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EXAMINER	
GREENE, IVAN A	

ART UNIT	PAPER NUMBER
1619	

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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.

Office Action Summary	Application No.	Applicant(s)	
	12/150,192	REDDY ET AL.	
	Examiner	Art Unit	
	IVAN GREENE	1619	

-- 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 *27 October 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) *1-13,19-31 and 39* 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) *1-13,19-31 and 39* 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 *26 April 2008* 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

Status of the claims

Claims 1-13, 19-31 and 39 are currently pending, claims 1, 19 and 39 being independent claims. Claims 14-18 and 32-38 have been canceled by applicants. Claims 1-13, 19-31 and 39 are being examined herein.

Restriction

Applicant's election without traverse of Group I, drawn to a semi-solid composition, in the reply filed on 11/05/2011 is acknowledged.

The examiner acknowledges applicant's election of (a) a species of natural product extract is a non-aqueous extract of *Wrightia tictoria*; (b) a species of edible oil-absorbing ingredient in powdered form is a starch; and (c) a species of oil medium is coconut oil, in the reply filed on 11/05/2011.

Information Disclosure Statement

No Information Disclosure Statements have been filed in the instant application. Applicants are reminded of their duty to disclose patents and publications relevant to the patentability of the instant claims. Applicant is reminded of the requirements of 37 CFR 1.56 and *Li Second Family Limited Partnership v. Toshiba Corp.*, 56 USPQ2d 1681 (Fed. Cir. 2000); accord *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.* 487 F.3d 897, 913. (Fed.Cir.2007). Additionally, the examiner notes that the instant specification references several document which have not been properly cited in an IDS or provided for consideration (see, e.g., instant specification paragraphs [0005] to [0007]).

Priority

The U.S. effective filing date has been determined to be 04/26/2008, the filing date of the instant application.

Rejections

Claim Rejections - 35 U.S.C. 112, Second Paragraph

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

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 19-31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "without the need for a post-fill sealing step" in line 2, claim 19 recites "without the need for a post-fill sealing step" in line 2, and claim 39 recites "the hard gelatin capsule requiring no post-fill sealing step" in lines 1-2, it is unclear what the required semi-solid composition constituents should be to meet these recited limitations. The claims are indefinite because it is not clear what the test should be for requiring (or not requiring) a "post-fill sealing step." Additionally, it is noted that the claims do not require any specific amounts of ingredients or recite an specific limitations with respect to a hard gelatin capsule such that placing any size portion of the recited semi-solid composition in a capsule of any size could be demonstrated to not require a post-fill sealing step. Appropriate clarification is required.

Claims 3 and 21 are rejected as being indefinite because they each recite "coconut oil (*Cocus nucifera*)" and "gingelly oil (sesame oil)," it is unclear whether those words in the parentheses are required claim limitations or not (see MPEP § 2173.05-d).

Claim 4 recites the limitation "the extract" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 4 is further rejected as being indefinite because the claim recites "wherein the non-volatile oil is present in the extract in the amount of form 80% to 99% by weight of the extract." However, there is no recited weight for "the extract" therefore it not possible to determine the amount of oil with respect to the amount of "the extract." Appropriate clarification is required. Claim 4 is not being further examined in the merits herein.

Claim 2 recites the limitation "the natural product extract" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the oil absorbent ingredient" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the powdered edible oil-absorbent ingredient obtained from natural sources" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the powdered edible oil-absorbent ingredient obtained from synthetic sources" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is rejected as being indefinite because the claim recites "wherein the ratio of oil to oil absorbent powder is 5 to 40 weight percent of the mixture." It unclear what exactly the

relationship between "the ratio of oil to oil absorbent powder" is to "the weight percent of the mixture." Appropriate clarification is required. Claim 9 is not being further examined in the merits herein.

Claim 19 is indefinite because the claim includes two periods, one in line 10 and one in line 11, it is unclear where applicants intend the claim to conclude (see MPEP §608.01-m).

