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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/519.137	03/25/2010	Manish Saxena	449-103	1510

23448 7590 07/11/2014
Hultquist IP
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EXAMINER

CLARK, AMY LYNN

ART UNIT PAPER NUMBER

1655

NOTIFICATION DATE DELIVERY MODE

07/11/2014

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):

hip@hultquistip.com

Office Action Summary

Application No.
12/519,137

Applicant(s)
SAXENA, MANISH

Examiner
Amy L. Clark

Art Unit
1655

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 07/10/2012.
 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) 7,8,10-16 and 18-23 is/are pending in the application.
5a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 7,8,10-15,18 and 19 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:
- 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 _____.
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 4) Other: _____.

Art Unit: 1655

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

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2012 has been entered.

Election/Restrictions

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

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicant's amendments to the claims.

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

Claims 7, 8, 10-16, 18 and 19 are currently under examination.

Claim Rejections - 35 USC § 112

Claims 7, 8, 10-16, 18 and 19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (newly reapplied as necessitated by amendment).

The metes and bounds of claim 7 and 17 are rendered uncertain by the term "Stelleta wild" because does not appear to be a plant with the name "Stellata wild". There are several genres of plants that have the name "Stellata" in them. For example, there is Quercus stellate, Halieutaea stellate, Nymphaea stellata Willd. or Magnolia stellata. Therefore, it is unclear as to what plant Applicant is

Art Unit: 1655

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

Please note that since the identity of stellata wild is not clear (there is no guidance in the specification, either. Therefore, Applicant must supply evidence that the plant that they are claiming is the one that they actually used, if the entire name is not being claimed. If the plant is actually called "Stellata Wild, Applicant should supply the common name and Latin name and provide evidence showing that the names are synonymous). However, the Examiner is examining *Nymphaea stellata* Willd., since this plant name appears to contain two of the names (although willd is misspelled, if this is the plant being claimed by Applicant).

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 7, 8, 10-16, 18 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claims 7, 8, 10-16, 18 and 19 are determined to be directed to a law of nature/natural principle.

The rationale for this determination is explained below: The claims are drawn to a topical wound healing formulation useful for treating infections and chronic, non-healing wounds comprising:

i) 4 to 7 % by weight of an aqueous extract of bark of *Azadirachta indica*; ii) 0.5 to 4% by weight of an extract of the following herbs: a) root of *Berberis aristata* or *Berberis vulgaris*, -b) stem of *Glycyrrhiza glabra*, c) stem, leaves or flowers of *Jasminum officinale*, d) rhizomes of *Picrorhiza kurroa*, e) seeds or leaves of *Pongamia pinnata*, f) stem of *Rubia cordifolia*, g) rhizomes of *Saussurea lappa*, h) fruits of *Terminalia chebula*, i) fruits of Capsicum, j) flowers of *Stellata willd*; iii) 6-9 % by weight of an extract of *Curcuma longa*; iv) 6-9 % by weight of an extract of fruits or leaves of *Tricosanthes dioica*; and v) a

Art Unit: 1655

mixture of two or more oils, said mixture comprising one or more adjuncts selected from the group consisting of thickening agents, preservatives, coloring agents, decolorizing agents, fragrances, opacifiers, vitamins and combinations thereof, wherein the components are present in an amount sufficient to treat wounds selected from the group consisting of diabetic foot ulcer, dry and wet gangrene, venous ulcer, varicose veins, war wounds, burn wounds and post-operative wounds, which is not markedly different than a natural product and compositions thereof. The way the claims are written, the formulation requires an aqueous extract of bark of *Azadirachta indica*, which is not considered to be different from the bark of *Azadirachta indica* itself, since water does not change the chemical composition or structure of compounds found in *Azadirachta indica*, and further comprising an extract of various plant parts, which can read on one or more compounds found in the claimed plant parts. These compounds can be the same compounds naturally found in *Azadirachta indica* bark. The additional ingredients of one or more adjuncts can also be compounds found in *Azadirachta indica* bark. Therefore, the formulation, as claimed, is not considered to be different from *Azadirachta indica* bark found in nature since all of the compounds and properties of the extract are the same as those found in the plant itself, since no chemical alteration occurs. Compositions comprising the extract, particularly lacking additional ingredients not found in the plant itself, read on the plant itself and do not distinguish the extract from the plant itself. Even claiming an oil extract would not alter the chemical composition and an aqueous alcohol extract would also not be expected to alter the chemical composition of *Azadirachta indica* bark, so no chemical change within the plant would be expected and would be expected to be an extract that is chemically identical to the plant itself. Furthermore, the claims do not include elements in addition to the judicial exception that add significantly more to the judicial exceptions and do not include feature that demonstrate that the recited product is significantly different from what exists in nature.

Claim Rejections - 35 USC § 103

Claims 7, 8, 10-16, 18 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jatyadi Tailam (U*), in view of Doka et al. (N*, WO 0033855 A1), Balcdygha tam (X*), Nguyen (A*), "Coconut-info" (U1*), Suguna (V*) and Tiladi Yoga (W*).

