Case No. 2023-1545

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

URVASHI BHAGAT,
Plaintiff-Appellant

v.

THE UNITED STATES PATENT AND TRADEMARK OFFICE, KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, UNITED STATES[1],
Defendants-Appellees.

On Appeal from The United States District Court
For the Eastern District of Virginia, Alexandria Division,
No. 1:20-cv-1515-CMH-IDD, Senior Judge Claude M. Hilton.

CORRECTED OPENING BRIEF OF THE APPELLANT

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Pro se Appellant

Dated: December 17, 2023

[1] Amended caption per order dated December 1, 2023, ECF No. 33.

INDEPENDENT PATENT CLAIMS AT ISSUE

82. A packaged product comprising one or more nutritional formulations for an individual including at least one formulation comprising an intermixture of omega-6 fatty acid(s) and antioxidant(s) from different sources; wherein the one or more formulations are so packaged and labeled indicating suitability for consumption that collectively provide a dosage from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols in the dosage of greater than 5mg; wherein the intermixture of omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

96. The method according to claim 97, wherein the dosage is administered to aid acid-base balance in the individual.

97. A method of prophylaxis and/or treatment of a medical condition or disease in the individual, the method comprising:
administering a dosage of the product according to claim 82 to the individual.

98. The method according to claim 97, wherein the medical condition or disease is selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases

99. A method for preparing a product comprising one or more nutritional formulations for an individual, the method comprising the steps of:

(a) determining for the individual a diet cohort based on diet and/or a demographic factor of the individual; and

(b) on the basis of the diet cohort, selecting and preparing one or more nutritional formulations for the individual, including at least one formulation comprising omega-6 fatty acid(s) and antioxidant(s);

wherein the one or more formulations collectively provide to the individual a daily dosage from 1 to 40g of omega-6 fatty acids, and from 25mg to 10g of antioxidants comprising one or more polyphenols in a daily dosage of greater than 5mg;

wherein the omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed.

112. A computer system configured to computationally implement a method according to claim 99, comprising:

(a) a computing device having a memory;

(b) an input device for entering information regarding the individual's dietary preferences into the memory;

(c) a database in the memory for storing the information;

(d) a first program module, for execution in the computing device, for determining a dietary cohort of the individual corresponding to the individual's dietary preferences, wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences; wherein the dietary cohort of the individual is

(i) predetermined and entered directly in the computing device; and/or

(ii) determined either manually or computationally in response to remote user inputs of dietary preferences via a web connection; and/or

(iii) selected from predominantly vegetable-based, seafood based and meat based;

(e) a nutrient database for storing dietary guidelines relative to dietary cohorts of an individual; wherein optionally the nutrient database comprises suitable ranges for average daily dietary consumption of nutrients corresponding to each dietary cohort, and/or suitable ranges for daily dietary consumption of carbohydrates, protein, vitamins, minerals and phytochemicals;

(f) a knowledge database having rules for manipulating the information in the database to provide a recommended future nutrition program for the individual, the nutrition program comprising one or more of nutrients selected from antioxidants, phytochemicals, lipids, vitamins and minerals in amounts that provide a beneficial effect to the individual, wherein a suitable daily dosage of omega-6 fatty acids and antioxidants including polyphenols is included in the program;

(g) a second program module, for execution in the computing device, for applying the rules in the knowledge database to the information in the database and to the guidelines in the nutrient database and for generating a nutrition program for the individual in a result database; and

(h) means for outputting the contents of the result database, under the direction of the second program module,

wherein the nutrition program comprises a listing of formulations, optionally comprising food items, wherein from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants comprising at least 5mg of one or more polyphenols are included in the program for daily consumption by the individual.

115. A nutritional formulation comprising a mixture of:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10 g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

116. A method for treating medical conditions or diseases selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases, the method comprising:

administering to a subject the nutritional formulation in a dosage sufficient to treat the medical condition or disease wherein the nutritional formulation comprises:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins,

phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

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STATEMENT OF RELATED CASES

Petition for writ of mandamus from improper Fed.R.Civ.P.12(b)(1) and 12(b)(6) dismissals to the district court was filed in the Supreme Court (case No. 22-228), which was denied review[2] without implicating merits[3]. No other appeals from the action were filed before any appellate court and no related cases are pending in any court in the United States. However, the Federal Circuit's decision in this appeal will influence nearly 36 issued patents and 10 pending patent applications before patent offices, appeal boards, and courts in several jurisdictions[4] related to the underlying patent application in the civil action.

ORAL ARGUMENT REQUESTED

Oral argument is pled because complex and vital issues to constitutional rights to due process and discoveries are raised, in view of poorly understood proportional intake of omega-6 fatty acids and antioxidants including polyphenols, long-felt unresolved need, and public suffering witnessed by the Appellant *firsthand* and public interest from inability of market to solve the problem without limited exclusivity. It will benefit the Court to hear the Appellant in person[5].

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[2] supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/22-228.html.
[3] *Maryland v. Baltimore Radio Show, Inc.*, 338 U.S. 912, 918-919 (1950).
[4] asha-nutrition.com/research/intellectual-property/
[5] Appellant has good knowledge of patent laws from prosecuting patent matters through credible law firms in US and abroad, and as pro se for over ten years.

JURISDICTIONAL STATEMENT

The Plaintiff invoked district court's subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 1361, and 35 U.S.C. §145. The court entered summary judgement and final judgement on March 30, 2023, dismissing the case (Appx19-33) while *2nd Am.Complaint* was pending. The very next day on March 31, 2023, the Court denied the motion for leave to file *2nd Am.Complaint* under the pretext the case is dismissed (Appx34). Timely amended notices of appeal from final judgment were filed on April 7, 2023, and June 5, 2023 (ECF.No[6].12; ECF.No.15; Appx14000-14001). Appellant contests all district court's orders upon final judgment. This Court has appellate jurisdiction under 28 U.S.C. §1295(a)(1).

STATEMENT OF ISSUES

1. Whether the district court violated Appellant's due process rights by dismissing,

a. causes of action to damages and taking without just compensation *arising under* the Fifth Amendment for alleged lack of jurisdiction and sovereign immunity despite invocation of jurisdiction under §1331;

b. causes of action to bad faith and misconduct, and declaratory and injunctive relief, alleging failure to state a claim while refusing to recognize explicit statements on two full pages of *1st Am.Complaint* and the context of

[6] Refers to this Court's docket.

the entire Complaint despite *Ashcroft v. Iqbal*; and

c. demand for jury trial under Seventh Amendment in §1331 action?

2. Whether the district court violated Appellant's due process rights by,

a. placing higher filing burden on the Appellant than the Appellees shortening and eliminating Appellant's response time from paper filings;

b. barring all email and phone communications from the Appellant including on procedural matters related to medical emergency, establishing a new erroneous legal principle contrary to in Fed.R.Civ.P.6(b)(1)(A); and

c. denying discovery enlargement and continuance of the final pre-trial conference to Appellant from illness among Appellant's experts but granting the same relief to Appellees from the same episode of illness?

3. Whether the district court committed harmful legal errors in failing to consider judicially recognized factors under Fed.R.Evid. 104, 402, 403, 405, 406, and 702, *Daubert*, and *Sardis* on admissibility of appellees' expert testimony and failing to exclude the inadmissible testimony?

4. Whether the district court violated Appellant's due process rights and committed harmful error in denying Appellant's motion for leave to file *2nd Am.Complaint* where the amendments seek proper relief from matters already in the original complaint and conform complaint to facts on administrative record and discovery and issues raised about six weeks before in motion for summary

judgment?

5. Whether the district court violated Appellant's due process rights in granting the summary judgment because,

a. close of discovery is under appeal, Appellees' expert testimony is objected, and claims construction and related facts are disputed; and

b. record is rife with disputed facts; while,

c. summary judgment in favor of Appellees fails as a matter of law, at least because claims disclaiming products of nature are patent eligible under §101 and claims drawn to poorly understood factors are not obvious under §103?

6. Whether the district court violated Appellant's due process rights in failing to provide unbiased judges?

STATEMENT OF THE CASE AND FACTS

A. Nature of Action at District Court

The action at district court arises from Defendants' conspiracy to deprive, and bad faith deprivation, of the Plaintiff's rights to her discoveries. The Plaintiff's claims in the action include constitutionally guaranteed exclusive rights to discoveries, recovery of damages due to deprivation of rights in violations of due process and Takings under the Fifth Amendment of the Constitution from unreasonable delay in granting the rights, costs and fees of the action, and declaratory and injunctive relief.

B. Background of the '847 Application

The discoveries described in US Patent Application 13/877,847 ("the '847 application") pertain to precise dosage and proportional requirements of and interactions among omega-6 fatty acids and antioxidants including minor lipids (e.g., polyphenols) and adverse effects of sudden shifts in intake of the substances with profound health effects, such that individualized dosages (specified delivery) have the potential of mitigating chronic diseases and acute health events (such as strokes and heart attacks) and susceptibility to infections (such as COVID-19). (Appx347-422). The claims are directed to the innovative compositions, methods of tailoring, and methods of using the formulations comprising proportional dosages of omega-6 fatty acids and antioxidants including polyphenols in the broadest embodiments with additional features in narrower embodiments (Appx46-59).

The claimed features in the '847 application remain poorly understood in the art even today. To date there is no teaching available on proportional dosages of total omega-6 fatty acids and antioxidants including polyphenols for optimal health in literature, including the Dietary Guidelines for Americans, U.S.DHHS, or the most authoritative medical school textbooks (Table 3 infra). Scientific and mainstream publications and product labels direct public to consult physicians on intake of fatty acids and antioxidants, but medical textbooks fail to teach medical students

and physicians on requirements for these substances, even though they teach them to prescribe medications to "treat" various ailments rooted in deficiency, imbalanced, or excessive intake of these substances. (Appx7436-7438). Thus, no teaching on substrate ingestion is provided to physicians and/or public, but medicines to modulate the substrate effects in-vivo are thrown at patients, which at best just ameliorate symptoms or at worst compound the problem. ***That* is junk science**!

Plaintiff is directly affected by this failure of prior art from horrific suffering, precipitous decline in health, and demise of her own mother from neural disease without any familial basis (Appx10940). Subsequently, the Plaintiff investigated the matter in early 2000s, and conceived that deficiency of fatty acids critical for brain function, in particular omega-6 fatty acids, and disproportionately high antioxidants in her mother's diet were a significant cause of her progressive symptoms culminating into neural disease diagnosis a decade later. She also conducted experiments in live subjects in patient support groups in various indications, which are reported in her patent applications. (Appx10940-10942).

Appellant took copyrights to make an educational documentary on the subject for public health benefit in 2006-2007, but soon realized due to ***extreme variability*** (as much as 100%) of such substances in natural products, ***complexity*** of varying requirements for individuals (age, gender, diet type, etc.), and ***massive***

misinformation and disinformation in the art on the intake of these substances, a documentary would not be effective. She concluded individualized multi-part preformulated compositions need to be prepared for public health and such solutions would solve multiple public health problems and bring about ***quantum leap of advancement in nutrition and public health***. To finance and effectively implement the solutions she sought patents, resulting in filing of US applications 12/426,034 and 13/332,251 (WO 2009/131939) and 13/877,847 (WO 2012051591) between 2008 and 2013. (Appx10942-10943).

C. Conspiracy and Bad faith Deprivation of Rights from '034 Application

Appellees prefer to issue token patents in nutrition, which obstructs advancement in nutrition science, fosters stagnation, and creates more misinformation and disinformation in the art as parties hype their narrow products, compromising public health (Appx10918-10919). Holding scope of inventions against the Appellant, USPTO abused her previous applications 12/426,034 and 13/332,251. Although '251 application was granted, it was after 10 years drag and compromising the patent claims, implementation, and creating bias against Appellant's business. This Court aided Appellees' abuse of the '034 application refusing to answer almost entirety of Appellant's briefs and 100s of evidence documents submitted including testimony from skilled persons in appeal no. 2016-2525. The resulting opinion *In re Bhagat*, 726 F. App'x 772 (Fed.Cir.2018) is a

travesty of justice[7], contravening 35 U.S.C. §§ 100(b), 101, and 102, and many of Supreme Court's precedents including *Diamond v. Diehr,* 450 U.S. 175, 188 (1981) (the claims must be considered as a whole), *Bilski v. Kappos,* 561 U.S. 593, 603 (2010) ("process" under §100(b) does not require "transformation"), and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576, 577, 595 (2013) (dictated by nature is not the test). A glaring example of the travesty is the review of claim 102, <u>*solely*</u> rejected under §101:

Table 1	
Opening Brief, 58-59	***In re Bhagat,*** Opinion 11
"Examiner has admitted '*Relative to the compositions of Claims 102, 107, and 119, there does not appear to be a naturally occurring counterpart to all of these elements present together in the claimed combination'"* … Claim 102 recites, "**ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1" and that neither WebWOil (mono:poly 1:2.8) (Appx6985) nor WebOOil (mono:poly 7:1)** (Appx6970) meet the limitation."	Applicant **"has not provided adequate evidence that an oil from different sources would necessarily have a composition that is different** from one from the same source…"[8]

Thus, the Court disregarded <u>*specific composition differences*</u> in ratio of monounsaturated fatty acids to polyunsaturated fatty acids in claim 102 versus

[7]Institutions lose credibility when law is differentially applied to the detriment of one party and institutions deteriorate if public does not object.
[8] All emphasis is added, unless otherwise stated.

cited products. The Court similarly improperly rejected about *55 claims* and denied rehearing[9]. Many patent lawyers (unaffiliated with the Appellant) objected including, Brinckerhoff and Dahle[10], Miller[11], Woessner[12], and Graff[13] (Appx13242-13259).

