THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant	Urvashi BHAGAT
Serial No.	13/332,251
Filed	December 20, 2011
For	LIPID-CONTAINING COMPOSITIONS AND METHODS OF USE THEREOF
Examiner	Dennis HEYER
Group Art Unit	1628
Confirmation No.	5463
Customer No.	112,702

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

In response to the Advisory Action dated March 17, 2017 (hereinafter "1st Advisory Action") and Advisory Action dated January 18, 2018 (hereinafter 2nd Advisory Action), Appellant hereby appeals to the Patent Trial and Appeal Board from the decision of the Examiner in the Final Office Action dated December 21, 2016 (hereinafter "Final Office Action"). Appellant filed a Notice of Appeal on June 21, 2017. In the Office's Decision on Petition dated October 12, 2017, the Office reset the time period for filing an appeal brief to run from the Decision's mailing date of October 6, 2017. Appellant hereby petitions for a 5-month extension of time. The filing of this Appeal Brief is thus timely.

Appellant respectfully requests that the Board treat this application as special in accordance with M.P.E.P. § 708.01(I) (over 5-year pendency).

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REAL PARTY IN INTEREST

The real party in interest is Asha Nutrition Sciences, Inc., P.O. Box 1000, Suite H, Palo Alto, CA 94302, the assignee of the subject U.S. Patent Application No. 13/332,251.

RELATED APPEALS AND INTERFERENCES

The subject application of this appeal is a divisional of U.S. Patent Application No. 12/426,034 ("the '034 application"). The '034 application was appealed to the Patent Trial and Appeal Board ("PTAB"). *See* PTAB Appeal No. 2016-004154 ("the '154 appeal") (April 15, 2016). The Board's decision was appealed to the U.S. Court of Appeals for the Federal Circuit ("CAFC"). *See In re Urvashi Bhagat*, No. 2016-2525 (Fed. Cir. March 16, 2018). The appellant filed a petition for panel rehearing and rehearing *en banc* in the CAFC on April 25, 2018 (see Open Letter to USPTO/CAFC IFW entry April 27, 2018).

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 94 and claim 101 are the only two independent claims. *See* Amendment and Response to Final Office Action (February 21, 2017) (attached as Exhibit 1).

Claim 94 is directed to a method of preparing a lipid-containing formulation for a subject, comprising:

combining daily amounts of fatty acids for the subject based on one or more factors selected from:

- age of the subject,
- gender of the subject,
- diet of the subject,
- the body weight of the subject,
- physical activity level of the subject,
- lipid tolerance of the subject,
- medical conditions of the subject,
- family medical history of the subject, and
- ambient temperature range of the subject's living area,

wherein the formulation comprises omega-6 and omega-3 fatty acids, and

wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors;

wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:

- 4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or
- 1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or
- 4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or
- 2:1 to 30:1 if the subject has a diet of high seafood; or
- 1:1 to 45:1 based on lipid tolerance of the subject; or
- 1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or
- wherein, the fatty acid content is matched to Table 6;

wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

See, e.g., the Specification (attached as Exhibit 2) at page 3, ¶[0008]- ¶[0009]; page 4, ¶[0010]; page 7, ¶[0029]; page 9, ¶[0032]-[0033]; page 12, ¶[0040]; page 12, ¶[0041]; page 13, ¶[0042]; page 14, ¶[0043]- ¶[0045]; page 15, ¶[0046] - ¶[0047]; page 16, ¶[0048]; page 17, ¶[0049]; page 18, ¶[0050]- ¶[0056]; page 20, ¶[0057]; page 21, ¶[0058]- ¶[0059]; page 22, ¶[0060] ; page 23, ¶[0061] ; page 26, ¶[0062]- ¶[0063]; page 27, ¶[0064]- ¶[0066].

Claim 101 is directed to a method of selecting a lipid-containing formulation for administering to a subject, comprising:

a) evaluating the subject on the basis of one or more factors selected from:

- age of the subject,
- gender of the subject,
- diet of the subject,
- the body weight of the subject,
- physical activity level of the subject,
- lipid tolerance of the subject,
- medical conditions of the subject,
- family medical history of the subject, and
- ambient temperature range of the subject's living area, and

b) combining daily amounts of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors;

wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of

- 4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or
- 1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or
- 4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or
- 2:1 to 30:1 if the subject has a diet of high seafood; or
- 1:1 to 45:1 based on lipid tolerance of the subject; or

- 1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or
- wherein, the fatty acid content is matched to Table 6;

wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

See, e.g., Specification, Exh. 2, at page 3, ¶[0008]- ¶[0009]; page 4, ¶[0010]; page 7, ¶[0029]; page 9, ¶[0032]-[0033]; page 12, ¶[0040]; page 12, ¶[0041]; page 13, ¶[0042]; page 14, ¶[0043]- ¶[0045]; page 15, ¶[0046] - ¶[0047]; page 16, ¶[0048]; page 17, ¶[0049]; page 18, ¶[0050]- ¶[0056]; page 20, ¶[0057]; page 21, ¶[0058]- ¶[0059]; page 22, ¶[0060] ; page 23, ¶[0061] ; page 26, ¶[0062]- ¶[0063]; page 27, ¶[0064]- ¶[0066].

GROUNDS OF APPEAL

1. Rejection for indefiniteness under 35 U.S.C. § 112, 2nd paragraph of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-40, 145-150, 153-166, 168, 171, and 177-178: All claims stand rejected for alleged indefiniteness under 35 U.S.C. § 112 for use of the terms "high" and "low" in referring to "a diet of low antioxidants and/or low phytochemicals, "a diet of high antioxidants and/or high phytochemicals" and "a diet of high seafood." Appellant respectfully submits that the rejection should be reversed.

2. Claim construction: Appellant respectfully submits that the Examiner's construction of the claim terms "dosage" and "daily amounts" is in error and requests that the Appellant's construction of these terms be adopted.

3. Rejection for claiming allegedly ineligible subject matter under 35 U.S.C. § 101 of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178: Appellant respectfully submits that the rejection should be reversed.

4. Rejection for alleged anticipation under pre-AIA 35 U.S.C. § 102(b) of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178: Appellant respectfully submits that the rejection should be reversed.

5. Withdrawal of Restriction: On October 20, 2016, the Commissioner for Patents made final a decision to deny Appellant's Petition under 37 C.F.R. §1.181(a)(3) to withdraw the restrictions. To the extent that the Patent Trial and Appeal Board has jurisdiction, Appellant respectfully seeks reversal of this decision.

ARGUMENTS

The rejections of the Final Office Action dated December 21, 2016 (attached as Exhibit 3) are addressed sequentially below. For the reasons set forth below, Appellant respectfully submits that the pending rejections are in error and should be withdrawn.

I. Rejection for indefiniteness under 35 U.S.C. § 112, 2nd paragraph of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145-150, 153-166, 168, 171, and 177-178

All claims stand rejected for indefiniteness under 35 U.S.C. § 112 for use of the terms "high" and "low" in referring to "a diet of low antioxidants and/or low phytochemicals, "a diet of high antioxidants and/or high phytochemicals" and "a diet of high seafood."[1,2] For the reasons set forth below, Appellant contends that the person of ordinary skill in the art would understand the scope of the claims with reasonable certainty. Appellant respectfully requests that these rejections therefore be withdrawn.

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Appellant regards as his invention." 35 U.S.C. § 112, ¶ 2. The statute thus requires "that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). "[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter." *Id.* (citing *Minerals Separation, Ltd.* v. *Hyde*, 242 U. S. 261, 270 (1916)).