Claim 22 recites the limitation "the extract" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 22 is further rejected as being indefinite because the claim recites "wherein the non-volatile oil is present in the extract in the amount of form 80% to 99% by weight of the extract." However, there is no recited amount for "the extract" therefore it not possible to determine the amount of oil with respect to the amount of "the extract." Appropriate clarification is required. Claim 22 is not being further examined in the merits herein.

Claim 23 recites the limitation "the mixture of oil absorbent ingredients" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the powdered mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the powdered mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation "the powdered mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 is rejected is being indefinite because the claim recites "the powdered ginger is present in the powdered mixture in the amount of from 12% to 20% by weight," however, it is unclear what the recited weight is with respect to. Appropriate clarification is required.

Claim 29 is rejected as being indefinite because the claim recites "the herbal extract of Wrightia tinctoria is present in the amount of from 5% to 25% by weight," however, it is unclear what the recited weight is with respect to. Appropriate clarification is required.

Claim 29 recites the limitation "the herbal extract of Wrightia tinctoria" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "the hard gelatin capsule" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6 and 10-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by "Melt-In-Your-Mouth Coconut Oil Fudge" ("Raw Sacramento Recipes," as retrieved from <www.rawsacramento.net/recipies.htm> and <web.archive.org> web page dated 29-August-2006, pages 1-7 attached); and as evidenced by the web page on the web site <www.purejoyplanet.com> for "Cocopura Coconut Oil - raw, organic - 14 oz" (pp. 1-2,

attached); and "Health Benefits of Coconut Oil" (retrieved from <www.organicfacts.net> on 01/11/2012, pp. 1-6).

Applicant Claims

Applicant claims a semi-solid composition for encapsulation in hard gelatin capsules without the need for a post-fill sealing step, the compositions comprising: at least one natural product extract in oil medium, at least one edible oil-absorbent ingredient in powder form, and, optionally, at least one pharmaceutically acceptable excipient in oil or powder form, the ingredients blended together to form a uniform dispersion.

Disclosure of the Prior Art

> **Melt-in-Your-Mouth Coconut Oil Fudge**
>
> 1-1/2 cups Pure Joy Coconut Oil (liquefied by placing in a bowl of hot water)
> 1-1/2 cups Rapadura (a whole unprocessed natural sugar), Sucanat or honey
> 1 cup carob powder or organic cocoa powder
> 1/2 tsp. Celtic sea salt
> 1/8 vanilla bean (scrape the inner beans out with a spoon) or 1 tsp. vanilla extract
>
> Melt the coconut oil. If using Rapadura or Sucanat, blend it in a dry blender until it becomes a light powder. Mix all ingredients together in a blender until smooth.
>
> Pour into a large glass lasagna pan or something equivalent in size. Let set up at room temperature (below 70 degrees) or in the refrigerator. Cut into small candy-sized pieces. Store in the refrigerator for up to 12 months.

Melt-In-Your-Mouth Coconut Oil Fudge is a semi-solid composition that could clearly be encapsulated in a hard gelatin capsule without the need for a post-fill sealing step, the fudge includes a natural virgin coconut oil that would include (at least) vitamins E and K as active ingredients extracted from the coconut (Cocus nucifera) source (see "Health Benefits of Coconut Oil," p. 2, line 1). The fudge further includes the edible-oil-absorbent ingredient organic cocoa powder, the additionally pharmaceutically acceptable excipient sea salt (i.e. a powdered

flavoring agent). The powdered edible oil-absorbent ingredient, cocoa powder is obtained from the fruit of *Theobroma cacao*.

Regarding the limitation of claim 10 that "when packed into a hard gelatin capsule shell, and snap-fit locked, shows no visible evidence of syneresis of the oil form the oil absorbent powder for a period of up to 2 years at 25° C," where the prior art product is identical in structure or composition or produced by identical processes a *prima facie* case of either anticipation or obviousness has been established. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary the prior art composition must possess the claimed stability since it is identical or substantially identical to the claimed composition (see MPEP § 2112.01).