The public and the nation paid the price for atrocious decision in appeal no. 2016-2525 in form of adversity of COVID-19 pandemic on the heels of the case. The '034 application describes viral infections and susceptibility to infections can be mitigated from the disclosed inventions (#2016-2525, J.A. Appx0076, Appx0097) and recent COVID-19 specific investigation upholds Appellants findings and anticipation (Appx7130-7132; Appx7517-7518). Vaccines are useful in emergency, but long-term and broad mitigation of many infectious agents (including agents unknown at present) can be achieved from the implementation of the inexpensive innovations disclosed in the '034 and '847 applications.

The atrocious decision *In re Bhagat* damaged,

(i). the Appellant (ten plus years of Appellant's life, effort, and business

[9] asha-nutrition.com/wp-content/uploads/2018/04/Open-letter-to-USPTO-CAFC.pdf
[10] foley.com/en/insights/publications/2018/03/federal-circuit-finds-composition-of-matter-inelig
[11] oblon.com/publications/in-re-urvashi-bhagat-one-more-decision-denying-patent-eligibility-of-nature-based-product-claims
[12] natlawreview.com/article/re-urvashi-bhagat-slippery-slope-natural-product-claims
[13] swlaw.edu/sites/default/files/2020-04/6%20Graff_Final.pdf

was damaged);

(ii). the patent system (though the Opinion was issued as "non-precedential," but it is now patent policy[14]);

(iii). public health (about 1 million Americans die annually of chronic diseases (heart disease, stroke, and diabetes alone)[15], and 1.1 million Americans died of COVID-19[16]);

(iv). US economy ($4.1 trillion in annual health care cost of chronic diseases[17] and $14 trillion total cost from COVID-19[18]);

(v). guideposts for lower courts (e.g., violations in present action); and

(vi). this Court's, judiciary's, and the US government's credibility[19].

The Appellant has vociferously objected[20] for the foregoing reasons.

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[14]uspto.gov/web/offices/pac/mpep/s2106.html, uspto.gov/web/offices/pac/mpep/mpep-2100.pdf at 2100-48, and *Koganov, Michael.* 13821775(D) (P.T.A.B. Sep. 30, 2019)

[15]cdc.gov/nchs/fastats/deaths.htm

[16]covid.cdc.gov/covid-data-tracker/#datatracker-home

[17]cdc.gov/chronicdisease/about/costs/index.htm

[18]healthpolicy.usc.edu/article/covid-19s-total-cost-to-the-economy-in-us-will-reach-14-trillion-by-end-of-2023-new-research/.

[19]Substantially same claims were granted in 14 countries including Japan, Canada, and South Korea, albeit belatedly because initially they mimicked US actions (asha-nutrition.com/research/intellectual-property/).

[20]https://asha-nutrition.com/wp-content/uploads/2018/09/180829-US2009-Cert-Petition-.pdf, asha-nutrition.com/wp-content/uploads/2019/09/190628Bhagat_SCOTUS_Petition-cert-RFR-final.pdf, asha-nutrition.com/news-media/gallery/, asha-nutrition.com/wp-content/uploads/2019/09/190811LetterToCongress_w_Annexes-compressed.pdf, asha-nutrition.com/wp-content/uploads/2020/06/Doc4-200601-MandRFR2-

D. Conspiracy and Bad faith Deprivation of Rights from '847 Application

Appellees' violations of the Appellant's rights became more tyrannical after abuse of '034 Application. Extensive discussion of conspiracy and bad faith deprivation of Appellant's patent rights from the '847 application is provided in the *1st and 2nd Am.Complaints* filed at the district court (Appx298-299, Appx10984-11016), including:

- Refusing to honor Patent Prosecution Highway Agreements;
- Applying restrictions in violation of Patent Cooperation Treaty;
- Refusing to recognize multiple limitations in multiple claims;
- Refusing disclaimer of natural products to force §101 rejections;
- Refusing to recognize and answer arguments and evidence;
- Senior USPTO officers instructing the examiner to arbitrarily narrow the scope of the claims and necessitating mixing all ingredients in one container that could even harm public health from interactions;
- Refusing to enter expert testimony on record so it would not be available for appeal review;
- Rejecting claims under the pretext of claim numbering order (which should be corrected post allowance);

FINAL-w-APPENDIX.pdf, asha-nutrition.com/wp-content/uploads/2020/06/Doc7-200603-Letter-to-Justices.pdf

- Reconstructing prior art in hindsight to force §103 rejections; and
- Refusing to recognize overwhelming evidence of poorly understood factors, poor expectation of success from prior art, and critical unmet public health need.

Appellant did her utmost to avoid the expensive civil action begging the Chief Judge of Patent Trial and Appeal Board (PTAB) to fairly decide the matter in five petitions, but to no avail (Appx11016-11017). Section 145 action had to be filed at the district court because the Defendants had refused to enter expert testimony on record. During the ***15 years*** of abuse since the Appellant's first application was filed in 2008, the Defendants have caused enormous damage to Appellant's life and business, making the demand for damages and just compensation for Taking necessary.

E. Procedural History at District Court

Table 2 below provides a snapshot of the main proceedings at district court.

Table 2 **Filing (submission) [docketing] Dates[21]**
Original Complaint 12/9/20 (12/8/20) [12/10/20]
1st Am.Complaint 4/19/21 (4/17/21)

[21]Appellant is prohibited from electronic filing, creating up to 10-day delay in docketing for court review. Filing date for Appellant refers to district court mail room receipt date, submission date in () refers to the date Appellant dispatched and emailed the material to the court clerk, and docketing date (if different from filing date) in [] refers to the date the clerk entered the matter on the docket for the case. The relevant dates can be found in the Civil Docket Report (Appx35-45), although it has some errors in filing versus docketing dates.

Appellees' FRCP 12(b)(1), 12(b)(6) Motion to Dismiss	Motion 5/3/21	Opposition 5/24/21 (5/22/21)	Reply 6/1/21	Opinion Order **Granted** 7/22/21	Notice of Mandamus 8/3/21 (7/31/21) [8/4/21]
Answer 8/5/21					
Appellant's Motion for Stay Pending Mandamus **Denied** 4/12/22					
Scheduling Order 7/11/22 (setting Close of discovery to 12/9/22 and Final pretrial conference to 12/15/22)					
Final Joint Discovery Plan 8/11/22					
Scheduling Order 8/11/22 (adapting joint discovery plan)					
Mandamus Petition Not Accepted for Review 10/31/22					
Appellant's Requests for Conference Call for Discovery Enlargement	Emails & Calls 11/20-22/22 12/1/22 12/5/22	Order **Barring** Emails & Calls 12/16/22	Objections 12/21/22 (12/19/22) [12/22/22]	Order **Denied** 12/30/22	Notice of Appeal 1/13/23 (1/10/23) [1/17/23]
Appellees' Motion for Discovery Enlargement	Motion 12/5/22	Opposition None	Reply None	Order **Granted** 12/6/22	
Appellant's Motion for Discovery Enlargement	Motion 12/14/22 (12/11/22) [12/15/22]	Opposition 12/16/22	Reply 12/21/22 (12/19/22) [12/22/22]	Order **Denied** 1/10/23	Notice of Appeal 1/13/23 (1/10/23) [1/17/23]
Appellant's Motion Disqualification of Appellees' Expert	Motion 12/14/22 (12/11/22) [12/15/22]	Opposition 12/19/22	Reply 12/28/22 (12/22/22) [12/29/22]	Order **Denied** 1/17/23	Notice of Appeal 1/30/23 (1/26/23) [2/1/23]
Appellees' Motion for Summary Judgment	Motion 1/20/23	Motion to Strike/Stay 1/31/23 (1/30/23) [2/1/23]	Opposition 2/6/23 Reply 2/9/23 (2/7/23) [2/13/23]	Order MSJ **to be Granted** 2/27/23 Order MSJ **Granted**	Notice of Appeal 2/28/23 and 4/6/23 (3/30/23)

				3/30/23	
Appellant's Motion for Leave to File *2nd Am.Complaint*	Motion 3/15/23 (3/13/23) [3/22/23]	Opposition 3/22/23	Reply 3/28/23 (3/27/23) [3/29/23]	Order **Denied** 3/31/23	Notice of Appeal 4/7/23 (3/31/23) [4/10/23]

SUMMARY OF ARGUMENT

Fifth Amendment of the U.S. Constitution provides "due process of law." "Due process of law requires that the proceedings shall be fair." *Snyder v. Com. of Mass.*, 291 U.S. 97, 116, 137 (1934). Regrettably, the district court failed to provide fair proceedings violating Appellant's due process rights across the board. For the reasons, fully elaborated infra, reversal of nearly all of district court's decisions and orders is required.

I. Dismissal of causes of actions for damages and costs for due process violations in bad faith examination and Taking from regulatory delay should be reversed because district court has jurisdiction under well-paired statutes 28 USC §§ 1331, 1338(a), and 35 USC §145 invoked and sufficiently stated in *1st Am.Complaint* and supplemented in *2nd Am.Complaint*. See *United States v. Testan*, *FHA v. Burr, FDIC v. Meyer, First English, Bell Atlantic, Ashcroft, and Estelle* discussed infra. Appellant's right to jury trial under Seventh Amendment in the §1331 action should be restored.

II. Denial of discovery enlargement should be reversed under *Newell*,

Fitzpatrick, and *Datascope* standards, because district court procedural errors placed higher litigation burden on Appellant, denied legal provision under Fed.R.Civ.P.6(b)(1)(A) to Appellant, and denied discovery enlargement to Appellant while granting it to Appellees, from Appellant's suffering, unfairly affecting the outcome.

III. This Court must reverse admission of Harris testimony because the district court committed harmful legal errors in failing to make relevancy and reliability determinations required by Fed.R.Evid.702 and *Daubert* despite repeated reprimands from Advisory Committee on Rules and appellate courts. Each of *Garcia, Sardis, Gen. Elec., Burkhart, Hall,* and *Wickersham* require this Court to exclude Harris testimony replete with analytical gaps.

IV. Denial of entry of *2nd Am.Complaint* should be reversed under *Foman*, *Pittston*, *Johnson*, and *Edwards* standards because the amendments sought seek proper relief from matters already in the original complaint and clarify jurisdiction, supplement facts from administrative record, and conform complaint to discovery and issues raised about six weeks before in motion for summary judgment. It is a manifest injustice to deny the amendments for proper relief.

V. Summary judgment should have been withheld because of pending appeal, objected testimony, and record rife with disputed facts per Fed.R.Civ.P.56(a)-(c). Nonetheless, summary judgment as to unpatentability fails as a matter of law under

Abbott, Markman, Alice, Mayo, Graham, Continental, Ruiz, ATD, Ormco, and *Loctite* standards, because Appellant's patent claims disclaim products of nature and are drawn to poorly understood factors and solve critical unmet need. The judgment should be reversed and ordered in favor of Appellant on patentability.

VI. This Court should consider just and suitable relief for district court's failure to provide unbiased judges in the proceedings considering consistent refusal to consider Appellant's pleadings and briefs and reflexive denial of relief.

STANDARD OF REVIEW

In patent appeals, this Court applies the law of the regional circuit, here the Fourth Circuit, to issues not unique to patent law. *Berkheimer v. HP Inc*., 881 F.3d 1360, 1365 (Fed.Cir.2018). The Fourth Circuit reviews *de novo* both questions of statutory interpretation, *United States v. Abugala*, 336 F.3d 277, 278 (4th.Cir.2003), and legal determinations, *El-Masri v. United States*, 479 F.3d 296, 302 (4th.Cir.2007). Standard of review applicable to specific issues is provided before the argument in the following section.

ARGUMENT

I. DUE PROCESS VIOLATIONS IN DISMISSING CAUSES OF ACTION AND JURY TRIAL DEMAND

A. Standard of Review

A decision on a motion to dismiss under Fed.R.Civ.P.12(b)(1) for lack of

subject matter jurisdiction is an issue of statutory interpretation reviewed with plenary determinations. *Hunter Douglas, Inc. v. Harmonic Design, Inc*., 153 F.3d 1318, 1325 (Fed.Cir.1998). A decision on a motion to dismiss under Fed.R.Civ.P.12(b)(6) for failure to state a claim upon which relief can be granted is an issue of law reviewed *de novo*. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1134 (Fed.Cir.1995). This Court reviews Seventh Amendment constitutional right to jury trial as a matter of law. *In re Lockwood*, 50 F.3d 966, 969-970 (Fed.Cir.1995).

B. District Court Violated Appellant's Right to Justice in Dismissing Causes of Action to Damages and Taking

District Court has Jurisdiction to Try Damages from Due Process Violations:

The opinion below improperly states, "Congress has not waived its sovereign immunity for money damages in actions brought pursuant to 35 U.S.C. S 145," (Appx2-3), because Appellant expressly invoked jurisdiction under well-paired statutes 28 USC §§ 1331, 1338(a), and 35 USC §145 (Appx304) for damages for due process violations in bad faith examination, just compensation for regulatory delay, and to obtain patent (Appx298-300), and so emphasized in opposition to dismiss asserting statutes can be paired for money damages per Supreme Court precedent in *United States v. Testan*, 424 U.S. 392, 398 (1980) (Appx542-547; Appx524-619). Further, Fed.R.Civ.P.8 merely requires, "a short and plain statement of the grounds for the court's jurisdiction," not citation of statute, which

can be inferred from the explicit statements in the pleading.