"Claims reciting terms of degree 'ha[ve] long been found definite' if they provide reasonable certainty to a skilled artisan when read in the context of the patent." *Mentor Graphics*

[1] The rejection omits claim 172. Claim 172 depends from claim 101 and remains pending.
[2] The rejection for indefiniteness for use of the claim term "gradual" in the phrase "a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary" was withdrawn. *See* Office Action at 3-4 (listing the indefiniteness claim rejection based on "a condition wherein . . ." among the withdrawn rejections). The only claim recitations identified as objectionable in the maintained indefiniteness rejection include "high" and "low" and omit "gradual." *See id.* at 4-5 (listing the objected-to claim limitations). The text of the indefiniteness rejection refers to "[t]he terms 'high,' 'low' and 'gradual'" is therefore in error. *See id.* Applicant therefore does not address the term "gradual" herein.

Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1290 (Fed. Cir. 2017) (citing *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015)). "This requires a patent to provide some standard for measuring that term of degree." *Id.* (internal quotations omitted). A term that appears to be "purely subjective" can satisfy § 112, ¶ 2 when the term "had an established, sufficiently objective meaning in the art, and [the specification at issue] used the term consistent with that meaning." *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1260 (Fed. Cir. 2014).

The present claims are as definite as the subject matter permits. There are many variations in amounts and types of antioxidants, phytochemicals, or seafood in a subject's diet that can be "high" or "low." Further, a number of antioxidants and phytochemicals with significant variation in sensitivity to amounts can materially affect the requirement for or tolerance of omega-6 and omega-3 and their suitable ratio for administration to a subject. It is not possible to list hundreds of different antioxidants, phytochemicals, and hundreds of possible amounts in the diet in the claims. *See*, *e.g.*, Specification, Exh. 2, ¶¶ 0022, 0040, 0072, 0097;[3] *cf. Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) ("The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims."). The references of record establish that a number of antioxidants and phytochemicals with significant variation in sensitivity to amounts can materially affect the requirement/tolerance of omega-6 and omega-3 and their suitable ratio for administration to a subject.

While it is not possible to list hundreds of different antioxidants, phytochemicals, and hundreds of possible amounts in the diet in the claims, the specification provides sufficient guidance regarding the recited levels to satisfy § 112 ¶ 2. The specification teaches that antioxidants and phytochemicals reduce the requirement/tolerance for omega-3 fatty acids and allow for a higher omega-6 to omega-3 ratio. *See*, *e.g.*, Specification, Exh. 2, ¶¶ 21-22, 40, 72, 97. The specification also teaches the following:

[3] *See also* the following references of record: Y. Fujiyama-Fujiwara *et al.*, J Nutr Sci Vitaminol 38:353-63 (1992), Bhagat *et al.*, Arch Med Sci 11, 4: 807–818 (2015), Chu *et al.*, Food Chemistry 62: 191-95 (1998), O'Leary *et al.*, Mutat Res. 551: 245-54(2004), Shah *et al.*, Biochemical Pharmacology 58: 1167–72 (1999), Thiebaut *et al.*, Int. J. Cancer: 124: 924–31 (2009), Wu D. *et al.*, Am J Physiol. 275: C661-8 (1998).

> One method of measuring antioxidant and phytochemical consumption is to measure the number of fruits, vegetables, whole grains, and legumes servings per day, where two or more per day may provide high-antioxidant, high-phytochemical content. However, because certain foods, particularly herbs such as turmeric may contain potent phytochemicals (even in small quantities, e.g., a quarter-teaspoon), the disclosure provides a number of different compositions, including one with varying levels of omega-3 to suit a consumer's diet and/or tolerance level. As used herein, "tolerance" and the like mean the ability of a consumer to withstand the composition without any adverse effect. In some embodiments, the compositions designed for consumers with high seafood diet (two or more servings per week).

Id. ¶ 0033. This passage thus provides guidance for recognizing high-antioxidant diets, high-phytochemical diets, high seafood diets. The specification also teaches that omega-6 and omega-3 fatty acid metabolism and requirements are affected by a number of antioxidants and phytochemicals, and how to adjust the formulation accordingly. For example, referring to a list of supplements and nutrients, the specification teaches that "each of these supplements/nutrients may reduce the requirement for omega-3 fatty acids and allow for a higher omega-6 to omega-3 ratio than in the absence of said supplement(s)/nutrient(s)." *Id.* ¶ 0022. *See also id.* ¶ 76 (stating, with respect to one case study, "Olive oil is 75% monounsaturated oil and rich in polyphenols. Since all fatty acids compete for the same enzymes in the metabolic pathway and antioxidants and phytochemicals increase the requirement for omega-6, in her case the deficiency of omega-6 acid appears to be the culprit.").

In addition to the guidance that the specification provides regarding the meaning of the contested terms, the literature evidences that the person of ordinary skill in the art used and understood the meaning of these terms. For example, references of record refer to the following:

- "high intakes of vitamin E and PUFA," "high arachidonic acid intakes among women with low vitamin E intakes," and "women with both high arachidonic acid and vitamin E intakes" (*see* Thiebaut *et al.*, *supra* n. 2),
- "[h]igh intakes of ω-3 fatty acids," (*see* Brasky *et al.*, J Natl Cancer Inst, July 10, 2013. Page 1, col. 1),
- "high consumption of oily fish (regularly more than twice per week)," (*see* Morse, Prostaglandins, Leukotrienes and Essential Fatty Acids 81: 373-89 (2009),
- "Mediterranean diet supplies large amounts of cereals, legumes, vegetables, and fruits," Renaud et al., Am J Clin Nutr 61(suppl): 1360S-67S, at 1364S col. 2 (1995),

and the following table, which applies "high" and "low" to a variety of nutrient levels:

Simopoulos, Biomed Pharmacother 56: 365–379, Table 1 (2002).

Table 1
Characteristics of hunter-gatherer and western diet and lifestyles

Characteristic	Hunter-gatherer diet and lifestyle	Western diet and lifestyle
Physical activity level	High	Low
Diet		
Energy density	Low	High
Energy intake	Moderate	High
Protein	High	Low-moderate
Animal	High	Low-moderate
Vegetable	Very low	Low-moderate
Carbohydrate	Low-moderate (slowly absorbed)	Moderate (rapidly absorbed)
Fiber	High	Low
Fat	Low	High
Animal	Low	High
Vegetable	Very low	Moderate to high
Total long-chain ω6 + ω3	High (2.3 g/d)	Low (0.2 g/d)
Ratio ω6/ω3	Low (2.4)	High (12.0)
Vitamins, mg/d	*Paleolithic period*	*Current US intake*
Riboflavin	6.49	1.34–2.08
Folate	0.357	0.149–0.205
Thiamin	3.91	1.08–1.75
Ascorbate	604	77–109
Carotene	5.56	2.05–2.57
(Retinol equivalent)	(927)	–
Vitamin A	17.2	7.02–8.48
(Retinol equivalent)	(2870)	(1170–429)
Vitamin E	32.8	7–10

In addition to guidance in the specification and the common use in the art of the terms at issue, testimony from persons skilled in the art indicates that the person of ordinary skill in the art would have understood the terms at issue with reasonable certainty. Testimony included the following:

> As part of the correct fatty acid delivery teaching the following is clearly evident from the specifications:
> a. Omega-6 to omega-3 ratio greater than 4:1 with the exception of low-antioxidant and low-phytochemical consumers (Tables 9, 10, 11, 14, 15, 16, 17, 18, original claim 4).
> Skilled artisans can easily obtain the definition of low-antioxidant and low phytochemical consumer from paragraph 33 and rest of the disclosure. . . .
> f. Antioxidants and phytochemicals will reduce the requirement/ tolerance for omega-3 and/or increase the requirement for omega-6 (paragraph 22 and rest of the disclosure).
> g. Nuts, seeds, and nut oils have high antioxidants, mineral, and phytochemical content and other properties that can render excessive omega-3 unnecessary.