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 1-3, 5-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Melt-In-Your-Mouth Coconut Oil Fudge" ("Raw Sacramento Recipes," as retrieved from <www.rawsacramento.net/recipies.htm> and <web.archive.org> web page dated 29-August-2006, pages 1-7 attached); and as evidenced by the web page for "Cocopura Coconut Oil - raw, organic - 14 oz" on the web site <www.purejoyplanet.com> (pp. 1-2, attached); and "Health Benefits of Coconut Oil" (retrieved from <www.organicfacts.net> on 01/11/2012, pp. 1-6) in view of BEST (US 2004/0131752; published July, 2004).

Determination of the scope

and content of the prior art (MPEP 2141.01)

As discussed above, Melt-In-Your-Mouth Coconut Oil Fudge, a semi-solid composition that could clearly be encapsulated in a hard gelatin capsule without the need for a post-fill sealing step anticipates and therefore renders obvious claims 1-3, 5, 6 and 10-13.

Ascertainment of the difference between

the prior art and the claims (MPEP 2141.02)

The difference between the rejected claims and the teachings of Melt-In-Your-Mouth Coconut Oil Fudge is that Melt-In-Your-Mouth Coconut Oil Fudge does not expressly teach a chemically modified cellulose constituent such as carboxymethyl cellulose. This deficiency in a chemically modified cellulose constituent such as carboxymethyl cellulose is cured by the teachings of BEST.

BEST teaches a Melt-Resistant Fudge article (title) including a liquid fat component, a matrix of sugar and an emulsifier (abstract; [0008] & claim 1). BEST further teaches the embodiment in which their fudge article includes a stabilizer component such as carboxymethyl cellulose (among others) ([0011]; & claim 12).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to include a carboxymethyl cellulose component sufficient for stabilizing Melt-In-Your-Mouth Coconut Oil Fudge, as suggested by BEST, and produce the instantly claimed invention because the addition of a carboxymethyl cellulose stabilizer component would reasonable extended life of the fudge beyond the suggested 12 months in the refrigerator. Additionally, the selection of a known material base upon its suitability for its intended use supported a *prima facie* case of obviousness determination in Sinclair and Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (see MPEP § 2144.07).

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 because it would have required no more than an ordinary level of skill in the art pertaining to the

preparation of fudge articles to include an appropriate amount of a carboxmethyl cellulose component. Therefore, the invention as a whole would have been *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.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Claims 19-21, 23-31 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Traditional Knowledge Digital Library (<http://www.tkdl.res.in>, search pages 1-334 attached)[1], in view of CCRAS ("Clinical and Experimental Studies on the Efficacy of 777 oil - A Siddha preparation in the Treatment of Kalanjagapadai (Psoriasis)," Published 1987, pp. 1-58); KAUR ("The in vitro antimutagenic activity of Triphala - Indian herbal drug," Food and Chemical Toxicology, Vol. 40, 2002, pp. 527-534); RAVINDRAN ("Ginger: The Genus Zingiber," published 2005, Chapters 1 & 14).

Applicant Claims

Applicant claims a semi-solid composition for encapsulation in hard gelatin capsules without the need for a post-fill sealing step the composition comprising: (i) at least one herbal extract of *Wrightia tinctoria* in an oil medium, (ii) at least one mixture of an oil-absorbent powder of the dried fruits of *Terminalia chebula, Terminalia belerica and Emblica officinalis*, optionally, at least one pharmaceutically acceptable excipient in oil or powder form, and,

[1] See MPEP § 2128 which states: "An electronic publication, including an on-line database or Internet publication, is considered to be a "printed publication" within the meaning of 35 U.S.C. 102(a) and (b) provided the publication was accessible to persons concerned with the art to which the document relates. See *In re Wyer*, 655 F.2d 221, 227, 210 USPQ 790, 795 (CCPA 1981)."

optionally, at least one other active natural ingredient in powder or oil form the ingredients blended together to form a uniform dispersion.