Here expressly invoked §1331 ***specifically*** confers jurisdiction upon district courts for significant federal interest and constitutional standing matters providing, "The district courts shall have original jurisdiction of ***all*** civil actions arising under the Constitution, laws, or treaties of the United States," i.e., not some or most—but ***all***. Further, the Historical Revisions and Editorial Notes to §1331 confirm the statute is legislated to include "actions brought against the United States, any agency thereof, or any officer or employee thereof in an official capacity" without limitation on the amount in controversy. Accordingly, district court has subject matter jurisdiction for the action arising from conspiracy and bad faith deprivation of constitutionally protected rights to discoveries under Article I, Section 8, Clause 8 and resulting injuries to Plaintiff's life and business from violation of due process of law and Taking of Plaintiff's property without just compensation under the Fifth Amendment, that is likely to be redressed by a favorable judicial decision. The action properly seeks monetary relief under §1331, U.S. Const. Article I, Section 8, Clause 8, and the Fifth Amendment's Due Process and Takings clause. Rights to discoveries are "property for purposes of the Due Process Clause or the Takings Clause." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018).

The Supreme Court has repeatedly held "when a federal court has jurisdiction,

it also has a 'virtually unflagging obligation . . . to exercise that authority.'" *Mata v. Lynch*, 576 U.S. 143, 150 (2015).

Further, *FHA v. Burr*, 309 U.S. 242, 245-246, 250 (1940) held, "when Congress establishes such an agency, authorizes it to engage in commercial and business transactions with the public, and permits it to 'sue and be sued,' it cannot be lightly assumed that restrictions on that authority are to be implied," "that agency is not less amenable to judicial process than a private enterprise under like circumstances would be," and "Waivers by Congress of governmental immunity from suit in the case of such federal instrumentalities should be construed liberally." *Id.* 245-246, 250. Furthermore, in *FDIC v. Meyer*, 510 U.S. 471, 475 (1994) Supreme Court upheld its ruling in *FHA v. Burr* stating, "Because the claimant in each of these cases was seeking to hold the agency liable just like "any other business," [Federal Housing Administration, Franchise Tax Board, and U.S. Postal Service], it was only natural for the Court to look to the liability of private businesses for guidance. It stood to reason that the agency could not escape the liability a private enterprise would face in similar circumstances." *Id.* 482-483.

USPTO is clearly a "sue-or-be-sued" agency, which is spelled out in 35 U.S.C. §145 providing "remedy by civil action." Congress' intent in §145 leaves the possibility of money damages, unlike 5 U.S.C. §702 providing "relief other than money damages." Thus, §145 can be paired with other statutes for money

damages, such as §1338(a) and §1331, as Appellant did in the *1st* (and *2nd*) *Am.Complaint*.

District Court has Jurisdiction to Try Compensation for Regulatory Taking:

The opinion below improperly states,

> "The Tucker Act waives sovereign immunity with respect to non-tort monetary damage claims, such as violations of the Takings Clause of the Fifth Amendment, against the United States. But "a claim for just compensation under the takings clause must be brought to the Court of Federal Claims in the first instance." ***E.*** *Enters. v. Apfel*, 524 U.S. 498, 520 (1998)." (Appx3)

Title 28 U.S.C. §1491 ***does not mention specific or exclusive*** jurisdiction to the Court of Federal Claims to render judgment on the Fifth Amendment's Due Process or Takings clauses. Waiver of sovereign immunity is ***self-executing*** in Constitutional provision for just compensation for Takings, such as when regulation goes too far. See *First English Evangelical Lutheran Church v. Cnty. of Los Angeles*, 482 U.S. 304, 314-316 (1987); *San Diego Gas & Elec. Co. v. City of San Diego*, 450 U.S. 621, 654 (1981) (Brennan, J., dissenting); *Jacobs v. United States,* 290 U.S. 13, 15 (1933). Further, there is ***judicial economy*** in adjudicating the causes to damages and Taking with §145 action because the causes are interrelated and interdependent.

In 2019, Supreme Court clarified "Tucker Act is not a prerequisite to a Fifth Amendment takings claim," stating "A party who loses a Tucker Act suit has nowhere else to go to seek compensation for an alleged taking," and opined that

parties could pursue takings claims in federal courts. *Knick v. Township of Scott*, 139 S. Ct. 2162, 2174 (2019). *Knick* cancels inapposite decision in *E. Enters.*, a splintered decision on an unrelated matter (unconstitutional Congressional Act), which led to circuit split. *McCarthy, et al. v. City of Cleveland*, 09-4149 (6th.Cir.2010)[22]. The Solicitor General also argued in *Knick* as amicus curiae advising the Supreme Court "inverse condemnation claims 'aris[e] under" federal law and can be brought in federal court under §1331 through the *Grable* doctrine. See *Knick* brief for United States as *Amicus Curiae* 22–24. Previously also in *Duke Power Co. v. Carolina Environmental Study Group*, 438 US 59, 71 (1978) Supreme Court held, a Takings claim can be brought under §1331 federal question jurisdiction.

Accordingly, the District Court erred in dismissing the monetary damages claim and Takings claim because the court has jurisdiction at least under well-paired statutes, 28 U.S.C. §§ 1331, 1338(a), and 35 U.S.C. §145; §1331 is legislated to include actions against the United States and its agencies without limitation on the amount; USPTO is a "sue and be sued agency" waiving the agency's sovereign immunity; sovereign immunity does not shield bad faith actions of the government; and a waiver of sovereign immunity for Taking claims is unnecessary.

[22] https://caselaw.findlaw.com/court/us-6th-circuit/1544179.html at 7.

C. District Court Violated Appellant's Right to Justice in Dismissing Causes of Action to Bad Faith Deprivation of Constitutional Rights to Discoveries and Declaratory and Injunctive Relief Refusing to Recognize Most of the Complaint

The opinion below improperly states,

> "The [1st] Amended Complaint includes no facts supporting the conclusion that the USPTO violated Plaintiff' s constitutional rights," "that the USPTO made false statements or acted with misconduct," and "that Plaintiff is plausibly entitled to mandamus relief." (Appx5-6).

In stating the foregoing, the district court refused to recognize the entirety of the Complaint, specifically the immediate context in: (1) paragraphs 2-3, 36-37, 40-41, 45, 48-49, 55, and 56-63 providing facts that the right to patents is grounded in the US Constitution, which was violated by USPTO bad faith objections, refusal to recognize arguments and evidence submitted, refusal to enter evidence on record, and misconduct and false statements ***contradicting the record***; (2) paragraphs 11 and 46 asserting USPTO has tried to force Appellant to accept an extremely narrow patent which would have compromised the innovations; and (3) paragraph 13 and Prayer for Relief (b), (c), (d), and (f) specifying declaratory and injunctive relief requested (Appx298-318). Further, the allegation of lack of plausibility is hollow because having exclusive jurisdiction over §145 the court ***knows administrative record contains full prosecution history***. Furthermore, by dismissing the causes of action the court ***foreclosed*** revealing of evidence in discovery and complaint amendments, particularly in response to ***new defenses***

raised (new grounds of rejection and new art citations) by Appellees, necessitating ***new reasons*** for declaratory, injunctive relief, and mandamus relief. (Appx10952-10957; Appx11022-11023).

Thus, the district court refused to honor each of the following pleading standards: Fed.R.Civ.P.8(a)(2) and (e) requiring "short and plain statement of the claim showing that the pleader is entitled to relief"; "Pleadings must be construed so as to do justice;" *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 556 (2007) "plausible grounds [] does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence;" and *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009), "court can draw reasonable inferences from pleadings for the alleged misconduct."

Further, the district court disregarded the Supreme Court instruction to construe pro se pleadings liberally. *Estelle v. Gamble,* 429 U. S. 97, 106 (1976).

Furthermore, the district court's unfairness and prejudice against Appellant in dismissing the causes of action is confirmed by denial of motion to file *2nd Am.Complaint*, which provides ***extensive citations to administrative record supporting the conclusion the USPTO violated Plaintiff' s constitutional rights***, USPTO's misconduct and false statements, and provides specific reasons and form of necessary declaratory, injunctive, and mandamus relief (Appx10984-11015;

Appx11022-11023). Thus, the district court made excuses to violate the Plaintiff's rights.

Therefore, the dismissal of causes of actions should be reversed, because (1) the court refused to recognize the facts before it, (2) the court refused to apply the correct legal standard, and (3) the court refused to accept complaint amendments providing further facts and reasons for the requested relief.

D. District Court Refused to Recognize Seventh Amendment Right to Jury Trial Under §1331

The U.S. Constitution Seventh Amendment language puts forth right of trial by jury not as suggestion but a requirement, and any fair examination of the history reveals the substitution of government agencies for juries is flatly unconstitutional. Also see Fed.R.Civ.P. 38, 39, and 28 U.S.C. §1861.

Suits against government for money are commonly tried by jury, if demanded. *Law v. United States*, 266 U.S. 494, 496 (1925); *Hepner v. United States*, 213 U.S. 103, 115 (1909); *United States v. Regan*, 232 U.S. 37, 47 (1914).

There is no bar in 28 U.S.C. §§ 1331, 1338(a) and 35 U.S.C. §145 for jury trial. The USPTO is a "sue and be sued" agency that should be held to the same standards as a private corporation, as per Supreme Court precedents. *FHA v. Burr* 245-246, 250 and *FDIC v. Meyer* 482-483. Therefore, the Appellant has a right to jury trial as it would against a private enterprise.

The striking of jury trial should be reversed, especially because the district court

demonstrated bias failing to provide fair proceedings discussed in this paper.

II. DUE PROCESS VIOLATIONS STACKING PROCEDURE AGAINST UNREPRESENTED PARTY VIOLATING EQUAL ACCESS TO JUSTICE AND EQUAL PROTECTION OF THE LAWS UNFAIRLY AFFECTING OUTCOME

A. Standard of Review

Procedural errors that unfairly affect the outcome cannot be ignored. *Newell Co. v. Kinney Mfg. Co., 864 F.2d 757, 765* (Fed.Cir.1988). Appellate court will not defer at all in cases when the trial tribunal establishes a new legal principle. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 449-50, 456 (1976). "[a] manifest or clear error of judgment occurs 'only if we `come close to finding that the trial court had taken leave of its senses." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 828 (Fed.Cir.1989).

B. District Court Violated Appellant's Right to Equal Access to Justice Differentially Requiring Paper Filings from Appellant Reducing Her Discovery Time by About 10% Unfairly Affecting the Outcome

The district court prohibits unpresented parties, as the Appellant, from electronic filing and communications without motion[23]. The Appellant complied with paper procedure utilizing express delivery service throughout the proceedings and alerted the court via emails including delivery tracking information to expect the paper filings. However, the usurpation of time in printing (such as for large

[23] vaed.uscourts.gov/sites/vaed/files/EDVACOMPLETEProSeHandbook_7-26-22.pdf (7, 14).

filing of over 500 pages) and dispatch, delay in transit[24] and docketing (Table 2 supra), and docketing errors by clerk requiring ***more*** paper filings for correction has been ***unfair*** to Appellant (Appx670, Appx8187-8188), especially because of short discovery of four months and short motion schedule requiring quick response and hearings within 1-3 working days (Appx6954, Appx6957-6958). Provision for printing, dispatch, and transit at times leaves no time for substantive drafting. Additionally, over the course of litigation, cumulative extra time taken in paper filings shortens time available for substantive matters. Appellant estimates during the scheduled discovery period from August 10, 2022, to December 9, 2022, about ***12 days or 96 hours*** were usurped due to paper filings (printing, dispatch, follow up to ensure receipt and prompt docketing, and requests to correct docketing errors, without counting transit time and docketing delays) (Table 2 supra). Consequently, Appellant was provided about ***10% less discovery time*** than Appellees. Unrepresented parties are generally given extra time for drafting (Local Rule 7(K)[25]), but here the district court gave less time to the pro se Appellant.

Further, as evidenced by Table 2, Appellant's paper filings are filed (received in mailroom) up to 6 days after dispatch (exacerbated by Holidays and weather[26]) and

[24]Appellant is located 3000 miles from the court.
[25]https://www.vaed.uscourts.gov/sites/vaed/files/Local%20Rules%20EDVA%20Jan%2018%202023.pdf
[26] https://en.wikipedia.org/wiki/December_2022_North_American_winter_storm

docketed up to 7 days after receipt. As a result, some of Appellant's filings were made available to court after the hearing (Appx38-39, compare #53 with #57) or late, e.g., *2nd Am.Complaint* dispatched on March 13, 2023, was received in mail room on March 15, 2023 and docketed on March 22, 2023 (Appx43-44).

Appellant objected to the differential paper filing requirements and requested the court should either permit her to file electronically or allow her to email the documents to the clerk for docketing for equal access to justice (Appx8186-8188), but the requests were denied (Appx11-12) in ***manifest injustice*** (Fed.R.Civ.P.16(e)).

During the scheduled pre-trial discovery period, the approximately 12-day cumulative usurpation of Appellant's time due to paper filings unfairly affected the outcome because of progressive delay of series of substantive matters, including,

- precluded Appellant's timely completion of discovery (discussed infra);
- impeded her full opposition to motion for summary judgement (discussed infra); and
- delayed the filing of her motion for *2nd Am.Complaint* (discussed infra).

Therefore, the differential paper filing requirement by the district court is manifest injustice, it ***unfairly affected the outcome***, it cannot be ignored. *Newell* 765. This Court must reverse and remand with an order to enlarge discovery and to either accept electronic or email filings from Appellant going forward or

proportionately extend discovery and motion schedule for her.

C. District Court Established a New Erroneous Legal Principle Contrary to Fed.R.Civ.P.6(b)(1)(A) Refusing to Accept Appellant's Oral and Email Requests for Discovery Conference Call Unfairly Affecting the Outcome

November 20-22, 2022, Appellant telephoned and emailed the district court informing the court of ***medical emergency*** of one of her experts, requesting conference call with Appellees to enlarge discovery because paper motions would not reach the court in time to obtain ruling on the matter before the expert rebuttals ***due on November 25, 2022*** (November 24th being Thanksgiving). The emails also notified the court discovery close of December 9, 2022, and Final Pretrial Conference of December 15, 2022, also needs to be discussed in the conference call due to the illness and discovery abuses by Appellees. Receiving no response, the Appellant called and emailed the court again December 1st and 5th informing the court of ***second medical emergency*** in family of Appellant's second expert, requesting conference call and stressing paper motion will not enable resolution before ***discovery close on December 9, 2022***. (Appx7292-7294). She also notified the Appellees of her requests to the court to set a conference call for discovery enlargement.