Affidavit of Robert B. Rucker, Ph.D. (September 29, 2014) ¶ 0017 (Exhibit 4); *see also* Affidavit of Pradip K. Rustagi, M.D. (September 29, 2014) ¶ 0017 (stating the same) (Exhibit 5),

Affidavit of Undurti N. Das, M.D., FAMS (September 30, 2014) ¶ 0017 (stating the same) (Exhibit 6) (all of record). Additional support is found in statements by Kent L. Erickson, Ph.D., set forth in Applicant's Summary of the Interview held April 25, 2017 (of record) (Exhibit 7).[4] Dr. Erickson stated, for example, that "the concept of 'high' and 'low' of nutrients and food types is well known in the field of nutrition." *Id.* ¶ 7.5. Further,

> [t]he relative amounts of "high" and "low" of various nutrients and food types are well known. In context of pending claims 94 and 101, a skilled person will have no problem understanding and practicing the following limitations.
> 1: 1 to 10: 1 if the subject has a diet of low antioxidants and/or low phytochemicals; or
> 4: 1 to 45: 1 if the subject has a diet of high antioxidants and/or high phytochemicals; or
> 2: 1 to 30: 1 if the subject has a diet of high seafood.

Id.

The Examiner discounted the import of the affidavits because a scientific expert's opinion on the legal issue of satisfying § 112 ¶ 2 "is not entitled to any weight." *See* Office Action at 7 (citing M.P.E.P. § 716.01(b)). But the testimony evidence offered should be considered relevant to determining what the person of ordinary skill in the art would understand from the specification. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986) (stating that the jury had a right to treat as credible the testimony of patentee's "witnesses, who were skilled in the art," regarding whether the specification provided sufficient guidance to the person of ordinary skill in the art to perform a task necessary to practice the claim). Such a determination is akin to determining the level of skill in the art, and the USPTO accepts such testimony as relevant to the latter determination. *See* M.P.E.P. 716.01(c).III. (citing *In re Oelrich*, 579 F.2d 86 (CCPA 1978) for the proposition that "factually based expert opinions on the level of ordinary skill in the art were sufficient to rebut the prima facie case of obviousness").

[4] Appellant puts forward the statements in section 7 of the Summary as a sworn affidavit, although Appellant recognizes that the affidavit is not in standard form. The Summary includes the requisite verification that willful false statements are punishable, is signed by Dr. Erickson, and it is clear from the document that the signed verification refers to the statements of section 7, because the heading of that section clearly identifies it as the statements of "Dr. Kent Erickson."

Further, reliance on the specification to inform the claims is standard and does not represent importation of limitations from the specification into the claims. Rather, the specification appropriately functions as a guide to understanding the claims. *See*, *e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*) ("the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotations omitted)).

All of the above–the guidance in the specification, the knowledge of the person of ordinary skill in the art as evidenced by use of the contested terms in the literature, and the four sworn statements–support Appellant's position that the person of ordinary skill in the art would have been able to understand with reasonable certainty the meaning of "high" and "low" as recited in the claims.

II. Claim construction: "dosage," "daily amounts"

The Examiner's construction of the term "dosage" as "amount so administered" errs by omitting two elements of the term: the temporal element and the "specified amount" element. *See* Office Action at 9. The Examiner's construction is thus broader than Appellant's intended meaning. It is Appellant's position that "dosage" should be construed to refer to "a specified amount for ingestion at one time or regularly." This accords with the person of ordinary skill in the art's understanding, as detailed below. Even where alternate, broader definitions are available, "[a] patentee may also limit the scope of the claims by disclaiming a particular interpretation during prosecution." *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340 (Fed. Cir. 2004). *See also In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1990) (stating that, "[w]hen the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art.").

The person of ordinary skill in the art recognizes that prescribed administration includes the quantity administered and the frequency of administration. Thus, "dosage" may be defined as "[t]he size, frequency, and number of doses of medicine to be given." Medical Dictionary for the Health Professions and Nursing (Farlex 2012) (accessed online at https://medical-dictionary.thefreedictionary.com/dosage); *see also* Collins Dictionary (defining "dosage" as "1.

the administration of a drug or agent in prescribed amounts and at prescribed intervals"). These definitions both contain all the elements of the proposed definition. Further, both independent claims refer to "daily amounts," further conveying the notion that the recited dosage comprises both a quantity element and a time element. Thus, the "ordinary meaning" of "dosage" is "a specified amount for ingestion at one time or regularly."

Appellant provided additional support for this definition of "dosage" during an interview conducted between the Appellant and USPTO personnel, including this application's Examiner. *See* Applicant's Summary of the Interview held April 25, 2017 (Exhibit 7).[5] Kent L. Erickson, Ph.D. confirmed that "dosage" is understood by the person of ordinary skill in the art to mean "specified amount for ingestion at one time or regularly." *See* Applicant's Summary, Exh. 7, ¶ 7.1. He further confirmed that the person of ordinary skill in the art would have understood "dosage" as used in the specification to have this meaning. *See id.*

The specification provides additional support that the term "dosage" does not encompass any amount at all. For example, the specification provides Tables 9-13, each entitled (9-13) "Lipid Dosages . . ." and each disclosing ranges with an upper and lower limit for "total fat" and for ratios of various classes of lipids. *See* Specification at 15-21. This supports Appellant's contention that dosage refers to amounts within certain ranges. Additional support can be found throughout the specification, for example at: ¶ 34 (stating that "[t]he lipid formulations may be packaged in one, two, three, four or more mutually complementing daily dosages" (emphasis added) (indicating that each dosage completes the other in arriving at the specified daily dosage/amount for administration); ¶ 36 ("Oils, nuts, seeds, and herbs are potent; therefore, instructions may include recommended dosage, frequency, and suggestions for optimization." (emphasis added)); ¶ 39 ("This steady delivery requires a steady dosage within the optimal range lasting approximately 2 to 3 weeks at a minimum." (emphasis added)); ¶ 67 ("In addition to amount and composition, relatively steady dosages may also be important to reduce hormone fluctuations."). *See also*, *e.g.*, Specification ¶¶ 36, 39, 47-49, 57, 59, 67, 68, 89, 97, 103

[5] Appellant puts forward the statements in section 7 of Summary as a sworn affidavit, although Appellant recognizes that the interview summary is not in standard form. The Summary includes the requisite verification that willful false statements are punishable, is signed by Dr. Erickson, and it is clear from the document that the signed verification refers to the statements of section 7, because the heading of that section clearly identifies it as the statements of "Dr. Kent Erickson."

(providing similar support). Thus, construction of "dosage" as not limited with respect to amount is not reasonable in view of the specification.

For the reasons set forth above, Appellant submits that its definition of "dosage" does not represent the importation of limitations from the specification into the claims and should be adopted.

The term "daily amount," which is distinct from "dosage," should be construed to refer to "daily (regular) quota for ingestion in one or more dosages," that is, the total amount specified for ingestion each day on a regular basis. The amount ingested daily is necessarily ingested on a regular basis-this follows from the meaning of "daily." This meaning also finds support in the statements of Kent L. Erickson, Ph.D. *See* Applicant's Summary of the Interview held April 25, 2017, Exh. 7, ¶ 7.2. Further, the person of ordinary skill in the art would understand "daily amount" to have this meaning in view of the specification. *See id.*

Also, the amount ingested daily can be ingested all at once or in two or more portions that together add up to the daily amount. This construction is consistent with the use of the term "daily" in the specification. For example, the specification states that "[o]ne aspect of the disclosure is to deliver fatty acids in such a way that the total daily delivery of omega-6 and omega-3 from the lipid composition and the rest of the diet are optimal with respect to daily recommendations."

The Office Action asserts its construction of "daily amount" as any amount consumed in a day is supported under the "broadest reasonable interpretation" principle. *See*, *e.g.*, Office Action at 10. But the claim language recites "daily amounts" that are "based on" one or more recited factors, and which daily amounts comprise specific ratios of omega-6 to omega-3 fatty acids. Thus, the broadest reasonable interpretation does not extend to any amount consumed in a day, because such an amount is not based on the recited factors or limited with respect to the recited ratios, as the claim requires. Thus, it is not reasonable to construe "daily amount" to encompass any amount consumed in a day in view of the claim language. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("While the broadest reasonable interpretation standard is broad, it does not give the Board [PTO] an unfettered license to interpret the words in a claim without regard for the full claim language and the written description. . . . Construing

individual words of a claim without considering the context in which those words appear is simply not 'reasonable.'").