Determination of the scope

and content of the prior art (MPEP 2141.01)

Based upon a search of the Traditional Knowledge Digital Library, each of the constituents of the instantly claimed invention are known constituents of traditional Indian medicine compositions.

The claim limitation "at least one herbal extract of *Wrightia tinctoria* in an oil medium" describes the oil extract resulting from the traditional method of extracting the medicinal agent(s) form the traditional Indian medicinal plant species *Wrightia tinctoria*. From CCRAS the method of preparing the so called "777 oil" - a Siddha preparation, is as follows:

> Fresh healthy leaves of Vetpalai (*Wrightia tinctoria*) are collected, washed in water, dried and then cut into small- pieces on a neat platform using a sharp cutter and wooden block. The cut leaves are mixed with equal quantity of Tengaiennai (coconut oil) in a large aluminium pan and the mixture is spread uniformly. The pan is placed on a platform and well exposed to sunlight, protecting it from dust. The exposure to sunlight is done for 6-8 hours, for three consecutive days. On the fourth day the mixture is drained and decanted into a container through a filter and the final product the "777 oil" is preserved in well stoppered containers. The yield of the end product is about 60-70%.

(See CCRAS "Synopsis page," first paragraph and page 15). And it is particularly noted that the oil medium used is coconut oil, applicant's elected species as recited in instant claim 21.

The claim limitation "at least one mixture of an oil-absorbent powder of the dried fruits of *Terminalia chebula*, *Terminalia belerica* and *Emblica officinalis*" describes the traditional Indian medicinal powder preparation known as "Triphala[2]," described by KAUR as follows:

> The finely powdered Triphala was procured from Dabur India Ltd (Daburgram, Bihar, India). It is a mixture of *Terminalia bellerica, T. chebula and Emblica officinalis* in equal proportions.

(See KAUR, paragraph bridging pages 527-528). Regarding the function of "oil-absorbent" it is the examiners position that the traditional Indian medicinal powder preparation Triphala would have inherently had the property of being "oil-absorbent." From MPEP § 2112.01-II: "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding the constituent powdered ginger (as recited in claim 27) the reference RAVINDRAN describes the use of ginger in traditional Indian medicine as follows:

> In ancient India, ginger was not significant as a spice, but it was *mahabheshaj, mahaoushadhi*, literally meaning the great cure, the great medicine. For the ancient Indian, ginger was the god-given panacea for a number of ailments. That may be the reason why ginger found a prime place in the ancient Ayurvedic texts of Charaka *(Charaka samhita)* and Susruth *(Sushrutha samhita).* In *Ashtangahridyam* of Vagbhatt (a very important ancient Ayurvedic text), ginger is recommended along with other herbs for the cure of elephantiasis, gout, extenuating the juices, and purifying the skin from all spots arising from scorbutic acidities. Ginger is also recommended when exotic faculties were impaired due to indigestion. (chapter 1, p. 4, § "Ginger in India").

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[2] Also sometimes written in English as Thiriphala or Trifal.

> In the Ayurvedic system of medicine, both fresh and dry ginger are used. Ginger has been widely used as a common household remedy for various illnesses from ancient times. The properties and uses of ginger in Ayurvedic medicine are available from authentic ancient treatises like *Charaka Samhitha* and *Susrutha Samhitha*, which are the basics for this system. Descriptions of ginger are available from similar documents of Chinese and Sanskrit literature written in the subsequent centuries. Dry ginger seems to be an essential ingredient in several Ayurvedic recipes, and hence ginger is called *Mahaoushadha*, the great cure. This emphasizes the extensive usage of ginger in Ayurveda. (Chapter, 14, p. 4, § "Ginger in Indian System of Medicine").

RAVINDRAN sums up the traditional Indian view of ginger as follows: "For the Indians it is the *Mahaoushadha* and *Vishwa Bheshaja*—the great cure and the universal medicine, respectively." (Chapter 14, p. 15, § "Conclusion").