Art Unit: 1655

Jatyadi Tailam teaches a composition for treating ulcers/healing wounds, healing lacerated wounds and for wound cleansing comprising 1 part Azadirachta indica stem bark, 1 part Jasminum officinale leaf, 1 part Trichosanthes dioica leaf, 1 part Pongamia pinnata leaf, beeswax (which reads on a thickening agent), 1 part Glycyrrhiza glabra root, 1 part Saussurea lappa root, 1 part Curcuma longa rhizome (which send out roots and, therefore, contains and reads on root), 1 part Berberis aristata/Berberis asiatica/Berberis lycium root, 1 part Picrorhiza kurroa Rhizome, 1 part Rubia cordicolia stem, 1 part Pongamia pinnata seed, blue vitriol/copper sulfate (which reads on a preservative), water and sesamum indicum (black sesame) oil in the form of a medicated oil (which reads on an oil extract of herbs).

Baladygha tam teaches a composition useful for treating lacerated wounds comprising Glycyrrhiza glabra rhizome (which reads on stem, since rhizomes are defined as stems) in an amount of 192 grams.

Nguyen teaches a composition for treating skin conditions comprising turmeric and Saussurea lappa (please note that Nguyen teaches the whole plant of Saussurea lappa and that this would include rhizomes of Saussurea lappa).

"Coconut-info" teaches that coconut oil is effective for treating wounds.

Doka teaches a pepper (Capsicum) extract obtained by extracting fully ripe fruits of Capsicum in sunflower or pumpkin seed oil for treating burns or open injuries (which is synonymous with wounds).

Suguna teaches that a fine paste obtained by mixing Terminalia chebula fruit with water and carron oil is useful for treating burns and scales.

Tiladi Yoga teaches a therapeutic formulation for burns comprising Nymphaea stellate Willd. flower in sesame seed oil, milk and clarified butter.

Although the teachings above do not teach that the composition will protect against amputation, the claimed functional properties are intrinsic to the preparation taught by the above teaches because the ingredients and the route of administration for the delivery of the ingredients taught by the above teachings are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the compositions taught by the above teachings would inherently protect against amputation.

Art Unit: 1655

It would have been obvious to modify the composition used in the method taught by Jatyadi Tailam by combining a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem and *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate and water with coconut oil, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower for treating burns and wounds because at the time the invention was made, it was known that a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem and *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate, coconut oil, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower could be used for burns and other wounds, as clearly taught by the above references.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. Based on the disclosure by these references that a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem, *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate, coconut oil, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower were useful for treating burns and other wounds, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP

Art Unit: 1655

section 2144.06, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Thus, an artisan of ordinary skill would reasonably expect that combining a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem and *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate, with coconut oil, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower would provide an even more effective composition for treating burns and wounds. This reasonable expectation of success would motivate the artisan to use a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem, *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate, coconut oil, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower to treat burns and wounds.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of a black sesame oil extract of *Azadirachta indica* stem bark, *Jasminum officinale* leaf, *Trichosanthes dioica* leaf, *Pongamia pinnata* leaf, *Glycyrrhiza glabra* stem, *Saussurea lappa* rhizome, *Curcuma longa* root, *Berberis aristata/Berberis asiatica/Berberis lycium* root, *Picrorhiza kurroa* Rhizome, *Rubia cordicolia* stem and *Pongamia pinnata* seed, beeswax, blue vitriol/copper sulfate, an oil extract of *Capsicum* fruit extract, an oil extract of *Terminalia chebula* fruit and an oil extract of *Nymphaea stellate* Willd. flower to provide a more effective and safe preparation for treating burns and other wounds. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to

Art Unit: 1655

result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments regarding the 112, 2nd paragraph rejection have been fully considered but they are not persuasive.

Applicant argues that Applicant has submitted evidence to show the name of the herb "Stellata willd" is synonymous with *Nymphaea stellata willd*.

However, this is not found persuasive because no article was submitted and it does not appear on an IDS.

Applicant argues, with regards to the 103 rejection, that the unique combination of herbs, as claimed, provides surprising/unexpected therapeutic effects with respect to wound healing, and has proven to be particularly useful for preventing amputations that would be necessary due to complications from various wounds. Applicant further argues that the combination of ingredients taught by *Jatyadi Tailam* is different than that claimed by Applicant's instantly claimed invention. Applicant further argues that the ratio of ingredients are different and that only one oil is taught, not a combination of oils and that the oils contribute to the unexpected effect. Applicant further argues that the other references do not cure the deficiencies of *Jatyadi Tailam*.

However, this is not found persuasive because *Jatyadi Tailam* clearly teaches the combination of the majority of ingredients as claimed by Applicant and that these ingredients are useful for the same purpose as that claimed by Applicant. The additional ingredients are well known in the art to have the same functional effect of topical wound healing. Therefore, combining ingredients that can be applied topically and are well known for wound healing would be expected to provide an even more effective composition for wound healing. Therefore, these references are reapplied as set forth above.

Art Unit: 1655

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Primary Examiner, Art Unit 1655

Search Notes 	Application/Control No. 12519137	Applicant(s)/Patent Under Reexamination SAXENA, MANISH
	Examiner AMY L CLARK	Art Unit 1655

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
NONE	NONE		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST-See Search Notes	7/8/2014	ALC
Google/TKDL Search for plant names in the claims including common and Latin names	7/8/2014	ALC
Inventor's Name searched in PALM	7/8/2014	ALC

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
NONE	NONE		

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