In view of the above support, Appellant submits that its definitions of "dosage" and "daily amount" should be adopted.

III. Rejection for claiming ineligible subject matter under 35 U.S.C. § 101 of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178

"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." 35 U.S.C. § 101. An analysis of patent eligibility under § 101 entails two steps. The first step entails determining whether "whether the claims at issue are directed to one of those patent-ineligible concepts," namely, "laws of nature, natural phenomena, and abstract ideas." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). The second step entails determining whether the elements of the claim, individually or "as an ordered combination," "transform the nature of the claim into a patent-eligible application." *Id.* (internal quotations omitted). The second step should identify an "inventive concept" "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id.* (internal quotations and brackets omitted).

Independent claims 94 and 101 and dependent claims 95, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178 stand rejected under 35 U.S.C. § 101. Dependent claims 146, 150, 158, 163, and 172 are not rejected under 35 U.S.C. § 101 and are not addressed further with respect to subject matter eligibility. According to the Office Action, "the claimed invention is directed to a judicial exception" without significantly more. Specifically, the Office Action alleges that the rejected claims are "directed to a process of making a lipid-based formulation" which "are products of nature (a judicial exception)." Office Action (December 21, 2016) at 11.

A. Olive oil is not a product of nature

The contention that olive oil is a "product of nature" forms the core of the Office Action's § 101 analysis. The Office Action states that "[b]ecause each compound in olive oil is

naturally occurring, and, further the recited combination of compounds is known to occur together in nature (i.e. is present in olive oil), said combination formed by combining daily amounts of fatty acids is considered a 'product of nature'." *Id.* at 16 (some emphasis in original, some emphasis added). Similarly, the Office Action states that "[t]he basis for the 101 rejection relies on the fact that the claims read on a method for providing two tablespoons of olive oil (a product of nature and a judicial exception." *Id.* at 21. In other words, the Office Action contends that, under the *Alice* analytic framework, the claims are "directed to" a patent ineligible concept and therefore must be further examined to determine whether the claimed subject matter comprises "significantly more" than that concept.

The Office Action relies on "Olive Oil" (July 13, 2007) ("WHFOOil," Exhibit 8)[6] and "Olive Oil Nutrient Analysis" (July 14, 2007), ("WHFOONA," Exhibit 9")[7] to support the contention that claimed products occur in nature as olive oil.

Appellant contends that olive oil is not a product of nature because the very process for preparing oil from an olive causes significant changes. The oil obtained thus is a product of human ingenuity that differs from the component parts of the olive.[8]

Specifically, olive oil is prepared from olives through a non-natural manufacturing process. This transforms olives into olive oil and pulp. The products acquire new physical and chemical properties during and as a result of the process. For example, during oil extraction, triacylglycerols are partially hydrolyzed to yield mono- and diacylglycerols in the oil product. "Heat and pressure [during oil extraction] also accelerate fatty acid hydrolysis. Fatty acid hydrolysis, and thus mono- or diacylglycerol formation are especially prevalent in olives." Chaiyasit *et al.*, Crit Rev Food Sci and Nutr 47: 299–317, 304 col. 2, ¶ 3 (2007) (attached as Exhibit 10; of record, *see* Information Disclosure Statement ("IDS") (May 2, 2015)). The resulting oil therefore contains a higher concentration of mono- and diacylglycerols than the

[6] Available at http://web.archive.org/web/20070713174214/http://www.whfoods.com/genpage.php?pfriendly=1&tname=foodspice&dbid=132.

[7] Available at http://web.archive.org/web/20070714054939/http://www.whfoods.com/genpage.php?pfriendly=1&tname=nutrientprofile&dbid=110.

[8] Appellant presented a similar contention in the appeal of the parent case to the Board and to the CAFC. As indicated above, the contention remains pending while the CAFC considers Appellant's petition for rehearing and petition for rehearing *en banc*.

starting material. *See* Chaiyasit *et al.* Also, the olive oil product, for example, cannot germinate, unlike the plant starting material, and olive oil differs in its nutritional value from the starting material. The following table further highlights some of the differences between olives and olive oil.

Olives	Olive Oil
1. Plant fruits containing seeds	1. Non-naturally manufactured
2. Can reproduce olive plant	2. Cannot reproduce olive plant
3. Solid at room temperature	3. Liquid at room temperature
4. Shapely organized cellular structure	4. Shapeless fluid medium
5. Contain lipids, proteins, carbohydrates, non-lipid vitamins, minerals, pigments	5. Do not contain carbohydrates and proteins
6. Fatty acids are situated in highly structured cell-membranes	6. Fatty acids are randomly dispersed throughout the shapeless medium
7. High phospholipid content	7. Low phospholipid content
8. Low triglyceride content	8. High triglyceride content
9. Lower mono-diacylglycerol content	9. Higher mono-diacylglycerol content
10. Higher phenols	10. Lower phenols
11. Higher water content	11. Lower water content

See Chaiyasit *et al.*, *supra*, and Chen *et al.*, Crit Rev Food Sci and Nutr 51: 901–916 (2011) (attached as Exhibit 11; of record, *see* IDS May 2, 2015).

Consequently, olive oil should not be considered a "product of nature." When a starting material is transformed into a product that has "markedly different characteristics from any found in nature and one having the potential for significant utility," that product "is not nature's handiwork." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). As detailed above, olive oil has, for example, a different chemical composition from olives, different physical properties, and different nutritional value from olives. Olive oil is not merely a substance that exists in olives and that is removed from olives. Rather, olive oil differs substantially from olives and its constituent parts. Thus, the Office Action's reasoning that "the recited combination of compounds is known to occur together in nature (i.e. is present in olive oil)" errs because it relies on the false premise that olive oil is obtained, unchanged, from olives. *See* Office Action at 16 (emphasis omitted). As detailed above, hydrolysis takes place during preparation of olive oil

such that the material obtained differs from the starting material. Thus, the rejection should not rely on the composition of olive oil to establish that the claims read on a product of nature.

In view of the above, Appellant respectfully submits that the rejection under 35 U.S.C. § 101 should be reversed.

B. The claimed methods add significantly more to the claim-recited fatty acids

Assuming a one tablespoon serving size in view of the Olive Oil Nutrition Profile, the Office Action further contends that "the step of combining an amount of olive oil to provide two tablespoons is no different than a method of 'providing two tablespoons of olive oil'. Accordingly, per the patent eligibility Guidelines, there is no difference in substance from a product claim." *See* Office Action at 14, 17. Further, the Office Action dismisses the claim-recited steps of "combining . . . based on" (claims 94 and 101) and "evaluating the subject on the basis of one or more factors" as abstract ideas. The Office Action further reasons that these alleged abstract ideas do not add "significantly more" to the other recited subject matter because abstract ideas are not patent-eligible. *See id.* at 18-19.

Appellant contends that this analysis is incorrect because it omits from consideration several key elements of the claims. Appellant submits that pending independent claims 94 and 101 include the following 8 elements:

1. Method of preparing (Claim 94) / selecting (Claim 101) a lipid containing formulation
2. Combining daily amounts of fatty acids
3. Evaluating the subject (Claim 101)
4. Based on one or more recited factors
5. For [administering to (Claim 101)] a subject
6. The formulation comprises omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors
7. The formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of a recited list of options
8. wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

In other words, the claims require more than merely providing some quantity of the recited formulation. The claims require that the "combining" is done such that "the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors." This amounts to more than an abstract idea because the abstract idea is applied to the formulation such that the formulation's composition varies as a function of the factors considered. The claim term "controlled" indicates that "the ratio of omega-6 to omega-3 fatty acids and/or their amounts" are actively determined and adjusted to a level appropriate for the recited factors. This follows from the meaning of "control" (*see, e.g.*, Merriam-Webster's Collegiate Dictionary (10th ed. 1997) 252 (providing "regulate" as a synonym)) and finds additional support in the statements of Dr. Kent Erickson. *See* Applicant's Summary of the Interview held April 25, 2017, Exh. 7, ¶ 7.3 (defining "controlled" to mean "limit the level/intensity of").