Turning back to the Traditional Knowledge Digital Library the examiner has provided 334 pages describing various formulations that each include the active ingredient Wrightia tictoria and coconut. In addition the specific formulations that are noted as "semi-solid preparations" are underlined throughout for convenience. The specific Indian traditional medicinal preparations which are indicated as semi-solid preparations and include each of the following ingredients: (1) *Wrightia tinctoria*; (2) *Terminalia chebula*; (3) *Terminalia belerica*; (4) *Emblica officinalis*; (5) coconut; and (6) ginger, are as follows (i) Kannoikku Thylam (p. 286), (ii) Rana Iya Noikku ILAGAM (p. 295), (iii) Panduvirkku Karisalai ILAGAM (p. 299), (iv) Megarasanga Legium (p. 304), (v) Naakaravinthaathi Maga Kaamesura ILAGAM (p. 309), and (vi) Maha Mega Rasangam (p. 315). Additionally it is noted that additional pharmaceutically acceptable excipients are include, for example, sugar and honey in (ii) Rana Iya Noikku ILAGAM (see p. 296, items 41 & 42).

Ascertainment of the difference between

the prior art and the claims (MPEP 2141.02)

The difference between the rejected claims and the teachings of Traditional Knowledge Digital Library is that Traditional Knowledge Digital Library does not expressly teach (1) the ingredient *Wrightia tinctoria* as an extract in a coconut oil medium; (2) the specific weight percent of ginger and an herbal extract of *Wrightia tinctoria*; and the property of showing no visible signs of syneresis of the oil from the oil absorbent powder for a period of up to 2 years at 25° C.

The extraction of ingredient *Wrightia tinctoria* as an extract in a coconut oil medium is discussed above (see "777 - oil" above, & CCRAS page 15). Regarding the specific weight percent an herbal extract of *Wrightia tinctoria* it is the examiners position that the amount of herbal extract would have been the same because the instant specification describes the same extraction process as disclose in CCRAS page 15 resulting in the so called "777" oil (instant specification: "irradiating with a light source in the spectrum range of 300 - 1100 nm for a period of approximately 5 days," p. 7, [0023] as compared to "exposure to sunlight is done for 6-8 hours, for three consecutive days," CCRAS page 15, each in a coconut oil medium). Where the prior art product is identical in structure or composition or produced by identical processes a *prima facie* case of either anticipation or obviousness has been established. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary the prior art composition must possess the claimed specific weight percent an herbal extract of *Wrightia*

tinctoria since it is identical or substantially identical to the claimed composition. See MPEP § 2112.01.

Regarding the specific weight percent ginger, none of the references teaches adding the active ingredient ginger in the amounts claimed by Applicant. However, adjusting the amount of ginger is considered within the ordinary skill in the art pertaining to traditional Indian medicinal practice. A person having an ordinary level of skill in the art pertaining to traditional Indian medicine would have clearly considered the amount of ginger a result effective parameter that such a person would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for a skilled artisan to determine the optimal amount of ginger to add in order to best achieve any of the desired results cited in claims. Thus, in the absence of some demonstration of unexpected results from the claimed parameters, this optimization of the amount of ginger would have been obvious at the time of Applicant's claimed invention.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a psoriasis treating semi-solid composition comprising *Wrightia tinctoria* as an extract in a coconut oil medium (i.e. "777" oil) and at least one mixture of an oil-absorbent powder of the dried fruits of Terminalia chebula, Terminalia belerica and Emblica officinalis (i.e. Triphala), as suggested by Traditional Indian Knowledge, and produce

the instantly claimed invention because the compositions are taught by traditional Indian knowledge.

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 because it would have required no more than an ordinary level of skill in the art pertaining to traditional Indian Knowledge to produce the instantly claimed compositions. Therefore, the invention as a whole would have been *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.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Double Patenting

Nonstatutory 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 1-3, 5-8, 10-13, 19-21, 23-31 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 7,666,450 (hereafter '450) in view of ANSEL ("Pharmaceutical Dosage Forms and Drug Delivery Systems," pp. 179-228, 244 and 245); SHAH (US 5,693,327; published December, 1997); and Traditional Knowledge Digital Library (<http://www.tkdl.res.in>, search pages 1-334 attached).