Magistrate Judge responded to Appellant's email and phone requests for conference call on December 16, 2022, with order barring ***all*** email and phone communications from the Appellant (Appx9-10).

Appellant objected to the order in accordance with Fed.R.Civ.P.72(a) and 28 U.S.C. §636(b)(1)(A) within 14 days (Appx8188-8189) asserting,

(i) Fed.R.Civ.P.6(b)(1)(A) provides "the court may, for good cause, extend the time" "with or without motion or notice if the court acts, ***or if a request is made***, before the original time or its extension expires", therefore law provides that a request ***can be made*** without paper motion for good cause (see similar provision in Local Rule 26(B)); and

(ii) Fed.R.Civ.P.83 requires local rule must be consistent with federal rules therefore, the order requiring ***all*** requests on paper is erroneous violating Fed.R.Civ.P.6(b)(1)(A) and 83.

However, contrary to Fed.R.Civ.P.72(a) and 28 U.S.C. §636(b)(1)(A), which require ***district judge*** in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law, Magistrate Judge issued another order on December 30, 2022, upholding the previous order. (Appx11-12).

Fed.R.Civ.P.6(b)(1) provides the district court discretion to extend time, but Fed.R.Civ.P.6(b)(1)(A) ***requires accepting the request*** for good cause without filing a paper motion before the due date**.** The district court orders (Appx9-12) establish a new legal principle violating Fed.R.Civ.P.6(b)(1)(A).

Supreme Court has directed appellate courts to ***not defer at all*** in cases when

the trial tribunal establishes a new legal principle. *Fitzpatrick* 449-50, 456. Accordingly, this Court must decide without deferral whether district court order barring ***all*** email and phone communications, even in emergency, contravene 28 U.S.C. §2071 and Fed.R.Civ.P.6(b)(1)(A) and 83.

Further, the error by the district court in establishing a new legal principle contravening Fed.R.Civ.P.6(b)(1)(A) did ***unfairly affected the outcome*** because the district court refused to recognize timely requests made by emails and telephone for good cause, subsequently denied the paper motion under the pretext of untimely and lacking excusable neglect (Appx13-15), therefore the error cannot be ignored as per *Newell* 765. This Court must reverse and remand with an order to accept timely oral and email motions for good cause and enlarge discovery.

D. District Court Has Lost Senses—Discovery Enlargement Stemming from Medical Emergency Among Appellant's Experts Was Granted to Appellees but Denied to Appellant—Unfairly Affecting the Outcome

This Court said in *Datascope* "a manifest or clear error of judgment occurs 'only if we `come close to finding that the trial court had taken leave of its senses." *Id.* 828. Here the district court has clearly lost its senses, having buried the Appellant under extra paper filing burden (discussed supra) and rebuffed her timely emails and phone calls for discovery conference call for good cause/extraordinary circumstances of medical emergency, and in face of demonstration that the discovery schedule cannot be met despite her diligence

(Appx8222-8230), enlarged discovery for the Appellees on account of illness among ***Appellant's*** experts but ***denied same relief to Appellant*** under the pretext that paper motion was late and good cause (diligence) was not shown largely refusing to recognize the diligence shown in the paper motions (Appx13-15).

On November 20, 2022, Appellant's expert Dr. Kent Erickson was in emergency room for chest pains and related issues, and on November 27, 2022, her expert Dr. Undurti Das had to leave for India to provide his wife immunotherapy infusions that he could better administer in India (Appx7286).

On December 5, 2022, the Appellees filed unopposed motion for 30-day enlargement of discovery to depose Dr. Das. The district court promptly granted the motion the ***very next day*** on December 6, 2022, extending close of discovery to January 6, 2023, and continuing the final pre-trial conference to January 12, 2023 (Appx39).

Because Appellant's November 20-December 5 emails and calls for conference call to discuss discovery enlargement were rebuffed, on December 11, 2022, she dispatched and emailed paper motion to court (filed on December 14th and docketed on December 15th) for 13-day extension of time from November 25, 2022 to disclose rebuttals to Defendants' expert report, and 60-day discovery enlargement from December 9, 2022 to complete discovery (meet and confer, compel discovery, and take depositions) because **(1)** illness among Appellant's

experts, **(2)** extra time required in paper filings (discussed supra), and **(3)** discovery abuses by Appellees (111-pages forced expert report mutilating claims and massively reconstructing prior art, and extensive objections to written discovery) had prevented Appellant from completing discovery, despite her diligence (Appx7275-7288).

Appellant provided the district court a proposed order with blank spaces where the district court could insert ***narrower*** discovery enlargement such as less than 60 days (Appx7271).

On December 16th the district court issued the order barring all email and calls from the Appellant citing her motion for enlargement and email requests (Appx9-10). Subsequently, the court waited ***26 days*** and on January 10, 2023, at about 4pm EST, ***1 day before*** the final pre-trial conference on January 12, 2023 at 10am, issued the order denying discovery enlargement and continuance of final pre-trial conference knowing full well that last-minute order would make it impossible for the Appellant located on the west coast to prepare for and attend the pre-trial conference on the east coast (Appx13-16). Waiting 26 days until the last day to issue the order is another example of stacking procedure against the unrepresented party.

Thus, in accordance with Fed.R.Civ.P.6(b)(1)(A) and 16(b)(4), and Local Rules 16(B) and 26(B), Appellant timely requested discovery conference by email and

telephone November 20-22, and December 1-5, 2022, *before* November 25th and December 9th deadlines, dispatched paper motion on December 11, 2022, demonstrated diligence in executing discovery from July 2022 to December 9, 2022, worked round the clock and met most deadlines, and demonstrated that the schedule "cannot reasonably be met despite the diligence of the party seeking the extension," (Appx8220-8229) which is good cause to modify the schedule. Fed.R.Civ.P.16 Advisory Comm.'s Notes (1983 Amendment); and *Cook v. Howard*, 484 F.App'x 805, 815 (4th.Cir.2012).

The district court lost its senses and was unfair,

(1) in waiting till the last day before final pre-trial conference to issue the order on discovery enlargement; and

(2) in denying discovery enlargement to Appellant while granting to Appellees although Appellant had to endure medical absence of her experts and had worked diligently to meet the oppressive burdens placed on her by the Appellees and the court.

The district court's actions unfairly affected the outcome, in that Appellant could not attend the final pre-trial conference and discover further information from written and oral discovery necessary for trial preparation.

Therefore, the district court clearly erred, and the errors cannot be ignored because they unfairly affected the outcome. *Datascope* 828; *Newell* 765.

Therefore, this Court must reverse and remand with an order to enlarge discovery by 60 days, or as considered just and reasonable by this Court.

III. DUE PROCESS VIOLATIONS IN FAILING TO CONSIDER JUDICIALLY RECOGNIZED FACTORS TO EXCLUDE APPELLEES' EXPERT TESTIMONY, FAILING TO EXCLUDE THE INADMISSIBLE TESTIMONY, COMMITTING HARMFUL LEGAL ERROR

A. Standard of Review

Fourth Circuit, reviews "district court's decision [] on the admissibility of expert testimony for abuse of discretion." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 958 (4th.Cir.2020). "[W]e review a district court's abdication of its gatekeeping role for harmless error and require a new trial 'only when the admission of evidence affected the substantial rights of a party.' *Wickersham v. Ford Motor Co., 997 F.3d 526, 531 (4th.Cir.2021)*." *Sardis v. Overhead Door Corp.,* 10 F.4th 268, 283 (4th.Cir.2021).

B. Admission of Harris Testimony Must Be Reversed Because District Court Committed Harmful Legal Errors in Failing to Make Relevancy and Reliability Determinations Required by Fed.R.Evid.702 and *Daubert*

With her motion to disqualify Dr. Harris, Appellant presented strong grounds for ***inadmissibility*** with about 33-page briefing and about 500-page evidence (Appx7298-7304; Appx7309-7762; Appx8241-8292; Appx8297-8299)[27], asserting,

[27] It is not possible to list all facts here because of the word limit imposed on this brief, the number of issues on appeal, and the denial of request to enlarge the brief

"Dr. Harris' opinions and testimony ***lack any indicia of admissibility*** under *Daubert* [*v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)] and the Federal Rules of Evidence 104, [402], 403, 405, 406, and 702" (Appx8242) including:

1. *Inadmissible for Irrelevance and Unreliability Under Fed.R.Evid.702:* Dr. Harris has significant conflict of interest and financial interest in testifying against the patentability of '847 application. His company OmegaQuant (https://omegaquant.com/about/, https://omegaquant.com/shop/) operates in the same space and he draws consulting income from several companies that market fatty acids. His opinions tainted by self-interests are *irrelevant and unreliable*.

2. *Inadmissible for Failing All Fed.R.Evid.702 Tests*: Harris testimony (a) will not help the trier of facts to understand facts, (b) is not based on sufficient facts or data, (c) is not product of reliable principles or methods, and (d) has not reliably applied the principles and methods to the facts. The testimony is ***fausse*** as he failed to recognize multiple explicit disclosures and claimed limitations in the '847 application, he massively reconstructed and culled prior art to allege obviousness (Appx8264-8292), ***his testimony contradicts his own published statements post-2010 stating omega-6 fatty acids, antioxidants, and phytochemicals intake are poorly understood*** (Appx7695-7714) he contradicted himself within his testimony,

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(ECF.No.16). The Court is requested to refer to briefing and evidence submitted to the district court for further details.

and he did not assess secondary considerations for obviousness analysis.

3. Inadmissible for Failing Fed.R.Evid.402 Test "Irrelevant evidence is not admissible:" Harris testimony is irrelevant because he imposes his interpretation of law on assessment of priority, claim interpretation, obviousness, and unexpected results.

4. Inadmissible for Failing Fed.R.Evid.403 Tests: Harris testimony creates unfair prejudice because it misleads and seeks to sow confusion by mutilating each of Plaintiffs disclosure, claims, state of the prior art, and the law. It has caused and will cause further undue delay and waste of time. Appellant's ***unpaid*** experts have declared Harris testimony to be "insincere", "illogical", "absurd", "misrepresent[ations]", "offensive", "lack[ing] application of mind", and "dishonest." (Appx8255). Therefore, harm from admission of Harris testimony significantly outweighs any probative value.

5. *Inadmissible for Failing Fed.R.Evid.405-406 Tests*: Dr. Harris has a habit of issuing opinions motivated by financial interests[28], without regard to public health. He has promoted high omega-3 and high antioxidant intake most of his career which the '847 application teaches against, and ***he admitted in his post-2010***

[28]Dr. Harris was also part of Health Diagnostics Laboratory (HDL) (7716), and his company OmegaQuant sold research assays to HDL (en.wikipedia.org/wiki/William_S._Harris), and HDL is known to have bribed doctors to send business their way (https://www.medpagetoday.com/publichealthpolicy/ethics/59098).

publications that omega-6, antioxidants, and phytochemical intake is not well-understood (Appx7695-7714) (correct dosages of which are taught and claimed in the '847 application), yet, in his paid subject testimony he did a complete about-face from his published opinions to allege the claims as obvious (Appx7464-7466; Appx7592-7594).

Without responding to the arguments contesting admissibility, failing to consider judicially recognized factors constraining its exercise of discretion, and without providing factual and legal reasons for the conclusion, the district court denied the motion to exclude Harris testimony in a single sentence, ***making no relevancy and reliability determinations***, relegating entirety of Appellant's arguments to "weight of the expert's testimony, not admissibility," (Appx17) despite that Appellant challenged both relevancy and reliability of Harris testimony.

According to series of precedents Harris testimony should be excluded, including *Garcia v. Johanns*, 444 F.3d 625, 635 (D.C.Cir.2006) (rejecting statistical analyses as "analytically flawed because they did not incorporate key relevant variables connecting disparate impact to loan decisionmaking criteria"); *Sardis* 290 and *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the

expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *Burkhart v. Wash. Metro. Area Transit Auth*., 112 F.3d 1207, 1213-14 (D.C.Cir.1997) (affirming exclusion of expert [], because it constituted an impermissible legal conclusion); and "The burden of laying a proper foundation for the admissibility of an expert's testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." *Hall v. United Ins. Co. of America*, 367 F.3d 1255, 1261 (11th.Cir.2004) (citation omitted) (incorporated in Fed.R.Evid.702 itself effective December 2023). See Corrected Prior Art Tables demonstrating analytical gaps in Harris opinion (Appx8264-8292).

Fed.R.Evid.702 and *Daubert* require district judges to perform, a "gatekeeping role" to determine whether proposed expert testimony "rests on a reliable foundation and is relevant to the task at hand." *Id.* 597. Fourth Circuit in *Sardis* reaffirmed *Daubert*, and sent a strong message to district courts to stop punting gatekeeping function on the theory that the opinions' deficiencies bear on the weight—and not the admissibility, holding,

> "When a party challenges an opposing expert's testimony as irrelevant, the court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is "a precondition to admissibility." *Daubert,* 509 U.S. at 592 []. And if that expert's proffered evidence is further alleged to be unreliable, then "the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of the relevant discipline.'" *Kumho Tire*, 526 U.S. at 149 (alteration omitted) (quoting *Daubert*, 509 U.S. at 592). While district courts have "broad discretion" in analyzing reliability, "such discretion

> does not include the decision 'to abandon the gatekeeping function.'" *Nease*, 848 F.3d at 230 (quoting *Kumho Tire*, 526 U.S. at 158–59 (Scalia, J., concurring)). "Rather, it is discretion to choose among reasonable means of excluding expertise that is *fausse* and science that is junky." *Kumho Tire*, 526 U.S. at 159 (Scalia, J., concurring)." *Sardis* 282.