Further, the recited formulation so prepared "provides a dosage of omega-6 and omega-3." That is, given the proper construction of "dosage," it provides "a specified amount for ingestion at one time or regularly." In addition, the "omega-6 to omega-3 ratio" must be within one of the claim-recited specific ranges. Thus, the claims do not cover the two tablespoons of olive oil that the Office Action puts forward because "two tablespoons of olive oil" is not a "dosage of omega-6 and omega-3 fatty acids." That is, it is not "a specified amount for ingestion at one time or regularly." Rather, it is merely an arbitrary amount, not arrived at in consideration of the claim-recited factors and not prepared in order to provide an omega-6 to omega-3 ratio within one of the claim-recited ranges. "In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Further, the subject matter of the independent claims and their dependent claims encompass an inventive concept under *Alice* (*see Alice*, 134 S. Ct. at 2355) and do not represent "well-understood, routine, conventional activity previously engaged in by researchers in the field" that would fail to provide subject matter eligibility (*see Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)).

> Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination. Whether a particular

> technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.

Berkheimer v. HP Inc., 881 F.3d 1360, 1369 (Fed. Cir. 2018).

The present claims should be found to encompass an inventive concept because, for example, element 7 above requires that the formulation provide a dosage of omega-6 and omega-3, and that the omega-6 and omega-3 are present at one of the claim-recited ratios. These dosages and ratios were not well-understood, routine or conventional at the time of filing. *See*, *e.g.*, Response (July 24, 2016) (Exhibit 12) at 17-20 and Affidavits of Robert B. Rucker, Ph.D. (September 29, 2014), Pradip K. Rustagi, M.D. (September 29, 2014), Undurti N. Das, M.D., FAMS (September 30, 2014) (Exhibits 4-6) cited therein. For example, the Response, quoting the Rucker, Rustagi and Das Affidavits, states that "[p]rior to the filing of the subject application, one of ordinary skill in the art would have thought that it was beneficial to suppress omega-6 activity (and the activity of cyclooxygenases). However, the current patent application teaches that long-term deficiency or suppression of omega-6 activity is harmful (see Exh. 1, ¶¶ 39, 71, 85, 95, 98)." Response (July 24, 2016), Exh. 12, at 18.

The fact that the WHFOOil reference promotes "exclusive use" of oil to achieve health benefits further supports Appellant's contention that the claim-recited dosages and ratios of omega-6 and omega-3 fatty acids were not well-understood at the time of filing. *See*, *e.g.*, WHFOOil at 2 (promoting "exclusive use" of olive oil for coronary benefits); *see also id.* at 3, 5, 7 (making similar statements re olive oil and health benefits). In contrast, the specification discloses that a composition that comprises only "3-17%" olive oil may be beneficial in certain circumstances, and that certain subjects whose diets relied primarily on olive oil as a source of fats suffered from ill health. *See* Specification, Exh. 2, ¶¶ 69, 76, 79, 83.

Further support is found in the olive oil nutrition label of WHFOONA, in which the "%DV" for "omega 6 fatty acids" is blank. This indicates that, at that time, the art did not recognize or had not ascertained how much omega-6 should be consumed on a daily basis.

For the above reasons, Appellant contends that the claims, read in view of the specification, are directed to "significantly more" than the recited fatty acids alone.

C. Rejection under 35 U.S.C. § 101 cannot rely on items extraneous to asserted "product of nature"

The Office Action relies on materials other than olive oil itself to establish that the claims read on olive oil. This blurs the distinction between the analysis under 35 U.S.C. §§ 102 and 103 and the analysis under 35 U.S.C. § 101. *See Diamond v. Diehr*, 450 U.S. 175, 190 (1981) ("The question therefore of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'"), *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1066 (Fed. Cir. 2011) (stating that "patentability of subject matter that is facially within the classes set forth in §101 is most reliably resolved in accordance with the conditions of §§102, 103, and 112"). That is, the Office Action's § 101 rejection relies on the WHFOONA and WHFOOil references to determine how much olive oil constitutes one serving, and then proceeds to evaluate that serving to establish that the claim-recited amounts and ratios read on that serving amount. In the absence of the references' guidance, the analysis would fail. In other words, even if "olive oil" alone is a product of nature (which Appellant disputes), "one tablespoon of olive oil" or "two tablespoons of olive oil" is not a product of nature. The Appellant therefore respectfully submits that the § 101 rejection should be reversed.

These considerations also support the contention that the pending claims do not impermissibly "tie up" the use of any product of nature. The recited methods relate to the use of the recited ranges of amounts, ratios, and dosages of the recited fatty acids that the Applicant has newly identified as beneficial and useful, and not to all uses of those fatty acids.

D. Dependent claims argued separately

All of the arguments set forth above apply to the independent and dependent claims subject to the rejection under 35 U.S.C. § 101. As noted above, dependent claims 146, 150, 158, 163, and 172 are <u>not</u> rejected under 35 U.S.C. § 101. Appellant makes the following arguments with respect to certain of the rejected dependent claims. Appellant notes at the outset that the Final Office Action's rejection under 35 U.S.C. § 101 specifically addresses only the independent claims 94 and 101 and the dependent claims 95, 108, 116, 119, 124, 129-132, 134, 137, 139, 140, 157, 159, 164-166, 168, 171, 177-178. Thus, the rejection does not specifically address dependent claims 101, 122-123, 125, 128, 145, 147-149, 153-156, 160-162.

At least because the pending § 101 rejections do not specifically find facts relating to whether the subject matter of dependent claims 101, 122-123, 125, 128, 145, 147-149, 153-156, 160-162 constitutes something "well-understood, routine, and conventional," Appellant respectfully submits that the rejection of these dependent claims should be reversed. *See Berkheimer*, 881 F.3d at 1369 (Fed. Cir. 2018).

The rejection of claim 137, which depends from claim 94, under 35 U.S.C. § 101 should be reversed for the additional reason that claim 137 requires that the "factors are as set forth in Tables 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18" or that "three or more components are selected from Table 5." These factors as applied to the recited fatty acids are not found in the Office Action's asserted product of nature, "two tablespoons of olive oil." Olive oil by itself does not specify the age, gender, diet, or any of the other recited factors of the subject it is prepared for, and does not contain any of the items listed in Table 5 of the specification, such as various oils and nuts. Thus, claim 137 requires something "significantly more" than the fatty acids that it recites. The same analysis applies to dependent claim 168, which depends from claim 101 and recites the same additional limitation. Appellant respectfully submits that the rejection of dependent claims 137 and 168 should be reversed for this additional reason.

E. Conclusion regarding rejections under 35 U.S.C. § 101

In view of the above, Appellant respectfully submits that all of the claims rejected under 35 U.S.C. § 101 recite patentable subject matter and that the rejections under 35 U.S.C. § 101 should be withdrawn.

IV. Rejection for anticipation under pre-AIA 35 U.S.C. § 102(b) of claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178

The Final Office Action rejected Claims 94-95, 101, 108, 116, 119, 122-125, 128-132, 134, 137, 139-140, 145, 147-149, 153-157, 159-162, 164-166, 168, 171, 177-178 under pre-AIA 35 U.S.C. §102(b) as being anticipated by WHFOOil (cited above, Exh. 8) as evidenced by WHFOONA (cited above, Exh. 9).[9] The Advisory Action maintained the rejection.

[9] Dependent claims 146, 150, 158, 163, and 172 are not rejected for anticipation.