Instant claim 1 recites a semi-solid composition for encapsulation in hard gelatin capsules without the need for a post-fill sealing step, the compositions comprising: at least one natural product extract in oil medium, at least one edible oil-absorbent ingredient in powder form, and, optionally, at least one pharmaceutically acceptable excipient in oil or powder form, the ingredients blended together to form a uniform dispersion. Instant claim 19, a species of claim 1, recites a semi-solid composition for encapsulation in hard gelatin capsules without the need for a post-fill sealing step the composition comprising: (i) at least one herbal extract of Wrightia tinctoria in an oil medium, (ii) at least one mixture of an oil-absorbent powder of the dried fruits of Terminalia chebula, Terminalia belerica and Emblica officinalis, optionally, at least one pharmaceutically acceptable excipient in oil or powder form, and, optionally, at least one other active natural ingredient in powder or oil form the ingredients blended together to form a uniform dispersion.

'450 claim 1 recites an ointment suitable, when applied topically to a human, for the regression of chronic inflammatory skin disorders such as eczema, psoriasis and seborrheic dermatitis comprising: Wrightia tinctoria, which has been extracted in a non-aqueous medium, an extract of Tragia involucrata L., an extract of Salix L., an extract of cocos nucifera and one or more pharmaceutically or cosmetically acceptable excipients, wherein: the non-aqueous Wrightia tinctoria is present in an amount of from 20% to 30% by weight, the extract of Tragia involucrata L. is present in an amount of from 5% to 15% by weight, the extract of Salix L. is present in an amount of from 5 to 10% by weight and the extract of Cocos nucifera is present in an amount of from 25% to 30% by weight.

The difference between the instantly rejected claims and the claims of '450 is that the claim of '450 do not expressly claim a semi-solid composition or the at least one mixture of an

oil-absorbent powder of the dried fruits of *Terminalia chebula*, *Terminalia belerica* and *Emblica officinalis* (i.e. triphala).

ANSELS discloses that "[o]intments are semisolid preparations intended for external application to the skin or mucous membranes." (p. 245, col. 1, § "Ointments").

SHAH teaches (ointment) compositions for the treatment of skin disorders such as psoriasis, eczema, the compositions being based upon herbal plant extracts (abstract). SHAH further teaches the plant extracts include those from Phyllanthus emblica, Terminalia chebula, Terminalis belerica which taken as a powdered mixture in equal portions is known in traditional Indian medicine as triphala (or Trifala as is SHAH; col. 1, lines 48-60; col. 9, item 14).

The traditional Indian medicinal preparations including the claimed constituents are discussed above and incorporated herein by reference.

It would have been prima facie obvious at the time the claimed invention was made that the instantly rejected claims are an obvious variant of the claims of '450 because claim 1 of '450 is an ointment defined by ANSEL as a semi-solid preparation and the traditional Indian medicine Triphala is known to be useful in compositions for the treatment of psoriasis. The skilled artisan would have been motivated to modify the claims of '450 and produce the instantly rejected claim because the inclusion of Triphala would have provided the additional beneficial healing properties associated with Triphala. Furthermore, the skilled artisan would have had a reasonable expectation of success in producing the invention of the instantly rejected claims because it would have required no more than an ordinary level of skill in the art pertaining to traditional Indian Knowledge to produce the instantly claimed compositions from claim 1 of '450.

Claims 1-3, 5-8, 10-13, 19-21, 23-31 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 12/317,642 (hereafter '642) in view of ANSEL ("Pharmaceutical Dosage Forms and Drug Delivery Systems," pp. 179-228, 244 and 245); SHAH (US 5,693,327; published December, 1997); and Traditional Knowledge Digital Library (<http://www.tkdl.res.in>, search pages 1-334 attached).

