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13/157,040	06/09/2011	Fred M. COWAN	COW 101	6299	
59241 7590 09/18/2013 LATIMER INTELLECTUAL PROPERTY LAW, LLC P.O. BOX 711200 HERNDON, VA 20171			EXAMINER		
			CLARK, AMY LYNN		
			ARTUNIT	PAPER NUMBER	
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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):

correspondence@latimerip.com jen.carson@latimerip.com

_			Application No. 13/157,040 Examiner Amy L. Clark		Applicant(s) COWAN, FRED M.	
Office Action Summary					Art Unit 1655  AlA (First Inventor to File) Status No	
	e MAILING DATE of this commu	nication appears on th	he cover sheet wit	th the corresponder	nce address	
WHICHEV - Extensions after SIX (6 - If NO perior - Failure to re Any reply re	PIY ENED STATUTORY PERIOD FOR IS LONGER, FROM THE to filme may be available under the provision of Months from the mailing date of this conference of the reply is specified above, the maximum pily within the set or extended period for reply the Office later than three months and term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF T is of 37 CFR 1.136(a). In no e munication. statutory period will apply and by will, by statuto, cause the ap	THIS COMMUNIC event, however, may a re will expire SIX (6) MONI pplication to become ABA	CATION.  sply be timely filed  THS from the mailing date  ANDONED (35 U.S.C. § 1	of this communication. 33).	
Status						
1) Res	ponsive to communication(s) fi declaration(s)/affidavit(s) under	37 CFR 1.130(b) wa				
7_	action is FINAL.	2b) This action is				
4) Since	election was made by the appli ; the restriction requirement the this application is in condition the din accordance with the prace	and election have been for allowance excep	en incorporated in ot for formal matte	nto this action. ers, prosecution as	to the merits is	
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5a) C 6) Clai 7) Clai 8) Clai 9) Clai * If any claims h participating into http://www.uspt Application F 10) The 11) The	m(s) 1 and 3-24 is/are pending of the above claim(s) 21-24 is/a m(s) is/are allowed. m(s) 1 and 3-20 is/are rejected m(s) is/are objected to. m(s) are subject to restricted allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or another termined allowable, y ellectual property office for the core or an	are withdrawn from continuous and/or election ou may be eligible to be esponding application.	requirement. enefit from the Pate For more information to PPHteedback@	on, please see  Ouspto.gov.  Oy the Examiner.  Ce. See 37 CFR 1.8	5(a).	
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2) Information	deferences Cited (PTO-892)  Disclosure Statement(s) (PTO/SB/08			ummary (PTO-413) )/Mail Date 		

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#### **DETAILED ACTION**

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

Acknowledgment is made of the receipt and entry of the amendment filed on 06/21/2013 with the amendment of claims 1, 3-13, 15-17 and 19 and the cancellation of claim 2.

#### 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 1 and 3-20 are currently under examination.

### Claim Rejections - 35 USC § 112

Claims 1 and 3-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention (newly applied as necessitated by amendment).

Claim 1 is rendered vague and indefinite by the term "synergystically" because it is unclear as to what amount (e.g., amount range, proportion, and/or ratio) of each claimed ingredient actually define a synergistic amount with respect to the other ingredients so as to provide a combined synergistically effective amount of the overall composition. Accordingly, the metes and bounds of this phrase (e.g., the synergistically effective amounts of each ingredient with respect to the others) are not clearly nor adequately delineated with respect to the synergistic amounts of the individual components. Please note



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that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the independent claim language itself.

Claims 4-6 and 8-10 recites the limitation "extract" following the names of the spices. The independent claim recites the term "spice extract of", which is not the same as "extract". There is no mention of an extract aside from "a spice extract". There is insufficient antecedent basis for this limitation in the claim.

Claims 11, 15 and 19 are rendered vague and indefinite by the phrase "synergistically" because it is unclear as to what amount (e.g., amount range, proportion, and/or ratio) of each claimed ingredient actually define a synergistic amount with respect to the other ingredients so as to provide a combined synergistically effective amount of the overall composition. Accordingly, the metes and bounds of this phrase (e.g., the synergistically effective amounts of each ingredient with respect to the others) are not clearly nor adequately delineated with respect to the synergistic amounts of the individual components. Please note that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the independent claim language itself. While Applicant has recited the percentages (although the recited percentages are not related to a determined parameter of mass or volume) of each of the claimed ingredients, the Office notes that as drafted the claims are drawn to percentages that are not described as whether they are in relation to each other or to the composition as a whole. Furthermore, the data in the specification does not support these ranges as providing synergy. As drafted, the claims would appear to not read on a synergistic herbal insecticidal formulation, since synergism is generally defined by the enhanced overall activity of more than one ingredient when combined together as compared to the overall activity of each

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of the ingredients alone and requires specific parameters/amounts in relation to each other, which the claim does not recite at present.