The Final Office Action erred by not giving patentable weight to the following claim elements recited in claims 94 and 101; effectively ignoring a large part of the claim language.

> wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors . . . (claim 94)
>
> evaluating the subject on the basis of one or more factors selected from . . . (Claim 101)
>
> wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors . . . (Claim 101)

A claim construction that renders one or more claim terms superfluous is not favored. *Merck & Co., Inc. v. Teva Pharms. USA, Inc*., 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); *see also Diamond v. Diehr*, 450 U.S. 175, 188-189 (1981) ("It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made."), *Markman v. Westview Instruments*, Inc., 52 F.3d 967, 988 (Fed. Cir. 1995) (*en banc*), ("Both this court and the Supreme Court have made clear that all elements of a patent claim are material, with no single part of a claim being more important or "essential" than another.).

WHFOOil fails to disclose "controlled" amounts of omega-6 and omega-3 fatty acids based on the recited factors. Thus, the claimed element in each of claim 94 and claim 101 "the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors" is missing in WHFOOil. WHFOOil discloses, at best, "Exclusive use of olive oil during food preparation seems to offer significant protection against coronary heart disease, irrespective of various clinical, lifestyle and other characteristics of the participants." WHFOOil at page 2.

WHFOOil and WHFOONA fail to disclose ***any*** evaluating step, as required by claim 101.

WHFOOil, as evidenced by WHFOONA, does not disclose how to provide the proper amounts of fatty acids to a subject or how to identify and provide the appropriate ratio of omega-

6 fatty acid to omega-3 fatty acid in a formulation that contains such fatty acids, as the claims require, despite the Examiner's contention that two tablespoons of olive oil equate to a "formulation."

Also, as detailed above in Section III, "two tablespoons of olive oil" is not a "dosage." That is, it is not "a specified amount for ingestion at one time or regularly." Accordingly, WHFOOil and WHFOONA fail to disclose a "dosage of omega-6 and omega-3" at a recited omega-6 to omega-3 ratio.

WHFOOil and WHFOONA fail to disclose and enable how to prepare, select, and control omega-6 and omega-3 "based on" "age", "gender", "diet", "medical condition", or the "ambient temperature range" of the subject. WHFOOil and WHFOONA provide no such guidance. WHFOOil and WHFOONA fail to disclose and enable the dosages and the ratios recited in claims 94 and 101. To anticipate a claim, the prior art disclosure must provide an enabling disclosure of the desired subject matter. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

For at least the foregoing reasons, claims 94 and 101 are not anticipated by WHFOOil as evidenced by WHFOONA. To anticipate, a prior art reference must describe and enable every element of a claim. *See, e.g.*, *Crown Operations, Int'l Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). "[The law of anticipation] does not permit the Board to fill in missing limitations simply because a skilled artisan would immediately envision them." *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.,* 851 F.3d 1270, 1274 (Fed. Cir. 2017).

WHFOOil as evidenced by WHFOONA does not describe every element of claim 94 and claim 101. Claims 95, 108, 116, 119, 122 - 125, 128 - 132, 134, 137, 139 - 140, 145, 147-149, 153-157 and 159-162, 164-166, 168, 171 and 177-178 depend from either claim 94 or claim 101, either directly or indirectly, and thus for at least the same reasons, are not anticipated by WHFOOil as evidenced by WHFOONA. Appellants respectfully request that the anticipation rejection be reversed with respect to all claims rejected under § 102.

The rejection of claim 137, which depends from claim 94, under 35 U.S.C. § 102 should be reversed for the additional reason that claim 137 requires that the "factors are as set forth in Tables 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18" or that "three or more components are selected from Table 5." These factors as applied to the recited fatty acids are not found in the

Office Action's asserted product of nature, "two tablespoons of olive oil," or in the cited references WHFOOil and WHFOONA. They do not indicate the age, gender, diet, or any of the other recited factors of the subject the composition is prepared for, and do not contain or disclose any of the items listed in Table 5 of the specification, such as various oils and nuts. The same analysis applies to dependent claim 168, which depends from claim 101 and recites the same additional limitation. The rejection of dependent claims 137 and 168 for anticipation should be reversed.

V. Withdrawal of Restriction

On October 20, 2016, the Commissioner for Patents made final a decision to deny Appellant's Petition under 37 C.F.R. §1.181(a)(3). It is unclear whether this decision is appealable to the Patent Trial and Appeal Board. To preserve Appellant's rights, Appellant has included an appeal to that decision. If the Board does not have jurisdiction for an appeal of this issue, Appellant reserves the right to appeal this issue to another venue, such as the Court of Appeals of the Federal Circuit.

At least claims 95, 119, 123, 125, 137, 145, 148-150, 153-155, 157, 161-163, and 168 are improperly withdrawn.

In a September 30, 2015 Notice of Non Responsive Amendment, the Examiner stated that in an August 31, 2012 response, Applicant elected, without traverse, a composition based on the factor of the "climate of the subject's living area" with the statement "At least claims 94 and 137 encompass the elected species." The Examiner further stated that because Applicant did not elect a single composition including all components thereof, the response filed on August 31, 2012, was non-compliant. The Examiner did acknowledge that Applicant had disagreed with withdrawal of certain dependent claims in a January 4, 2013 response and that because no agreement appears to have been reached on this issue, Applicant is required to clarify the record with respect to the specie election requirement so that all claims reading on the election are examined in the next Office Action.

On September 30, 2015, Applicant responded to the required clarification by stating that:

- there is no requirement in the MPEP to elect "one specific composition including all components thereof;"

- this requirement on part of the previous Examiner was improper;
- the Election of Species requirement per MPEP 809.02(a) is (i) provisional election of a species to be examined and (ii) identification of the claims encompassing the elected species;
- "The record is corrected in that the species election is made with traverse because the factors "age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area" are not mutually exclusive. (MPEP 806.04(±))"
- claims 94-172 and 177-178 encompass the elected species.

On March 4, 2016, the Examiner issued an Office action withdrawing the requirement to elect one specific composition including all components thereof and rejoined some of the dependent claims. Additionally, the Examiner made the species election requirement directed to a single “factor” final and noted that “Applicant timely traversed the restriction (election) requirement in the reply filed on September 30, 2015.” On June 16, 2016, Applicant submitted a petition to the Director of the Technology Center to review the restriction requirement. But on July 8, 2016, the petition was denied. Applicant then filed an August 27, 2016 Petition for Supervisory Review by the Director; the Office then issued the October 20, 2016 Final Decision discussed above, denying the petition.

Applicant timely traversed the restriction (election) requirement in the response filed on September 30, 2015 (acknowledged by the Examiner).

Claims 94 and 101 are directed to "method of preparing [selecting] a lipid-containing formulation for a subject... based on one or more factors selected from: ... ," which are patentably distinct, but not mutually exclusive. The recited factors are, "age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area." The selection and preparation criteria involve combining daily amounts of fatty acids comprising omega-6 and

omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors. The elected species is "ambient temperature range of the subject's living area." These are Markush-type claims. All members of the group require daily omega-6 and omega-3, as disclosed in the specification, a common utility. Examination of all species together does not impose undue search burden because the searches would be directed to prior art disclosing the common structural feature controlling daily delivery of omega-6 and omega-3 fatty acids.

Further, this application has been pending for over five years and is entitled to "special" advancement (MPEP 708.01(1) and 707.02). Furthermore, the inventive solutions are extremely important for public health as evident from the record (Response (July 24, 2016), page 17-22, Exh. 12, and Patents for Humanity application).

Appellant respectfully requests that all “factors” in claims 94 and 101, and all dependent claims be examined together because it does not impose serious examination burden, and because the application is entitled to “special” advancement, having been pending for over five years and the inventive solutions are extremely important for public health. Timely patent grant is critical for timely and effective implementation of the solutions.

CONCLUSION

For at least the foregoing reasons, Appellant respectfully requests reversal of all pending rejections.