The instant claim are discussed above.

Copending '642 claim 1 recites an herbal composition that, when used topically in therapeutically effective amounts, is effective for the regression of stratum granulosum in keratinization disorders, comprising: an extract of Wrightia tinctoria in a non-aqueous medium, an extract of cocos nuciferia and pharmaceutically acceptable or cosmetically acceptable excipients for use in ointment, oil, soap and shampoo formulations.

The difference between the instantly rejected claims and the claims of copending '642 is that the claim of copending '642 do not expressly claim a semi-solid composition or the at least one mixture of an oil-absorbent powder of the dried fruits of *Terminalia chebula*, *Terminalia belerica* and *Emblica officinalis* (i.e. triphala).

ANSELS discloses that "[o]intments are semisolid preparations intended for external application to the skin or mucous membranes." (p. 245, col. 1, § "Ointments").

SHAH teaches (ointment) compositions for the treatment of skin disorders such as psoriasis, eczema, the compositions being based upon herbal plant extracts (abstract). SHAH further teaches the plant extracts include those from Phyllanthus emblica, Terminalia chebula, Terminalis belerica which taken as a powdered mixture in equal portions is known in traditional Indian medicine as triphala (or Trifala as is SHAH; col. 1, lines 48-60; col. 9, item 14).

The traditional Indian medicinal preparations including the claimed constituents are discussed above and incorporated herein by reference.

It would have been prima facie obvious at the time the claimed invention was made that the instantly rejected claims are an obvious variant of the claims of '642 because claim 1 of '642 is an ointment defined by ANSEL as a semi-solid preparation and the traditional Indian medicine Triphala is known to be useful in compositions for the treatment of psoriasis. The skilled artisan would have been motivated to modify the claims of '450 and produce the instantly rejected claim because the inclusion of Triphala would have provided the additional beneficial healing properties associated with Triphala. Furthermore, the skilled artisan would have had a reasonable expectation of success in producing the invention of the instantly rejected claims because it would have required no more than an ordinary level of skill in the art pertaining to traditional Indian Knowledge to produce the instantly claimed compositions from claim 1 of '450.

This is a provisional obviousness-type double patenting rejection.

Conclusion

The following non-patent literature documents are cited for applicant's consideration: BISWAS ("Biological activities and medicinal properties of neem (*Azadirachta indica*)," Current Science, Vol. 82, No. 11, June 2002, pp. 1336-1345) is cited in view of the Example in Table 1 of the instant specification; Wohlmuth, Hans ("Triphala - a short review," Botanical Pathways, 2002, Issue 2, pp. 1-8) is cited as knowledge of the traditional ingredient Triphala; and ROWE ("Handbook of Pharmaceutical Excipients," 6th ed., 2009, entries for "carboxymethylcellulose calcium," "carboxymethylcellulose sodium," "coconut oil," "Hypromellose" (i.e. hydroxypropylmethyl cellulose), "starch," "starch, pregelatinized," and "vegetable oil, hydrogenated," pp. 117-121, 184-185, 326-329, 685-694 and 762-763). The following US patent document are cited for applicants consideration: US 2,562,840 teaches oil soluble vitamins in combination with powders (e.g. starch) formulated as capsules (see, e.g., col. 7); US 3,196,078 teaches oil soluble actives adsorbed on powdered filler (see, e.g., col. 3, Example V); US 5,858,372 teaches a pharmaceutical preparation for topical treatment of skin disorders, particularly psoriasis, comprising *Wrightia tinctoria* (abstract); and US 5,882,713 teaches non-separable compositions of starch and water-immiscible organic materials (title).

Claims 1-13, 19-31 and 39 are pending and have been presented for examination on the merits. Claims 1-13, 19-31 and 39 are rejected under 35 U.S.C. 112, second paragraph; Claims 1-3, 5, 6 and 10-13 are rejected under 35 U.S.C. 102(b); Claims 1-3, 5-8, 10-13, 19-21, 23-31 and 39 are rejected under 35 U.S.C. 103(a); and claims are rejected based on obvious-type

double patenting over claims of US 7,666,450; and provisionally rejected based upon obvious-type double patenting over claims of copending 12/317,642. No claims allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Blanchard can be reached at (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.