Please note that the claims are construed as open because the independent claims recite additional active ingredients. For example, grape seed extract and grape skin extract are active ingredients. The independent claims also allows for multiple formulations of two active ingredients to be added together, thereby providing compositions containing one or more combinations of active ingredients. Furthermore, the ingredients can be formulated into a food composition, which requires additional ingredients and could contain active ingredients. Therefore, the claims are examined as being open claim language.

## Claim Rejections - 35 USC § 102

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (A\*, US 5972391 A).

Suzuki teaches a composition comprising spices, wherein the spices are ginger in an amount of 0.1% and cinnamon in an amount of 0.4% and further comprising vitamin E (which reads on a phytochemical) and wherein the spices can be incorporated as whole spice or in dried and pulverized form (See column 2, lines 43-56).

Although Suzuki does not teach his composition has an effect on the instantly claimed biomarker, the claimed functional properties are inherent to the preparation taught by Suzuki because the ingredients, the amounts of the ingredients, and the route of administration for the delivery of the ingredients taught by Suzuki are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the biomarkers are inherently affected by the composition taught by Suzuki.

Therefore, the reference anticipates the instantly claimed invention.

Claims 1, 3 and 10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nirei (N\*).

Nirei teaches a health food composition comprising sugarcane (sucrose), long pepper in an amount of 1% by weight (which reads on capsicum), cinnamon in an amount of 0.5% by weight, ginger in

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an amount of 0.5% by weight and turmeric in an amount of 0.5%. Nirei further teaches that the composition comprises refining butter (which reads on emulsifier).

Although Nirei does not teach his composition has an effect on the instantly claimed biomarker, the claimed functional properties are inherent to the preparation taught by Nirei because the ingredients, the amounts of the ingredients, and the route of administration for the delivery of the ingredients taught by Nirei are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the biomarkers are inherently affected by the composition taught by Nirei.

Therefore, the reference anticipates the instantly claimed invention

#### Claim Rejections - 35 USC § 103

Claims 1, 3-6 and 8-10 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Peat (B\*).

Peat teaches a spice containing composition consisting of an oil or oleoresin of spice and a carrier (which reads on a composition consisting essentially of spice extracts). Peat further teaches that the oleoresin and/or essential oil can be cinnamon, ginger, nutmeg, turmeric pimento and/or paprika (See lines 55-64). Peat further teaches that the spice containing composition can be added to spaghetti sauce in an amount of 1% in relation to the additional ingredients of tomato paste (which reads on emulsifier), sugar, starch, water, salt and margarine/edible oil (See column 4, lines 15-32). Peat further teaches that the spice containing composition is useful for flavoring and coloring foods (See claims and introduction).

Although Peat does not expressly teach his composition as a phytochemical composition, the claimed functional properties are intrinsic to the preparation taught by Peat because the ingredients and the route of administration for the delivery of the ingredients taught by Peat are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the formulation of Peat is intrinsically a phytochemical composition.

It would have been obvious to modify the composition taught by Peat by combining oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika to provide the instantly claimed compositions containing the instantly claimed combinations of ingredients because at the time

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the invention was made, it was known that oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika were useful ingredients for flavoring and coloring foods and could be used independently or together and could be formulated as combinations of two oleoresin or essential oil extracts as a single formulation as clearly taught by Peat.

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 oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika were useful for flavoring and coloring foods, 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 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 oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika were useful for flavoring and coloring foods would provide an effective composition for flavoring and coloring foods. This reasonable expectation of success would motivate the artisan to use a combination of two or more oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika for flavoring and coloring foods based upon the beneficial teachings of Peat.

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 an effective amount of oleoresins and/or essential oils of cinnamon, ginger, nutmeg, turmeric pimento and/or paprika for flavoring and coloring foods. 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

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art, and absent evidence to the contrary, there would have been a reasonable expectation of success to 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.

Claims 1 and 2-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bherata Bhijajya Ratnekara (U\*), in view of Pu (P, abstract only) and Moonga (Q) (newly applied as necessitated by amendment).