Respectfully Submitted,

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CLAIMS APPENDIX

The following claims are under appeal:

1-93. (Cancelled).

94. (Previously Presented) A method of preparing a lipid-containing formulation for a subject, comprising:

combining daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,

wherein the formulation comprises omega-6 and omega-3 fatty acids, and wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:

4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or

1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or

4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or

2:1 to 30:1 if the subject has a diet of high seafood; or

1:1 to 45:1 based on lipid tolerance of the subject; or

1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

95. (Previously Presented) The method of claim 94, wherein

(i) the ratio of omega-6 to omega-3 fatty acid is in the range of 4:1 to 45:1;

(ii) the ratio of omega-6 to omega-3 fatty acids is greater than 6:1; or

(iii) the ratio of omega-6 to omega-3 fatty acid is at least 9:1.

96-100. (Cancelled).

101. (Previously Presented) A method of selecting a lipid-containing formulation for administering to a subject, comprising:
a) evaluating the subject on the basis of one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area, and
b) combining daily amounts of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of
4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or
1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or
4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or
2:1 to 30:1 if the subject has a diet of high seafood; or
1:1 to 45:1 based on lipid tolerance of the subject; or
1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or
wherein, the fatty acid content is matched to Table 6;
wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

102. (Withdrawn) The method of claim 101, wherein the method comprises determining for the subject a diet type based on one or more of amount and type of antioxidants, phytochemicals, vitamins, minerals, seafood, legumes, fruits, vegetables, whole grains, herbs, spices, and sweeteners in the diet, and/or whether or not the diet is omnivorous, vegetarian, vegan, or ovo-lacto vegetarian.

103-106. (Cancelled).

107. (Withdrawn) The method of claim 101, wherein phytochemicals and nuts and seeds are minimized or eliminated to avoid unfavorable interactions.

108. (Previously Presented) The method of claim 101, wherein the formulation comprises one or more of oils, butters, nuts or their oils, seeds or their oils, legumes, dairy, cocoa, lentils, and grains.

109-111. (Cancelled).

112. (Withdrawn) The method of claim 101, wherein lipid-free or low-lipid foods are designed for and/or provided in combination with said lipid formulation.

113. (Withdrawn) The method of claim 101, whereby the lipid-containing formulation provides a substitution and/or supplementation of lipids that are typically added to food preparations so that when the formulation is provided in combination with a no-lipid or low-lipid food product, the combination of the formulation and the food preparation provides a balanced lipid intake to a subject ingesting the combination.

114. (Withdrawn) The method of claim 112, comprising foods selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs or spices, sweeteners, beverages, eggs, cheese, milk, poultry, seafood, and meat.

115. (Cancelled).

116. (Previously Presented) The method of claim 101, wherein the formulation is in the form of enteral, parenteral, a liquid, semi-solid, solid, granule, drop, gel, powder, capsule, tablet, lozenge, pill, or a combination thereof.

117. (Cancelled).

118. (Withdrawn) The method of claim 101, wherein the formulation is in the form of a meal or dietary component selected from an oil, sauce, spread, dressing, butter, drops, salad, side dish, bar, bread, dessert, pastry, truffle, pudding, cake, bakery product, dairy product, yogurt, drink, or a combination thereof.

119. (Previously Presented) The method of claim 101, wherein the formulation is administered in one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.

120-121. (Cancelled).

122. (Previously Presented) The method of claim 94, wherein omega-9 fatty acids are in the range of 10% to 90% by weight of total lipids.

123. (Previously Presented) The method of claim 94, wherein omega-6 fatty acids are in the range of 4% to 75% by weight of total lipids.

124. (Previously Presented) The method of claim 94, wherein the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of total fatty acids to saturated fatty acids is 1:1 to 15:1.

125. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more fatty acids selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic

acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

126-127. (Cancelled).

128. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more nutrients effective to reduce omega-3 requirement and/or allow for higher omega-6:omega-3 ratio than in the absence of the nutrient, and/or increase effective levels of omega-3 in a subject.

129. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more polyphenols, and is effective to increase omega-3 levels in the subject.

130. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more polyphenols selected from: a flavonoid, a flavonol, a flavanone, a flavone, an isoflavone, an anthocyanidin, an anthocyanin, a phytoestrogen, a catechin, a quercetin, a kaempferol, resveratrol, a lignan, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, and curcumin.

131. (Previously Presented) The method of claim 94, wherein the formulation further comprises one or more of phytochemicals, antioxidants, vitamins, and minerals, including vitamin A, folic acid or folate, vitamin, C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and/or Mg.

132. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more of oils, butters, nuts or their oils, seeds or their oils, legumes, dairy, cocoa, lentils, and grains.

133. (Withdrawn) The method of claim 94, wherein the fatty acids, phytochemical, antioxidant, vitamins and minerals content of the formulation is effective for the subject to

maintain oxidant balance, antioxidant balance, inflammation balance, and/or avoid unfavorable dietary interactions.

134. (Previously Presented) The method of claim 94, wherein the formulation is in the form of enteral, parenteral, a liquid, semi-solid, solid, granule, drop, gel, powder, capsule, tablet, lozenge, pill or a combination thereof.

135. (Withdrawn) The method of claim 94, wherein the formulation is in the form of a meal or dietary component selected from an oil, sauce, spread, dressing, butter, drops, salad, side dish, bar, bread, dessert, pastry, truffle, pudding, cake, bakery product, yogurt, drink, dairy product, or a combination thereof.

136. (Withdrawn) The method of claim 143, wherein foods are selected from one or more of grains, legumes, fruits, vegetables, herbs or spices, sweeteners, yogurt, beverages, eggs, cheese, milk, poultry, seafood, and meat.

137. (Previously Presented) The method of claim 94, wherein the factors are as set forth in Tables 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 or 19, or wherein three or more components are selected from Table 5.

138. (Cancelled).

139. (Previously Presented) The method of claim 94, comprising one or more phytochemicals selected from: phytosterol, campesterol, sitosterol, stigmasterol, organosulfur, sulfide, melatonin, carotenoid, beta carotene, lycopene, lutein, zeaxanthin, a phenol.

140. (Previously Presented) The method of claim 94, wherein the formulation is administered in one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.

141. (Cancelled).

142. (Withdrawn) The method of claim 94, whereby the formulation provides a substitution and/or supplementation of lipids that are typically added to food preparations so that when the formulation is provided in combination with a no-lipid or low-lipid food product, the combination of the formulation and the food preparation provides a balanced lipid intake to a subject ingesting the combination.

143. (Withdrawn) The method of claim 94, wherein lipid-free or low-lipid foods are prepared for and/or provided in combination with said lipid formulation.

144. (Withdrawn) The method of claim 94, wherein the method comprises determining for the subject a diet type based on one or more of amount and type of antioxidants, phytochemicals, vitamins, minerals, seafood, legumes, fruits, vegetables, whole grains, herbs, spices, and sweeteners in the diet and/or whether or not the diet is omnivorous, vegetarian, vegan, or ovo-lacto vegetarian.

145. (Previously Presented) The method of claim 94, wherein omega-3 fatty acids are in the range of 0.1% to 30% by weight of total lipids.

146. (Previously Presented) The method of claim 94, wherein the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1.

147. (Previously Presented) The method of claim 94, wherein the dosage of total fat in grams is from 10-100 grams, or is 10-75 grams, or is 15-80 grams, or is 20-100 grams.

148. (Previously Presented) The method of claim 94, wherein the dosage of omega-6 fatty acids is less than 40 grams, or from 1 to 10 grams, or from 2 to 15 grams, or from 2 to 25 grams, or from 1 to 40 grams, or from 2 to 40 grams.

149. (Previously Presented) The method of claim 94, wherein the dosage of omega-3 fatty acids is from 0.1 to 1.0 grams, or from 0.2 to 1.0 grams, or from 1.0 to 2.0 grams, or from 2.0 to 3.0 grams, or from 2.0 to 4.0 grams, or from 2.0 to 6.0 grams.