IVAN GREENE
Examiner, Art Unit 1619

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647

Notice of References Cited	Application/Control No. 12/150,192	Applicant(s)/Patent Under Reexamination REDDY ET AL.	
	Examiner IVAN GREENE	Art Unit 1619	Page 1 of 3

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0131752	07-2004	Best et al.	426/660
*	B	US-5,693,327	12-1997	Shah, Eladevi	424/734
*	C	US-2,562,840	07-1951	LEE CALDWELL ARCHIE	514/725
*	D	US-3,196,078	07-1965	CHATZINOFF ALBERT B et al.	514/725
*	E	US-5,858,372	01-1999	Jacob, George	424/195.18
*	F	US-5,882,713	03-1999	Eskins et al.	426/578
*	G	US-7,666,540	02-2010	Nakanishi et al.	429/483
	H	US-			
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	L	US-			
	M	US-			

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	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	"Melt-In-Your-Mouth Coconut Oil Fudge" ("Raw Sacramento Recipes," as retrieved from <www.rawsacramento.net/recipies.htm> and <web.archive.org> web page dated 29-August-2006, pages 1-7 attached.
	V	Web page from the web site <www.purejoyplanet.com> for the product "Cocopura Coconut Oil - raw, organic - 14 oz," pp. 1-2, attached.
	W	"Health Benefits of Coconut Oil" as retrieved from <www.organicfacts.net> on 01/11/2012, pp. 1-6.
	X	Traditional Knowledge Digital Library database search results retrieved from <http://www.tkdl.res.in>, on 01/04/2012, pp. 1-334 attached

*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.

Notice of References Cited	Application/Control No. 12/150,192	Applicant(s)/Patent Under Reexamination REDDY ET AL.	
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	E	US-			
	F	US-			
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	R					
	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Pandy, V. N. (director) Central Research Council for Research in Ayurveda and Siddha; "Clinical and Experimental Studies on the Efficacy of 777 oil - A Siddha preparation in the Treatment of Kalanjagapadai (Psoriasis)," Published 1987, pp. 1-58, (pp. 1-87 as supplied).
	V	Kaur, S. et al.; "The in vitro antimutagenic activity of Triphala - Indian herbal drug," Food and Chemical Toxicology, Vol. 40, 2002, pp. 527-534.
	W	Ravindran, P. N. and Badu, K. Nirmal editors; "Ginger: The Genus Zingiber," published by CRC PRESS, 2005, Chapters 1 & 14, pp. 1-50 as supplied.
	X	Ansel, Howard C. et al.; "Pharmaceutical Dosage Forms and Drug Delivery Systems," LIPPINCOTT WILKINS & WILLIAMS, 1999, pp. 179-228, 244 and 245.

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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	Q					
	R					
	S					
	T					

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Biswas, Kausik et al.; "Biological activities and medicinal properties of neem (Azadirachta indica)," Current Science, Vol. 82, No. 11, June 2002, pp. 1336-1345.
	V	Wohlmuth, Hans; "Triphala - a short review," Botanical Pathways, 2002, Issue 2, pp. 1-8.
	W	Rowe, Raymond C. et al.; "Handbook of Pharmaceutical Excipients," 6th ed., 2009, entries for "carboxymethylcellulose calcium," "carboxymethylcellulose sodium," "coconut oil," "Hypromellose" (i.e. hydroxypropylmethyl cellulose), "starch," "starch, pregelatinized," and "vegetable oil, hydrogenated," pp. 117-121, 184-185, 326-329, 685-694 and 762-763.
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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	Examiner	Art Unit
	IVAN GREENE	1619

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Google seaches, Traditional Knowledge Digital Library search, PALM and EAST inventor name searches.	01/13/2011	GREENE

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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