 ± 0.03	1.92 ± 0.05	1.00 ± 0.03
Group II (D)	2.98 ± 0.22**	3.63 ± 0.10**	0.37 ± 0.04**	0.52 ± 0.03**
Group III (H)	2.40 ± 0.14	2.78 ± 0.21	0.82 ± 0.06	0.70 ± 0.03
Group IV (HP)	1.97 ± 0.14**	2.40 ± 0.18**	1.26 ± 0.03**	0.85 ± 0.06**
Group V (YA)	2.42 ± 0.12	2.88 ± 0.17	0.69 ± 0.02	0.68 ± 0.02

where Group I is a water control, Group II is the ethylene glycol solution used to induce renal calculus, Group III is the ethylene glycol solution plus Herbmed, Group IV is the ethylene glycol solution plus Herbmed plus and Group V is the ethylene glycol solution plus a combination of components (c) and (d) as instantly claimed (see Declaration pages 2-4, remarks pages 12-14). The results show the results of Group IV to be closest to those of Group I. However, these results are drawn to but one composition while the instant claims are broad. Applicant needs to demonstrate these results hold across the full scope of the instant claims.

Applicant submits that a person of skill in the art would not expect a reduction of the amount of the extract of banana root ash from 50% as in Herbmed to 15% as in Herbmed plus to lead in an increase in efficacy. Replacing a portion of the extract of banana root ash in with the YA composition (Group V above) would also not be expected to increase efficacy.

This is not found persuasive because while Patankar teaches typically the proportion of 'A' and 'B' are on an equal weight basis (abstract), Patankar also broadly teaches typically 15 to 85% of both the active ingredients are included in the formulation (last paragraph of page 5). Patankar explicitly teaches at page 5 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. Patankar alone render obvious Applicant's hypothetical situation of adjusting the amount of banana ash relative to the *Crataeva nurvala*.

In view of the teachings Vatsyayan, apamarga (*Achyranthes aspera*) is a drug of choice that is considered the foremost ayurvedic medicine for urinary afflictions like calculus because of its diuretic and alkalizer properties. And in view of the teachings of Ayurveda Sanjeevani

and Vagabhata, barley water (extract of seed) is a very good medicine for kidney stones and may be prepared as a kshar (ash). Because the components "new" to Herbmed plus are known in the art for the exact same purpose as Herbmed and in fact apamarga is known as the drug of choice for the condition, it is unclear why Applicant concludes one of skill in the art would not expect the combination to known ingredients to not be effective. It is *prima facie* obvious to optimize within prior art conditions are through routine experimentation as per MPEP § 2144.05 II.

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

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 ALISSA PROSSER whose telephone number is (571)272-5164. The examiner can normally be reached on M - F, 10 am - 6 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.

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

/ILEANA POPA/

Primary Examiner, Art Unit 1633