150. (Previously Presented) The method of claim 94, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams; the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1.

151. (Withdrawn) The method of claim 94, wherein the formulation supplies 60-90% of the diet's fat calories.

152. (Withdrawn) The method of claim 94, wherein 20-45% a of diet's calories are from fat, 45-65% of a diet's calories are from carbohydrates, and 10%-25% of a diet's calories are from protein.

153. (Previously Presented) The method of claim 101, wherein one or more fatty acids are selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1, linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

154. (Previously Presented) The method of claim 101, wherein omega-6 fatty acids are present at 4% to 75% by weight of total lipids.

155. (Previously Presented) The method of claim 101, wherein omega-3 fatty acids are 0.1% to 30% by weight of total lipids.

156. (Previously Presented) The method of claim 101, wherein omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

157. (Previously Presented) The method of claim 101, wherein
(i) the ratio of omega-6 to omega-3 fatty acid is in the range of 4:1 to 45:1;
(ii) the ratio of omega-6 to omega-3 fatty acids is greater than 6:1; or
(iii) the ratio of omega-6 to omega-3 fatty acid is at least 9:1.

158. (Previously Presented) The method of claim 101, wherein the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1.

159. (Previously Presented) The method of claim 101, wherein the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of total fatty acids to saturated fatty acids is 1:1 to 15:1.

160. (Previously Presented) The method of claim 101, wherein the dosage of total fat in grams is from 10-100 grams, or is 10-75 grams, or is 15-80 grams, or is 20-100 grams.

161. (Previously Presented) The method of claim 101, wherein the dosage of omega-6 fatty acids is less than 40 grams, or from 1 to 10 grams, or from 2 to 15 grams, or from 2 to 25 grams, or from 2 to 40 grams.

162. (Previously Presented) The method of claim 101, wherein the dosage of omega-3 fatty acids is from 0.1 to 1.0 grams, or from 0.2 to 1.0 grams, or from 1.0 to 2.0, or from 2.0 to 3.0 grams, or from 2.0 to 4.0 grams, or from 2.0 to 6.0 grams.

163. (Previously Presented) The method of claim 101, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams; the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1.

164. (Previously Presented) The method of claim 101, wherein the formulation comprises one or more polyphenols selected from: a flavonoid, a flavonol, a flavanone, a flavone, an isoflavone, an anthocyanidin, an anthocyanin, a phytoestrogen, a catechin, a quercetin, a kaempferol, resveratrol, a lignan, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, and curcumin.

165. (Previously Presented) The method of claim 101, comprising one or more phytochemicals selected from: phytosterol, campesterol, sitosterol, stigmasterol, organosulfur, sulfide, melatonin, carotenoid, beta carotene, lycopene, lutein, zeaxanthin, a phenol.

166. (Previously Presented) The method of claim 101, comprising selection of one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements, including vitamin A, folic acid or folate, vitamin, C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and/or Mg.

167. (Withdrawn) The method of claim 101, wherein the fatty acids, phytochemical, antioxidant, vitamins and minerals content of the formulation is effective for the subject to maintain oxidant balance, antioxidant balance, inflammation balance, and/or avoid unfavorable dietary interactions.

168. (Previously Presented) The method of claim 101, wherein the factors are as set forth in Tables 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, or 19, or wherein three or more components are selected from Table 5.

169. (Withdrawn) The method of claim 101, wherein the formulation supplies 60-90% of the diet's fat calories.

170. (Withdrawn) The method of claim 101, wherein 20-45% of a diet's calories are from fat, 45-65% of a diet's calories are from carbohydrates, and 10%-25% of a diet's calories are from protein.

171. (Previously Presented) The method of claim 101, wherein the formulation is configured for gradual and/or steady administration, wherein any omega-3 withdrawal is gradual, and/or any omega-6 and/or other fatty acid increase is gradual.

172. (Previously Presented) The method of claim 101, wherein the one or more nutrients are effective to provide a therapeutic effect comprising prophylaxis or alleviation of one or more symptoms associated with a disease or condition selected from menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia or cardiovascular disease.

173. (Withdrawn) A method of prophylaxis and/or treatment of a medical condition and/or ameliorating one or more symptoms of a medical condition in a subject, comprising administering a lipid-containing formulation produced by the method of claim 101.

174. (Withdrawn) A method of prophylaxis and/or treatment of a medical condition and/or ameliorating one or more symptoms of a medical condition in a subject, comprising administering a lipid-containing formulation produced by the method of claim 94.

175. (Withdrawn) The method of claim 173, wherein a disease or condition is selected from menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia or cardiovascular disease.

176. (Withdrawn) The method of claim 174, wherein a disease or condition is selected from menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia or cardiovascular disease.

177. (Previously Presented) The method of claim 94, wherein the formulation comprises one or more of the following:
(i) dosage of eicosapentaenoic acid (C20:5) not more than 0.5 grams, and/or a dosage of docosahexaenoic acid (C22:6) not more than 0.2 grams;
(ii) dosage of phytosterols less than 150mg;
(iii) one or more of: dosage of campesterol less than 1.5mg, dosage of sitosterol less than 30mg, and dosage of stigmasterol less than 1.5mg;
(iv) one or more of: dosage of vitamin A less than 30000IU, dosage of folic acid or folate less than 800mcg, dosage of vitamin C less than 400mg, dosage of vitamin D less than 400IU, dosage of vitamin E tocopherol beta less than 0.5mg, dosage of vitamin E tocopherol delta less than 0.5mg, dosage of vitamin E tocopherol gamma less than 4mg, dosage of vitamin E tocopherol alpha less than 15mg, dosage of copper less than 3mg, dosage of zinc less than 14mg, dosage of manganese less than 8mg, dosage of iron less than18mg, dosage of selenium less than 80mcg, and dosage of magnesium less than 700mg;

(v) one or more of: dosage of alpha carotene less than 4000mcg, dosage of beta carotene less than 14000mcg, dosage of beta cryptoxanthin less than 850mcg, dosage of betaine less than 50mg, dosage of choline less than 250mg, dosage of lycopene less than 1900 mcg, and dosage of lutein/zeaxanthin less than 14000mcg;
(vi) vitamin E in the range of 0.001 % to 0.5% by weight of total lipids; or
(vii) dosage of fiber less than 45g.

178. (Previously Presented) The method of claim 101, wherein the formulation comprises one or more of the following:
(i) dosage of eicosapentaenoic acid (C20:5) not more than 0.5 grams, and/or a dosage of docosahexaenoic acid (C22:6) not more than 0.2 grams;
(ii) dosage of phytosterols less than 150mg;
(iii) one or more of: dosage of campesterol less than 1.5mg, dosage of sitosterol less than 30mg, and dosage of stigmasterol less than 1.5mg;
(iv) one or more of: dosage of vitamin A less than 30000IU, dosage of folic acid or folate less than 800mcg, dosage of vitamin C less than 400mg, dosage of vitamin D less than 400IU, dosage of vitamin E tocopherol beta less than 0.5mg, dosage of vitamin E tocopherol delta less than 0.5mg, dosage of vitamin E tocopherol gamma less than 4mg, dosage of vitamin E tocopherol alpha less than 15mg, dosage of copper less than 3mg, dosage of zinc less than 14mg, dosage of manganese less than 8mg, dosage of iron less than18mg, dosage of selenium less than 80mcg, and dosage of magnesium less than 700mg;
(v) one or more of: dosage of alpha carotene less than 4000mcg, dosage of beta carotene less than 14000mcg, dosage of beta cryptoxanthin less than 850mcg, dosage of betaine less than 50mg, dosage of choline less than 250mg, dosage of lycopene less than 1900 mcg, and dosage of lutein/zeaxanthin less than 14000mcg;
(vi) vitamin E in the range of 0.001 % to 0.5% by weight of total lipids; or
(vii) dosage of fiber less than 45g.