Advisory Committee on Evidence Rules has also amended Fed.R.Evid.702 notes directing, "[U]nfortunately many courts have held that the critical questions of the sufficiency of an expert's basis [for his testimony], and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment." *Sardis* 283.

"Where the admissibility of expert testimony is specifically questioned, Rule 702 and *Daubert* require that the district court make ***explicit findings***, whether by written opinion or orally on the record, as to the challenged preconditions to admissibility." *Sardis* 283. In the present case, "Just as in *Nease*, "[t]he court did not use *Daubert*'s guideposts or any other factors to assess the reliability of [Dr. Harris] testimony, and the court did not make any reliability findings." 848 F.3d at 230. Instead, it reflexively "[found] that [Plaintiff's objections] go to the weight [of the expert's] testimony, not [] admissibility." *Id.* at 230–31. By doing so, the court "abandoned its gatekeeping function," thereby abusing its discretion. *Id.* at 230." *Sardis* 282 (modified to reflect current case).

Further, the district court's error was ***harmful*** because the court relied on Harris

testimony explicitly in granting the summary judgement alleging,

> "As Defendants' expert witness Dr. William S. Harris explained, in addition to being obvious over Morris and Anthony the benefits of consuming the claimed nutrients were well-known in the art as of 2010. This is reflected in an additional three combinations of references..." (Appx31)

The error was ***also harmful*** because Harris testimony created unfair prejudice against the Appellant, in that the district court explicitly and implicitly followed the Harris testimony in its opinion and decision granting summary judgment for the rejection of claims of the '847 Application, such as by the *same* mutilation of the disclosure and claims (Appx7352), *same* reconstruction of prior art to allege obviousness under §103 (Appx7359-7363), and *same* grounds of rejection under §101 citing same art "almonds," as suggested by Harris testimony not cited in USPTO examination (Appx7342-7349).

Had the district court faithfully executed its Fed.R.Evid.702 and *Daubert* responsibilities before granting the summary judgement, "[Fourth Circuit] precedent would have compelled it to exclude [Harris] experts' testimony." *Sardis* 279. And without the Harris testimony, the Appellees failed to meet their evidentiary burden on causes of action in this case including patentability. For example, without Harris testimony evidentiary support for medically complex issues such as "widely divergent conditions and diseases" (Appx21) and "well-known [in the art]" (Appx31) is absent. See *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 646

(4th.Cir.2018), ("all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience").

Therefore, the admission of Harris testimony was a harmful error that compromised Appellant's substantial rights. *Wickersham* 531. Therefore, this Court must reverse district court's admission of Harris testimony.

IV. DUE PROCESS VIOLATION AND HARMFUL ERROR IN FAILURE TO CONSIDER FACTS AND CIRCUMSTANCES FOR RELIEF IN PENDING 2nd AMENDED COMPLAINT

A. Standard of Review

"Rule 15(a) declares that leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded. *See generally*, 3 Moore, Federal Practice (2d ed. 1948), §§ 15.08, 15.10. If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Also see *Johnson v. Oroweat Foods Co.,* 785 F.2d 503, 509 (4th.Cir.1986); *Pittston Co. v. U.S.,* 199 F.3d 694, 705 (4th.Cir.1999); *Edwards v. City of Goldsboro*; 178 F.3d 231, 240-243 (4th.Cir.1999).

B. District Court Disregarded Supreme Court Mandate to Enter *2nd Am.Complaint*

Appellant's motion for leave to file *2nd Am.Complaint* was filed on March 15, 2023 (Appx10908), for clarity and conformation to evidence on administrative record and crystallized during discovery and to new issues injected by Appellees in

the motion for summary judgment on January 20, 2023. In an unlawful act, the district court first granted Appellees' motion for summary judgment on March 30, 2023, without considering the underlying facts and circumstances relied upon by the Appellant for proper relief in the *2nd Am.Complaint*, then the very next day on March 31, 2023, the district court denied the motion to file the amended complaint without justifying reasons, under the pretext that the case is dismissed (Appx34).

The law is well settled, absent "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment," "leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded." *Foman* 182; *Pittston* 705; *Johnson* 509; *Edwards* 240-243. Delay alone is an insufficient reason to deny leave to amend. *Id.* Rather, the delay must be accompanied by prejudice, bad faith, or futility. *Id.*

There is no prejudice to the Appellees because the amendments sought here derive from matters already contained in some form in *1st Am.Complaint* (filed and automatically entered before the Appellees' filed their answer), evidence on administrative record and from discovery, and issues raised for the first time in motion for summary judgment filed on January 20, 2023, see table at Appx13901-13903. Further, the amendments merely clarify jurisdiction under 28 USC §1331

for adjudication of Plaintiff's constitutional rights to discoveries, due process, and just compensation for taking of her property and supplement facts to bad faith deprivation of patent rights, *already invoked in original complaint*. There is no alleged bad faith and no previously allowed amendments. Furthermore, *2nd Am.Complaint* would also not be futile. "Leave to amend . . . should only be denied on the ground of futility when the proposed amendment is clearly insufficient or frivolous on its face." *Johnson* 510.

Under similar circumstances as here, Fourth Circuit has reversed denial of amendments to complaint, requested about *17 months* after the original complaint was filed and after original complaint *had been dismissed*. *Edwards* 240-243; also *Pittston* 705; *Johnson* 509.

C. District Court Committed a Harmful Error in Denying the Entry of *2nd Am.Complaint* Violating Appellant's Right to Conform Complaint to Underlying Facts and Circumstances for Proper Relief on Merits

The denial of the entry of *2nd Am.Complaint* is clearly a ***harmful error*** because it denies the "opportunity to test [Plaintiff's] claim[s] on the merits" of specific "underlying facts [and] circumstances relied upon by a plaintiff may be a proper subject of relief" requested in the *2nd Am.Complaint* such as declaratory and injunctive relief to allow amendment of priority and pending claims considering new rejections raised in the motion for summary judgment, and to supplement facts from administrative record to bad faith deprivation of rights to discoveries

(Appx13900-13910). It cannot be ignored. *Foman* 182.

The Appellees injected new issues into the civil action, during discovery such as in Harris testimony served on November 9, 2022 (e.g., priority issues) (Appx10957), and in the motion for summary judgement filed on January 20, 2023 (e.g., new prior art citations; Appx13901-13903). There were no 35 U.S.C. §101 rejections in examiners' and PTAB Decision (Appx6487-6488); although §101 was injected as a defense in Appellees' Answer filed on August 8, 2021, but without cited art and specific claims implicated. Section 101 rejections over "almonds" and 103 rejections over *Debbouz, Rusing, Howard, Rath, Barker*, and *OIG Label Report* are new rejections vaguely raised during discovery (November-December 2022), but with particularity in the motion for summary judgement filed on January 20, 2023 (Appx8359-8370).

Thus, Appellees have injected new issues since the filing of 1st *Am.Complaint* in their motion for summary judgment. These points were noticed in the *2nd Am.Complaint* itself (Appx10953; Appx10957). Clearly, the Plaintiff has a right to amend the Complaint to conform to new issues injected by the Appellees including to request corresponding declaratory and injunctive relief such as to amend priority and pending claims due to newly raised grounds of rejection and art citation, in case instant claims are held unpatentable over those grounds or art. (Appx11022-11023). *Edwards* 243. "Entitlement to priority under §120 is a matter of law, and

receives plenary review on appeal." *In re Daniels*, 144 F.3d 1452, 1455-56 (Fed.Cir.1998).

Further, Appellant has right to supplement facts in the Complaint from administrative record, to overcome the allegation that Complaint does not provide enough facts (Appx5).

The timing of filing amendments was outside Appellant's control. The *2nd Am.Complaint* was being drafted in November 2022 (Appx13895-13896) for clarity and conformation to further evidence but was delayed because new evidence and issues continually surfaced in discovery and motion for summary judgment and because higher litigation was burden placed on Appellant by the district court (Section II.B supra).

It is a harmful error and manifest error of judgment on part of district court to deny entry of the *2nd Am.Complaint*, it amounts to district court taking leave of its senses. *Datascope* 828. Courts have mandated entry of such amendments. *Foman* 182; *Edwards* 240-243. This Court should reverse district court's denial of the entry of *2nd Am.Complaint*.

V. DUE PROCESS VIOLATIONS IN SUMMARY JUDGMENT GRANT WHILE PENDING INTERLOCUTORY APPEAL ON THE RECORD RIFE WITH DISPUTED FACTS, WHILE SUMMARY JUDGMENT FAILS AS A MATTER OF LAW

A. Standard of Review

Fourth Circuit undertakes plenary review of a district court's grant of summary judgment. *Lee v. Town of Seaboard*, 863 F.3d 323, 327 (4th.Cir.2017).

B. Summary Judgment is Unlawful Because Close of Discovery is Under Appeal, Appellees Expert is Objected, Claim Construction and Factual Issues Are Disputed

1. Close of Discovery is Under Appeal

The district court did not have authority to grant/enter summary judgment on March 30, 2023 (Appx19-33), because of pending interlocutory appeal filed on January 13, 2023 (Appx8326) from improper denial to enlarge discovery.

Fed.R.Civ.P.56(b) provides,

> "Unless a different time is set by local rule or the court orders otherwise, a party may file a motion for summary judgment at any time until 30 days after the close of all discovery."

Fed.R.Civ.P.56(d)(2) also "allows time [] to take discovery". This is also the interpretation of the US Supreme Court and added to the Notes of Advisory Committee, "*Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, *after* adequate time for discovery…)", 2010 Amendment. Also see *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th.Cir.2002) holding "[S]ummary judgment prior to discovery can be particularly inappropriate when a case involves complex factual questions about intent and motive" which is the case here as the Appellant has alleged bad faith deprivation of rights to discoveries by Appellees.

Hence, it is unambiguous that summary judgment must be entered *after* the close of discovery.

Further, Fourth Circuit has excused technical noncompliance with Rule 56(d), even in counseled cases, where the nonmoving party "has adequately informed the district court that the motion is premature and that more discovery is necessary." *Harrods* 244–45 ("nonmoving party's objections before the district court served as the functional equivalent of an affidavit" under Rule 56(d)) reversing grant of summary judgment under abuse of discretion standard. *Id.* 247. Accordingly, *Pro se* Appellant had motioned the district court to strike the motion for summary judgment as premature and defective because of the need for additional discovery, including to identify witnesses for trial (Appx9858-9863; Appx9910-9914).

2. Appellees' Expert Testimony is Objected

Fed.R.Civ.P.56(c)(2) provides,

> "A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence."

The Notes of Advisory Committee on Rules, 2010 Amendment, elucidate "the objection functions much as an objection at trial, adjusted for the pretrial setting." Accordingly, Appellant *objected* to Harris testimony in motion to disqualify Dr. Harris asserting testimony is *inadmissible* (Section III supra) and again in motion to strike or stay motion for summary judgment because the denial to exclude Harris testimony is under appeal (Appx9858-9863; Appx9910-9914). The Appellant

specifically pointed out that the district court has acknowledged that 'the weight of the expert's [Dr. Harris'] testimony" is in question (Appx9861), and a district court's weighing the evidence at summary judgment is impermissible. *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam); *Jacobs v. N.C. Admin. Office of the Courts,* 780 F.3d 562, 568-569 (4th.Cir.2015).

Yet the district court explicitly and implicitly relied on Harris testimony in its opinion to grant the summary judgment even with respect to the question of patent eligibility (Section III.C supra). A court improperly weighs the evidence "[b]y failing to credit evidence that contradict[s] some of its key factual conclusions." *Tolan* 1866.

3. Claim Construction and Related Facts Are Disputed

On legal determination of patent eligibility under 35 USC §101, the entry of summary judgment is unlawful before claim construction hearing, when *express disclaimer* "wherein [the intermixture of] omega-6 fatty acid(s) and antioxidant(s) [is] are not any single specific variety of a vegetable, a fruit, a nut, or a seed" (brackets indicate the variations) in *independent* claims 82, 99, and 115-116 is not given weight without explanation. The opinion on summary judgment grossly misinterprets the claims leaving out numerous limitations. See Section V.D.1 infra.

Further, both *1st* (¶¶25-27) and *2nd* (¶¶30-53) *Am.Complaints* assert proportional

dosages of omega-6 fatty acids and antioxidants including polyphenols claimed in the '847 application is not well understood, routine, or purely conventional step in the prior art (Section V.C. and Table 3 infra), which is also asserted in Appellant's expert testimony (Appx7139-7163; Appx7196-7202; Appx7457-7536; Appx7585-7657) and opposition to summary judgment (Appx9912), while Harris testimony is objected to (discussed above).

Therefore, claim construction and related facts are disputed. "Whether claims [at issue] perform well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact making summary judgment inappropriate with respect to these claims." *Berkheimer v. HP Inc*., 881 F.3d 1360, 1370 (Fed.Cir.2018).

Thus, entry of summary judgement is unlawful because of the foregoing reasons, which were submitted to the district court, but were not answered in the opinion (Appx19-32).