Bherata Bhijajya Ratnekara teaches a composition for treating itching (which is an inflammatory response), eczema (which is a type of inflammation), and pitta dominance conditions (which includes inflammation) comprising cinnamomum zeylanicum (cinnamon) in an amount of 0.33 parts, zingiber officinale (ginger) in an amount of 1 part, curcuma longa (turmeric) in an amount of 1 part and vitis vinifera (whole fruit, grape and reads on grape skin and grape seed, since whole grape contain both the seed and the skin) in an amount of 1 part and wherein the composition is a powder comprising powders of the above ingredients and wherein the powder can be combined with expressed juice of plants or formulated into a decoction for oral administration.

Although Bherata Bhijajya Ratnekara does not teach his composition has an effect on the instantly claimed biomarker, the claimed functional properties are inherent to the preparation taught by Bherata Bhijajya Ratnekara because the ingredients, the amounts of the ingredients, and the route of administration for the delivery of the ingredients taught by Bherata Bhijajya Ratnekara are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the biomarkers are inherently affected by the composition taught by Bherata Bhijajya Ratnekara.

Pu teaches a composition for treating inflammation comprising cayenne pepper in an amount of 40-55.

Moonga teaches a delivery systems for delivering anti-inflammatories comprising capsicum oleoresin and emulsifiers.

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It would have been obvious to modify the composition taught by Bherata Bhijajya Ratnekara by combining cinnamon, ginger, turmeric and grape skin and seed extract with cayenne pepper and/or oleoresin capsicum and an emulsifier because at the time the invention was made, it was known that cinnamon, ginger, turmeric, grape skin and seed extract, cayenne pepper and oleoresin capsicum were all useful ingredients that could be orally administered to treat inflammation 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 cinnamon, ginger, turmeric, grape skin and seed extract, cayenne pepper and oleoresin capsicum were all useful ingredients that could be orally administered to treat inflammation, 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 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 cinnamon, ginger, turmeric, grape skin and seed extract and capsicum would be even more effective for treating inflammation. This reasonable expectation of success would motivate the artisan to orally administer cinnamon, ginger, turmeric, grape skin and seed extract, cayenne pepper and oleoresin capsicum to treat inflammation based upon the beneficial teachings of the above references.

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 an effective amount of cinnamon, ginger, turmeric, grape skin and seed extract and capsicum for treating inflammation based upon the teachings of the above references. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

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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 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

#### Claim Rejections - 35 USC § 102

Applicant's arguments filed 06/21/2013 with regards to Suzuki have been fully considered but they are not persuasive.

Applicant argues that Suzuki teaches ingredients in addition to the instantly claimed ingredients and that Applicant's new limitations recite that the composition consists essentially of and, thus, cannot contain additional active ingredients.

However, this is not found persuasive because the language is construed as open claim language, since Applicant recites additional active components that are combined with the ingredients of the independent claim and even requires the addition of several active components in the independent claim. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments filed 06/21/2013 with regards to Nirei have been fully considered but they are not persuasive.

Applicant argues that the preferred composition taught by Nirei contains various spices and that the teachings do not anticipate the claim language "consisting essentially of" or "synergistically" and that the teachings of Nirei do not teach treating inflammation or a phytochemical composition. Applicant further argues that the term "long pepper" is actually synonymous with Piper longum, which is not a capsicum pepper.

However, this is not found persuasive because the language is construed as open claim language, since Applicant recites additional active components that are combined with the ingredients of

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the independent claim and even requires the addition of several active components in the independent claim. Furthermore, although Nirei does not expressly teach that the composition is a phytochemical composition, the composition inherently has these characteristics based upon the fact that Nirei teaches the instantly claimed ingredients. With regards to Applicant's argument regarding "long pepper", please See "Botany.com" (reference V, page 3 top of page, "Varieties" line 2), which teaches that a synonym for Capsicum frutescens longum is "long pepper". With regards to the language "synergistically" see the 112 2<sup>nd</sup> paragraph rejection above. Therefore, the rejection is maintained for the reasons of record.

## Claim Rejections - 35 USC § 103

Applicant's arguments filed 06/21/2013 with regards to Bherata Bhijajya Ratnekara, in view of Iwahashi are moot in view of the new rejection.

#### Conclusion

No claims are allowed.

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.

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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.

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/Amy L Clark/ Primary Examiner, Art Unit 1655