C. Summary Judgment is Unlawful Under Fed.R.Civ.P.56(a)Because Record is Rife with Disputed Facts

Fed.R.Civ.P.56(a) provides summary judgment is appropriate *only*,

> "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

Appellant asserted in briefing to strike the motion to summary judgment,

> "pending claims [] expressly disclaim natural products such as almonds, and indisputably meet the requirements of 35 U.S.C. §101…The Amended

> Complaint (Dkt. 13 [Appx297-319]) asserts that the features in the '847 application remain poorly understood at ¶¶ 6-8, 10, 25-28, and 31, which is also asserted in expert reports and rebuttals (Dkt. 57.1, 66.1, 66.2, 66.3, 66.4, 74.1, and 74.2). Accordingly, clearly there is a dispute in the present case as to both the claim interpretation and whether they are directed to well-understood, routine, and conventional activities." (Appx9912)

Therefore, there is ***genuine dispute*** at least to ***two material facts***, (1) natural products (such as almonds) are expressly disclaimed in each of the *independent* claims 82, 99, 115, and 116, and therefore in *all* claims, which refer to independent claims including 96-98 and 112; and (2) whether claimed proportional dosages of omega-6 fatty acids and antioxidants including polyphenols are well-understood, routine, and conventional activities, both of which have been ***repeatedly cited as disputed***, which are material facts affecting outcome of both eligibility under §101 and obviousness under §103. A disputed fact is material if it might affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Appellant adequately opposed the motion for summary judgment in the briefing to strike the motion asserting the above disputed facts and that record is rife with further disputed facts citing *1st Am.Complaint* (¶¶6-8, 10, 25-28), Dr. Das' and Dr. Erickson's Expert Reports (Appx7139-7163; Appx7196-7202), Harris Report (Appx7309-7419), Dr. Das' Rebuttal to Harris Report (Appx7421-7546), Dr. Erickson' Rebuttal to Harris Report (Appx7548-7667), Excerpts from Harris Publications demonstrating relative dosages of omega-6 fatty acids and antioxidants including polyphenols remain poorly understood and long-felt

unresolved need (Appx7669-7714), Institute of Medicine Report on DRIs confirming "lack of data on [omega-6] fatty acid requirement" (Appx8260-8262), Corrected Prior Art Tables vociferating massive reconstruction by Dr. Harris (Appx8264-8292), Reply in Support to Disqualify Dr. Harris (Appx8241-8256; Appx8297-8299). Each of the foregoing cited documents prominently disputes genuine issues of material facts, such that 70-90% of each document are directed to the disputed material facts. For example, Das and Erickson Rebuttals dispute each of ¶¶19-224 in Harris Report (compare Appx7309-7419 with Appx7421-7546 and Appx7548-7667). Therefore, the district court did not need to search the documents for evidence, the evidence is ***glaringly visible***.

Celotex ruled summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Id.* 322-26. Even the absence of opposition to summary judgment itself does not warrant the entry of judgment in the movant's favor. *Custer v. Pan Am. Life Ins. Co*., 12 F.4th 410, 415-16 (4th.Cir.1993).

Further, the evidence must be viewed in the light most favorable to the party opposing the motion, *Poller v. Columbia Broad. Sys., Inc*., 368 U.S. 464, 473 (1962), with doubts resolved in favor of the nonmovant, *Cantor v. Detroit Edison*

Co., 428 U.S. 579, 582 (1976).

The district court failed to consider—let alone in the light most favorable to the Appellant—in its decision and opinion granting summary judgment the two genuine issues of disputed material facts discussed above, prominently cited in the pleadings, in the Appellant's expert report, and in the briefing to strike the summary judgment.

Because the record is replete with genuine dispute to many material facts, this Court must vacate the grant of summary judgment on patentability of claims as failing to meet the first requirement of Fed.R.Civ.P.56(a).

D. Summary Judgment Ruling Fails Under Fed.R.Civ.P.56(a) as a Matter of Law on Patent Eligibility and Obviousness

1. Claims at Issue Are Patent Eligible as a Matter of Law

Whether a claim is directed to statutory subject matter under 35 USC §101 is a question of law reviewed *de novo*, without deference. *AT&T Corp. v. Excel Communications, Inc*., 172 F.3d 1352, 1355 (Fed.Cir.1999).

Claims Recite New Processes, Compositions, Manufacture, and Machine

During examination the Appellees agreed the terms "mixture"/"intermixture" will overcome §101 rejections (Appx3610) and withdrew the §101 rejection from claims at issue (Appx3622). See *In re Garnero*, 412 F.2d 276, 278-79 (CCPA 1969). Rather, claims 115-116 were substantially drafted by USPTO (Appx3635-3636). Accordingly, there is ***no §101 rejection in the PTAB decision*** (Appx6487-

6488), it was improperly forced in this action.

35 USC §101 provides,

> "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."

Confirmed by ***no §102 novelty rejection*** against any claim at issue (Appx6487-6488),

- Independent claims 82 and 115 are patent eligible as *new and useful manufacture and composition of matter*, as "packaged product" "intermixture"/"mixture";
- Independent claim 99 is patent eligible as *new and useful manufacture*, as "product" utilizing material where new process (§100(b)) yields daily tailored formulations based on diet cohorts;
- Claim 112, is patent eligible as *new and useful machine* "computer; system" utilizing new process (§100(b)) e.g., "remote user inputs" to facilitate the manufacture of *new and useful* product of claim 99; and
- Independent claim 116 is patent eligible as *new and useful process* of administering the formulations for new uses (§100(b)).

//

Claim Interpretation: Incontrovertible Disclaimer of Natural Products

"Because claim construction is a matter of law, the construction given the claims is reviewed *de novo* on appeal." *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 976-979, 989 (Fed.Cir.1995) (en banc).

Independent claim 82 includes the limitation, "wherein the intermixture of omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed," and independent claims 99 and 115-116 include the limitation, "wherein omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed." Therefore, *all* claims including 96-98 and 112 disclaim "a vegetable, a fruit, a nut, or a seed," including "almonds" cited in the opinion below (a nut and seed, Appx11574). This ***disclaimer is incontrovertible by law***, "[i]nventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim." *Abbott Laboratories v. Sandoz, Inc*., 566 F.3d 1282, 1288 (Fed.Cir.2009). "[t]he inventor's intention, as expressed in the specification, is regarded as dispositive." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed.Cir.2005).

The '847 Patent Application is a legal instrument, which makes it illegal to interpret the claims outside the express limitations in the claims, requiring "***the scope of the present invention is defined by the appended claims***" (Appx354).

Markman v. Westview Instruments, Inc., 517 U.S. 370, 388 (1996). It is a ***legal error*** to excise limitations from the claims including the disclaimer, and to interject arbitrary interpretation into the claims contradicting the terms of the claims. *Markman* 52 F.3d 967, 980.

Because claims are not drawn to laws of nature, natural phenomena, and abstract ideas, ***§101 inquiry is over at step one*** of *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S.Ct. 1289, 1296-97 (2012). Appellants claims explicitly disclaim "a vegetable, a fruit, a nut, or a seed [almonds]," therefore ***do not tie up*** the use of the allegedly underlying naturally existing subject matter.

Claim Interpretation: Proportional Dosages of Omega-6 and Antioxidants, and Remote User Inputs, and Specific Uses

In *Mayo* at 1298 the Supreme Court emphasized the importance of considering claims as a whole as part of the eligibility analysis; *also Alice* 2355 n.3 (quoting *Diehr* 188). Violating the Supreme Court precedent, district court ***left out numerous limitations*** from independent claims besides the disclaimer, including:

> Claim 82: "wherein the one or more formulations are so packaged and labeled indicating suitability for consumption that collectively provide a dosage from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the ***antioxidants comprise*** one or more polyphenols in the dosage of greater than 5mg";

Claim 99: "wherein the one or more formulations collectively provide to the individual a daily dosage from 1 to 40g of omega-6 fatty acids, and from 25mg to 10g of ***antioxidants comprising*** one or more polyphenols in a daily dosage of greater than 5mg";

Claim 112: "wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences"; and

Claim 115-116: "from 1 to 40 g dosage of omega-6 fatty acid(s)… from 25 to 10 g dosage of antioxidant(s)…the dosage of ***antioxidants includes*** at least 5 mg of phytochemical(s)" and "medical conditions or diseases [specified]".

Notably dosage—by definition—means restriction (Appx7451; Appx7579), and each of the claims, the specification, and the prosecution history comport with claims being drawn to proportional dosages (restricted) of omega-6 and antioxidants including polyphenols (Appx7486-7487; Appx7527; Appx7614-7615; Appx7651). "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." *Markman* 979.

Appellees' ***professional opinion*** confirms that claimed inventions as a whole are ***not*** "well understood, routine, or conventional activity' previously known to the industry," because there is no §102 rejection against the claims at issue. Likewise, the district court opinion fails to explain based on what expert opinion it finds the claims as a whole to be "well-known, routine, and conventional activity."

Lipitor 646. On the contrary, the '847 application and Appellant's expert testimony demonstrate claims as a whole are not well-understood. (Section V.C. supra, Table 3 infra). Therefore, the claims transform (though unnecessary) any alleged ineligible subject matter, and step two of §101 inquiry is also met. *Alice* 2359-2360.

For all the foregoing reasons, this court must reverse district court's ***legally erroneous*** ineligibility decision under 35 USC §101.

2. Claim 112 is Not Held Obvious and Claims 82, 99, 115-116 and Dependent Claims Are Not Obvious as a Matter of Law

"Obviousness [including on summary judgment], 35 U.S.C. §103, is reviewed as a legal conclusion [subject to our full and independent review] based upon underlying facts of four general categories, *viz.* the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill at the time the invention was made, and any objective considerations that may be present. *Graham v. John Deere Co*., 383 U.S. 1, 17 [] (1966)." *Continental Can Co. USA, v. Monsanto Co*., 948 F.2d 1264, 1270 (Fed.Cir.1991).

District court finds claim 112 to be patentable under §103 (Appx29-31). Further, the facts indisputably lead to legal conclusion of non-obviousness of independent claims 82, 99, and 115-116, as discussed below.

This Court Must First Excise Erroneously Admitted Harris Testimony

This Court must first excise Harris testimony that was erroneously admitted

(Section III.C. supra), because "[i]nadmissible evidence contributes nothing to a 'legally sufficient evidentiary basis.'" *Weisgram v. Marley Co.,* 528 U.S. 440, 453–56 (2000).

No Suggestion in Prior Art to Combine Elements as Claimed

Each of claims 82, 99, and 115-116, include the limitations or variation thereof in [],

> "collectively provide a [daily] dosage [based on cohorts] from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and ***wherein the antioxidants*** comprise one or more polyphenols [specific phytochemicals including polyphenols] in the dosage of greater than 5mg…," and

wherein claims 82 and 99 are product claims ***comprising labeling/tailoring processes*** and claim 116 is directed to ***new uses***. Specification explains restricted and proportional requirements of omega-6 and antioxidants including polyphenols/phytochemicals are not well-understood, they should be preformulated to keep consumers in "optimal/safe range," and tailored based on cohorts for prevention/treatment. (Appx349-355, Appx358-359, Appx369-373, Appx394-395).

Motion and reply (Appx9861; Appx9911-9912) to strike/oppose motion for summary judgment ***expressly directed*** the court to following documents on record evidencing poorly understood factors, although the court should consider entire record, including PTAB appeal (e.g., Appx4744-4752; Appx4767) and *2nd Am.Complaint* (Appx10923-10984). *Celotex* 322-26.

Table 3	
Document	**Teaching/Suggestion**
Lands WE, Ann. N.Y.Acad.Sci. 1055: 179–192(2005) (*1st Am.Compl.*, Appx305¶25 (Appx4773-4786))	<0.5% of calories from n-6 linoleic acid (<*1g/day* for 1800 calorie diet) (Appx4777). No suggestion on dosage of total antioxidants including polyphenols.
US 2008/0213239A1 ("Morris") (*1st Am.Compl.* Appx305-307 ¶¶25-27, (Appx9401-9424))	Omega-6 is not essential and replaceable with omeg-3; no or zero omega-6 in formulations 1-6; and 0.070g in formulations 7-27 (70mg GLA). No suggestion on proportional dosage of total antioxidants including polyphenols. Open-ended dosages of antioxidants add up to significantly more than 10g restriction in present claims, e.g., 31g/day (formulation #27 is about 15,000mg/day (three times daily ¶164) and claims 1+2+3+4+9+13+18+19 yields antioxidants over 24,000mg/day). (Appx8264-8271)
US 2007/0166411A1 ("Anthony") (*1st Am.Compl.*, Appx306 ¶¶25-26 (Appx9426-9439))	Defines linoleic acid as omega-3 and α-linolenic acid as omega-6 (¶49, ¶51) and its exemplary formulations in Tables 2 and 7 comprise 0.2-0.4g α-linolenic acid [omega-6]. No suggestion on dosage of total antioxidants including polyphenols. (Appx8264-8271)

Niki, "Lipid peroxidation: Physiological levels and dual biological effects" Free.Radic.Biol Med.2009 Sepl:47(5):469-84. (*1st Am.Compl.,* Appx306¶26 (Appx4834-4845))	Antioxidants are randomly recommended in prior art without teaching dosages and context. (Appx4844-4845)
Mennen, "Risks and safety of polyphenol consumption" Am.J.Clin Nutr.2005;81(suppl):326S–9S (*1st Am.Compl.*, Appx306¶27 (Appx4787-4789))	Dosage of polyphenols is not well understood, routine, or purely conventional step in the prior art. No mention of dosage of omega-6 and antioxidants.
Appellant's Experts Drs. Das and Erickson Testimonies (Appx7129-7163; Appx7188-7203; Appx7421-7546; Appx7548-7667).	Total dosage of omega-6 fatty acids and total antioxidants including polyphenols are poorly understood. '847 application demonstrates unexpected results and solves long-felt critical unmet need.
Dietary Guidelines for Americans, U.S.DHHS (Appellant's Expert Testimonies (Appx7470; Appx7522; Appx7598; Appx7647))	No suggestion on total omega-6 fatty acids and total antioxidants including polyphenols.
Harrison's Principles of Internal Medicine, 20th Edition (2018) (Appellant's Expert Testimony (Appx7437))	No suggestion on total omega-6 fatty acids and total antioxidants including polyphenols, while teaching the use of medications to modulate the effect of prostaglandins, omega-6 metabolites.
University of California, Division of Agriculture and Natural Resources (2008) (Appellant's Expert Testimonies (Appx7470; Appx7598))	Confirms dosages of phytochemicals including polyphenols are not well-understood (Appx12023-12026).
Excerpts to Dr. Harris' Publications (Appx7669-7714) and Appellant's	Admitting requirements for omega-6 fatty acids and antioxidants are poorly

Expert Testimonies (Appx7462-7466; Appx7590-7594))	understood.
Institute of Medicine 2005 Dietary Reference Intake (Appellant's Expert Testimonies (Appx7520-7521; Appx7646-7647))	Because of the lack of data on the n-6 fatty acid requirement in healthy individuals, an EAR cannot be set based on correction of a deficiency. (Appx8260-8262). No suggestion on dosage of total antioxidants including polyphenols.
Randomly sold products comprising omega-6 fatty acids, antioxidants, and polyphenols (*1st Am.Compl.*, Appx301-307 ¶¶ 6, 10, 30 (Appellant's Expert Testimonies (Appx7131-7142; Appx7161-7163; Appx7197; Appx7201; Appx7467-7471; Appx7478; Appx7533; Appx7595-7599; Appx7606))	No suggestion on dosage of total omega-6 fatty acids and total antioxidants including polyphenols
Tables delineating detailed differences between instant claims 82 and 99 and cited art: M*orris+Anthony+Howard*, *Debbouz+OIG*, and *Rusing+OIG* (Appx8264-8292) and (Appellant's Expert Testimonies (Appx7478-7513; Appx7607-7640)	Different problems to be solved; and no suggestion on total omega-6 fatty acids and total antioxidants including polyphenols.

Thus, the prior art as a whole, including *Morris* and *Anthony*, fails to recognize let alone solve, the problem of proportional dosages of total omega-6 fatty acids and total antioxidants including polyphenols/phytochemicals. The court alleges "three combinations of references" allegedly "disclose the claimed omega-6 fatty acid, antioxidant, and polyphenol dosages" but fails to mention which references and pincite the disclosures (Appx31). To the extent the reference is to

M*orris+Anthony+Howard*, *Debbouz+OIG*, and *Rusing+OIG*, these references do not provide any teaching on total proportional dosages of omega-6 fatty acids and antioxidants including polyphenols, taken alone or in combination (see Table 3).

There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. *Ruiz v. A.B. Chance Co*., 234 F.3d 654, 665 (Fed.Cir.2000). "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed.Cir.1998).

No Overlapping Ranges, Teaching Away, and Unexpected Results

Morris does not teach overlapping ranges because there is no suggestion of dosage of polyphenols in *Morris* (Appx9412; Appx8267). Further, "The presumption [of obviousness] can be rebutted if it can be shown that the prior art teaches away from the claimed range, ***or*** the claimed range produces new and unexpected results." *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1311 (Fed.Cir.2006). Both foregoing factors hold true here:

(1) *Morris* teaches omega-6 is optional (¶46), formulations 1-6 contain no or zero omega-6 and formulations 7-27 contain 0.070g omega-6 (70mg GLA), and

teaches unlimited antioxidants, e.g., above 31g (Appx7149; Appx7199). Thus, *Morris* teaches away from lower limit of 1g omega-6 and upper limit of 10g antioxidants dosage, and "***too frequently"*** (Appx7609-7613). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference [] would be led in a direction divergent from the path that was taken by the applicant." *Ormco* 1308.

(2) Appellant has demonstrated unexpected results as testified by expert testimonies. "USPA '847 Examples 6, 8, 9, 10, 12, and 14, teach at least 11g/day omega-6 dosage was required to overcome adverse health. In other words, Morris' 210 mg/day [if taken 3x/day] GLA formulations will not be able to meet the 11g or higher needs of omega-6 of some individuals. This is an unexpected result in comparison to Morris and prior art as a whole. USPA '847 teaches in Example 8 that low intake of fatty acids and high intake of antioxidants including polyphenols resulted in neural disease in the subjects. Example 13 similarly show low intake of omega 6 fatty aid and high intake of antioxidants associated with neural disease. These are unexpected results with respect to antioxidants." (Appx7152).

Secondary Considerations Confirm the Claimed Inventions Were Not Obvious

> "[s]econdary considerations [long felt but unsolved needs, failure of others] which, when present, must be considered. [] It does not appear that that was done." *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 873 (Fed.Cir.1985).

Appellant has provided abundant evidence of long felt but unsolved needs and failure of others (Appx7131-7132; Appx7153-7158; Appx7202; Appx7522-7536; Appx7648-7657) including,

> "Although it was known in the art that high dosages of polyphenols could be harmful to health Harris, Mennen, Morris, Dietary Guidelines for Americans, IOM, and University of California and others failed to solve the problem in teaching dosages of polyphenols proportional to omega-6 intake, including that polyphenols 'increase the requirement for omega-6'. Therefore, the others tried and failed to meet the need. This is evidence of non-obviousness… Abundant evidence has been provided in the '847 application that multiple chronic and infectious diseases can be prevented and mitigated by the claimed inexpensive solutions. It is irresponsible not to implement and nurture the claim[ed] solutions." (Appx7657).

The district court ignored those vital facts of non-obviousness despite *Graham* and *Loctite*.

3. Rights to Further Arguments Reserved

Further patentability discussion, including on dependent claims, is not possible here because of word limitation and denial of brief enlargement to properly argue the number of issues (ECF.No.16). This Court is referred to further arguments and evidence on patentability on record including the *2nd Am.Complaint* (Appx10923-10984). Rights to further arguments are reserved, disregarding the right would result in an unfair procedure. *Advanced Magnetic Closures v. Rome Fastener*, 607 F.3d 817, 833 (Fed.Cir.2010).

4. Reversal of District Court Decision is Required

The record here provides abundant facts essential to formulating a conclusion of patentability of claims 82, 99, 112, and 115-116, and the dependent claims, requiring this Court to reverse district court's unpatentability decision (Appx19-33). *Gardner v. TEC Systems*, 725 F.2d 1338, 1344 (Fed.Cir.1984).

E. 2nd Reason to Enter Judgment as a Matter of Law in Appellant's Favor on Patentability per *Weisgram* Standard

The inadmissibility of Harris testimony (Section III. supra), and the equitable considerations of fairness to both parties counsel this Court to direct the district court to enter patentability judgment as a matter of law in Appellant's favor. One of the "key[s] to [our] exercise of . . . discretion" in this analysis is "fairness to the parties." *Weisgram*, 528 U.S. at 454.

"Writing for the unanimous *Weisgram* Court, Justice Ginsburg observed that '[s]ince *Daubert*, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet.' *Id.* at 455…So it is fair to enter judgment as a matter of law for the losing party below when the appellate court finds the prevailing party's expert testimony inadmissible on appeal, because "[i]t is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail." *Id.* at 455–56…That fairness is only amplified in a case like this, where '[the Appellees were] on notice every step of the way that [Appellant] was challenging [their] expert[], [and they] made no attempt to add or substitute other

evidence.' *Id.* at 456." *Sardis* 299. As in *Weisgram*, the Appellees have held that the evidence presented below was sufficient to support the judgment entered in their favor (Appx9881).

Given similar circumstances of this case and that in *Weisgram*, this Court should follow the path already cleared by the Supreme Court, and direct that judgment as a matter of law be entered in Appellant's favor holding instant claims patentable.

VI. DUE PROCESS VIOLATIONS IN FAILING TO PROVIDE UNBIASED JUDGES

The district court failed to provide due process and fair proceedings in accordance with Fifth Amendment and *Snyder*. The court's opinions and orders encompass the following legal errors: (1) non-consideration of invocation of jurisdiction under 28 USC §1331; (2) non-consideration of Appellant's express statements in pleadings; (3) non-consideration of Fed.R.Civ.P.83; (4) non-consideration of *Daubert* standards for admissibility; (5) non-consideration of *Foman* mandate for complaint amendment; (6) non-consideration of the invention as claimed; (7) absence of the factual findings on the four inquiries mandated by *Graham*; (8) application of improper overlap test under 35 U.S.C. §103; and (9) non-consideration of objective indicia of non-obviousness. Further, the court silenced the Appellant in hearing (Appx9922-9948) and pressed her to withdraw the action (Appx9932). The foregoing and every ruling substantially against the

Appellant (Table 2 supra) demonstrate failure to provide unbiased judges. Recusal is required when, objectively speaking, the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable. *Aetna Life Ins. Co. v. LaVoie*, 475 U.S. 813, 825 (1986).

CONCLUSION AND RELEIF SOUGHT

Review establishes that the judgment was premised on "parade of legal errors" cited above. Decisions based on such fundamental legal errors cannot stand. *Jones v. Hardy*, 727 F.2d 1524, 1527 (Fed.Cir.1984). Reversal of each of the decisions at issue (Appx1-34 and Appx13998-13999) is required, except for decision to grant extension to disclose expert rebuttals (Appx13). This Court must direct the district court to enter judgment as a matter of law in Appellant's favor on patentability of all claims at issue, remand the case for further proceedings as to non-patent counts, order costs on the civil action and this appeal in favor of Appellant, and consider just and suitable relief for district court's failure to provide unbiased judges.

/s/ Urvashi Bhagat
Urvashi Bhagat, Pro se Appellant

ADDENDUM

ADDENDUM A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Defendants' Partial Motion to Dismiss Plaintiff's First Amended Complaint pursuant to Federal Rules of Procedure 12(b)(1) and 12(b)(6). The Court also considers Defendants' Motion to Strike Plaintiff's Jury Demand pursuant to Rule 39(a)(2).

In 2013, Plaintiff filed a patent application with the U.S. Patent and Trademark Office ("USPTO"). This application contained claims for nutritional formulations comprising omega-6 fatty acids and antioxidants. The USPTO examiner who reviewed Plaintiff's application withdrew claim 112 for lack of "unity of invention." The USPTO rejected Plaintiff's other pending claims for lack of written description, indefiniteness, improper dependency, and/or obviousness. Plaintiff appealed the USPTO's rejections to the Patent Trial and Appeal Board, which affirmed all rejections except

for the lack of written description. Plaintiff then filed the present case in this Court appealing the Board's decision. She amended the Complaint on April 19, 2021.

Defendants filed the present Motion to Dismiss on May 3, 2021. The Motion seeks dismissal of all Plaintiff's causes of action unrelated to the patentability of Plaintiff's application claims. Defendants identify several causes of action unrelated to Plaintiff's patent claims, including a takings claim under the Fifth Amendment, a general claim for damages due to the USPTO's allegedly bad faith delay of Plaintiff's patent issuance, a claim of tortious harassment, and a mandamus compelling the USPTO to issue Plaintiff's requested patent claims. Plaintiff demands a jury trial on all issues triable by a jury. Defendants filed a Motion to Strike such demand on May 3, 2021.

A district court must dismiss an action if the court has no subject matter jurisdiction over the claim. See Fed. R. Civ. P. 12(b)(1). The Court finds it lacks jurisdiction over the Amended Complaint's Fifth Amendment takings claim, general claim for money damages, and harassment claim.

Generally, agencies of the United States are shielded from liability under the doctrine of sovereign immunity unless Congress expressly waives such immunity. Congress has not waived its sovereign immunity for money damages in actions brought pursuant

to 35 U.S.C. § 145. Any claims for money damages brought under this statute are dismissed for lack of subject matter jurisdiction.

The Tucker Act waives sovereign immunity with respect to non-tort monetary damage claims, such as violations of the Takings Clause of the Fifth Amendment, against the United States. But "a claim for just compensation under the takings clause must be brought to the Court of Federal Claims in the first instance." E. Enters. v. Apfel, 524 U.S. 498, 520 (1998). The U.S. Court of Federal Claims has exclusive jurisdiction over any such claims alleging damages greater than $10,000. See id.

In the present action, Plaintiff claims $500,000,000 in damages against the United States. Thus, the Court of Federal Claims has exclusive jurisdiction over this claim. Plaintiff's Fifth Amendment takings claim is dismissed for lack of subject matter jurisdiction.

Like the Tucker Act, the Federal Tort Claims Act ("FTCA") waives the Government's sovereign immunity for any "injury or loss caused by the negligent or wrongful act of a Government employee acting within the scope of his or her employment." Medina v. United States, 259 F.3d 220, 223 (4th Cir. 2001). This waiver includes actions for tortious harassment, so long as they are otherwise proper before the Court. But for an FTCA claim to be properly before the Court, a plaintiff must first present an administrative

claim to the agency allegedly responsible for the plaintiff's injury. See 28 U.S.C. § 2675(a).

In this case, the relevant agency would be the USPTO because the Amended Complaint alleges the USPTO is responsible for harassing Plaintiff. But the Amended Complaint does not indicate that Plaintiff first filed a claim with the USPTO regarding said harassment. Without first filing this claim with the USPTO, this Court has no authority to review the harassment claim. It is dismissed for lack of subject matter jurisdiction.

A complaint should be dismissed for failure to state a claim pursuant to Rule 12(b)(6) "if after accepting all well-pleaded allegations in the plaintiff's complaint as true . . . it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999). A plaintiff must allege "a *plausible* claim for relief," instead of merely stating facts that leave open "the *possibility* that a plaintiff might later establish some set of undisclosed facts to support recovery." McCleary-Evans v. Md. Dep't of Transp., State Highway Admin., 780 F.3d 582, 587 (4th Cir. 2015) (emphases in original).

Although a court considering a motion to dismiss must accept all well-pleaded factual allegations as true, this deference does not extend to legal conclusions. Neither "naked assertions devoid of further factual enhancement," nor "[t]hreadbare recitals of the

elements of a cause of action, supported by mere conclusory statements" suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

Courts are instructed to construe *pro se* pleadings liberally. "[W]hen reviewing a *pro se* complaint, a court must carefully examine the plaintiff's allegations, no matter how inartfully pleaded to determine whether they could provide a basis for relief." Johnson v. Lyddane, 368 F. Supp. 2d 529, 531 (E.D. Va. 2005) (citing Gordon v. Leeke, 574 F.2d 1147, 1151 (4th Cir. 1977)).

The Amended Complaint includes no facts supporting the conclusion that the USPTO violated Plaintiff's constitutional rights, that the USPTO made false statements, and that Plaintiff is plausibly entitled to mandamus relief.

To establish she is eligible for mandamus relief, a plaintiff must plead (1) she has a clear right to the relief requested and (2) no other relief is available. See Heckler v. Ringer, 466 U.S. 603, 616 (1984). The Amended Complaint does not plausibly allege either. Plaintiff has not established that the USPTO owes her a clear duty to issue her a patent. And there is at least one other form of relief, i.e., 35 U.S.C. § 145, which Plaintiff has also asserted in her Amended Complaint. Plaintiff's petition for mandamus is thus dismissed for failure to state a claim.

The Amended Complaint also fails to allege plausible misconduct or false statements by the USPTO. Though Plaintiff

alleges the USPTO erred in the adjudication in her patent application, she provides no factual support for the allegation that the USPTO made false statements or acted with misconduct. The conclusion that the USPTO acted with "misconduct" is insufficient without providing any factual support of alleged misconduct. And the conclusion that "the Chief Judge also made false statements" is insufficient without any plausible explanation as to what statements were objectively false. These claims must be dismissed for failure to state a claim.

The Amended Complaint similarly alleges the USPTO violated Plaintiff's constitutional rights, but Plaintiff fails to set forth what action the USPTO took that violated her rights, or even which constitutional right was violated. This cause of action also must be dismissed for failure to state a claim.

Finally, Defendants ask the Court to strike Plaintiff's request for a jury trial. "It has long been settled that the Seventh Amendment right to trial by jury does not apply in actions against the Federal Government." Lehman v. Nakshian, 453 U.S. 156, 160 (1981). When Congress waives its sovereign immunity—as it has done with respect to patent appeals pursuant to 35 U.S.C. § 145—a plaintiff has a right to a jury trial only when Congress "unequivocally expresse[s]" such right in the authorizing statute. Id. Here, 35 U.S.C. § 145 provides no such unequivocal waiver.

Thus, Plaintiff has no right to a jury trial on her sole remaining claim.

For the foregoing reasons, all causes of action in the Amended Complaint—except that which was brought pursuant to 35 U.S.C. § 145—must be dismissed pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6). Plaintiff's request for a jury trial is struck. An appropriate order shall issue.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
July 22, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,	)	
	)	
	)	
Defendants.	)	

ORDER

For the reasons stated in the accompanying Memorandum Opinion, it is hereby

ORDERED that Defendants' Partial Motion to Dismiss Plaintiff's First Amended Complaint is GRANTED. It is further

ORDERED that Defendants' Motion to Strike Plaintiff's Jury Demand is GRANTED. A scheduling order shall issue.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
July 22, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT, Plaintiff, v. UNITED STATES PATENT AND TRADEMARK OFFICE, et al., Defendants.	)	Civil Action No. 1:20-cv-1515 CMH/IDD

ORDER

This matter is before the Court on Plaintiff Urvashi Bhagat's continued ex parte email communications with the Court. By Plaintiff's own admission, she has been constantly emailing and calling the Court requesting various forms of relief despite being informed by the Court, on more than one occasion, that written motions are the only appropriate form by which to request relief from the Court. [Dkt. No. 64-1]. As the Court has previously stated, email is an inappropriate way to request relief. Ex parte communications, or communicating with the Court without including the other party on any communication with the Court, are even more inappropriate.

This Court granted Plaintiff's motion for Pro Se E-Noticing [Dkt. No. 7], but that does not allow Plaintiff to file documents or requests for relief electronically. The proper procedure for requesting relief from the Court is filing a paper copy of any motion through the Clerk's Office that includes the relief requested and a legal basis for granting such relief. Plaintiff is

directed to obtain a copy of, and review, the United States District Court for the Eastern District of Virginia Pro Se Reference Handbook from the Clerk's Office concerning the rules applicable to and the appropriate manner by which to proceed in this civil action. The Court will respond to no further email or phone communications.

ENTERED this 16th day of December 2022.

/s/ Ivan D. Davis
Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT, Plaintiff, v. THE UNITED STATES PATENT and TRADEMARK OFFICE, *et al.*, Defendants.	)	Civil Action No. 1:20-cv-1515 CMH/IDD

ORDER

This matter is before the Court on Plaintiff's Objections to the Entry of the Order Dated December 16, 2022 ("Motion") [Dkt. No. 70]. The Court interprets the Motion as a Motion to Vacate the December 16, 2022 Order. This matter can be resolved without oral argument, as such argument would not aid the decisional process. Upon consideration of the Motion and for lack of good cause shown, it is hereby

ORDERED that the Motion is **DENIED**. To clarify the Court's December 16, 2022 order, Plaintiff should never contact chambers regarding any substantive issues concerning the case unless authorized by the Court in advance. However, Plaintiff may contact the Clerk's Office for any administrative or logistical questions. In addition, the Court finds no inconsistencies between the United States District Court for the Eastern District of Virginia Pro Se Reference Handbook ("Handbook") and Federal Rule of Civil Procedure 6(b)(1)(A). The Court's ability to *sua sponte* grant an extension of time "with or without motion or notice" as noted in the rule, is different from the Handbook's requirement to file a motion if a litigant wants "to ask the Court to order something." Furthermore, it is not "routine practice" for parties to directly contact chambers to

request a conference call without first meeting and conferring with one another in good faith to narrow any areas of disagreement or to jointly request relief, even in urgent matters. Generally, the Court does not consider extensions of time urgent, and such extensions/continuances are disfavored by the Court.

ENTERED this 30th day of December 2022.

/s/ Ivan D. Davis
Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT, Plaintiff, v. THE UNITED STATES PATENT and TRADEMARK OFFICE, et al., Defendants.	)	Civil Action No. 1:20-cv-1515 CMH/IDD

ORDER

This matter is before the Court on Plaintiff's Motion for Extension of Time for Expert Rebuttal Reports & Further Enlargement of Discovery and a Continuance of the Final Pre-Trial Conference ("Motion") [Dkt. No. 62]. This matter can be resolved without oral argument, as such argument would not aid the decisional process. Upon consideration of the Motion, it is hereby

ORDERED that the Motion is **GRANTED in part and DENIED in part**. The Court extends the due date for Plaintiff's rebuttal disclosures to December 9, 2022. The motion is denied in all other respects.

The Motion is denied in part for the following reasons. First, Plaintiff fails to show good cause, based upon excusable, neglect for any extension of the current discovery cutoff and Final Pretrial Conference date. Regarding the timeliness of her motion, Plaintiff argues that she contacted Ms. Jessica Leonardo, law clerk to the Honorable U.S. District Judge Claude M.

Hilton, on numerous occasions, by phone and email, prior to the expiration of the discovery cutoff date, in an attempt to request a discovery enlargement. However, Ms. Leonardo was no longer a law clerk for Judge Hilton on the dates the Plaintiff attempted to contact her. In addition, the Court has repeatedly notified Plaintiff that the proper way to request relief is through a written motion. While "the court *may*, for good cause, extend the time" "with or without motion or notice if the court acts, or if a request is made, before the original time or its extension expires," the Court is not *required* to accept oral motions. Fed. R. Civ. Pro. 6(b)(1)(B). Once again, the Court reminds Plaintiff that a written motion is the proper way to request relief from this Court. Therefore, the Court does not excuse Plaintiff's failure to file her written motion until after the discovery cutoff.

Nevertheless, even if the Court deemed Plaintiff's motion timely filed, the Court finds that Plaintiff has failed to show good cause for her requested extensions. The District Judge's Initial Scheduling order noted that the parties could begin discovery as of the date of the order, August 11, 2022. However, Plaintiff waited until November 1, 2022 to participate in the discovery process, eight days before the close of discovery. Plaintiff states that she waited to serve discovery requests until after the Supreme Court ruled on the petition for writ of mandamus. Dkt. No. 64. Waiting to serve discovery requests until after a Supreme Court ruling on her writ was a legal strategy, the consequences of which Plaintiff must face. The Court cannot allow the Plaintiff to benefit from her failed legal strategy. In addition, since any ruling from the Supreme Court could have only affected discovery regarding the appealed dismissed claims and not the remaining claims in the case, failing to proceed with discovery concerning those remaining claims, prior to any Supreme Court ruling, constituted a lack of due diligence by the Plaintiff in participating in the discovery process. While pro se litigants are afforded "some

leeway" in cases, the Court finds that waiting until November 1, 2022 to participate in discovery is far more than "some leeway." Therefore, Plaintiff fails to meet her burden under the good cause standard.

Plaintiff also raises two other reasons in support of granting her motion; the Court will address each in turn. First, Plaintiff states that Defendants have more manpower and resources than Plaintiff so she should be granted more time. However, parties in this District routinely have disparity in manpower and resources. That disparity alone does not amount to good cause for an extension of deadlines. Second, Plaintiff also raises concerns about her personal workload on the case, stating that she was unable to take depositions of the Defendants because she did not have the time. She further states that she has not reviewed Defendants' responses to her discovery requests because she was busy working on the expert rebuttal disclosures. Plaintiff's inability to manage her time throughout the litigation also constitutes a lack of due diligence and, therefore, does not amount to good cause for an extension of previously scheduled court deadlines. Accordingly, this Court does not find good cause for the discovery enlargement or continuance of the final pretrial conference.

On January 9, 2023, the Court received an email from Plaintiff inquiring about the status of the Motion and informed the Court of her intent to appeal the order if the Court denied the Motion. The Court reminds Plaintiff that it is inappropriate to address the Court on a pending motion, and that it is also inappropriate for Plaintiff to notify the Court of her intent to appeal a pending motion if it is denied. The Court also reminds Plaintiff, once again, that a written motion is the proper way to request relief from this Court.

ENTERED this 10th day of January 2023.

/s/ Ivan D. Davis
Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

ORDER

THIS MATTER comes before the Court on Plaintiff's Motion to Disqualify Dr. William S. Harris as Expert Witness for Defendants.

Plaintiff argues that Dr. Harris should be excluded because he is bias and Plaintiff disagrees with his opinions. Plaintiff's objections go to the weight of the expert's testimony, not admissibility. It is hereby

ORDERED that Plaintiff's Motion to Disqualify Dr. Harris as Expert Witness for Defendants is DENIED.

Alexandria, Virginia
January 17, 2023

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

ORDER

THIS MATTER comes before the Court on Defendant's Motion for Summary Judgment. The Court is of the opinion that Defendant's Motion should be granted. It is hereby

ORDERED that this case is stricken from the Court's trial docket, and a memorandum opinion and order will be forthcoming.

Alexandria, Virginia
February 27, 2023

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Defendant's Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56 and Plaintiff's Motion to Strike Defendant's Motion for Summary Judgement.

The Court first addresses Plaintiff's Motion to Strike Defendant's Motion for Summary Judgement or Stay Briefing of the Motion Pending the Outcome of Plaintiff's Appeal. The Motion for Summary Judgement is not premature. Plaintiff has had over four months to conduct discovery and has used that time to conduct her discovery. The Motion to Strike should be denied.

The Fourth Circuit's February 23, 2023 Order that consolidated Plaintiff's appeals also dismissed as moot Plaintiff's Motion for a Stay of the District Court proceedings. This Court finds Plaintiff has failed to carry the burden to

support a stay pending interlocutory appeal of discovery matters.

Plaintiff is the inventor of the United States Patent Application No. 13/877,847 (the "Application"). The Application describes nutritional formulations as supplements, meal components, or meals, that may be administered in any orally acceptable form, including, capsules, tablets, liquid formulations, or whole foods. This includes specifying that the nutritional formulation may comprise one or more nuts, including almonds, and that nuts are a source of omega-6 fatty acids, antioxidants, and polyphenols. The Application discusses administering the formulations at various frequencies including one to three times a day.

The Application also includes that different formulations may be packaged together or in single units and in different types of packaging including in a gelatinous case, a vial, a bottle, a pouch or a foil, or plastic or card-board box. It further states that formulations may be marked to indicate the intended consumer, the frequency of consumption, the suitability for consumption according to a general diet plan, or the maximum amounts for average daily consumption.

There are "method of using" claims included in the Application. This includes Claim 88 which recites steps to administer a dosage to an individual selected from a diet cohort

that is based on gender, age, genetic profile, family history, climactic temperature, or medical condition. Claims 97 and 116 relate to methods of treatment of either unspecified medical conditions or diseases, or any of a long list of widely divergent conditions and diseases, through administering nutritional formulations. One of the examples included in the Application is a subject given a composition that included a combination of vegetable oils, nuts, and seeds. Claim 99 relates to methods of preparing a product comprising nutritional formulations, including the steps of determining the individual's diet cohort and selecting and preparing at least one formulation that provides 1 to 40 g of omega-6 fatty acids, 25 mg to 10 g of antioxidants, and greater than 5 mg of polyphenols.

However, none of the Application's method claims include tailoring the nutrient dosages in the product to the diet cohort or restricting the total daily intake of any of the claimed nutrients.

Claim 112 deals with a computer system to implement the method of Claim 99 and recites a system that outputs a nutritional plan for an individual based on their dietary preferences and dietary guidelines.

The United States Patent and Trademark's Patent Trial and Appeal Board (the "Board") affirmed the rejection of the

Plaintiff's Application claims because they were obvious in light of numerous past expert studies and disclosures. In particular, the Board used a work by inventor Claudia R. Morris, US Published Patent Application Number 2008/0213239 A1 (hereinafter "Morris"), which discloses preparing and administering dietary formulations comprising omega-6 fatty acids and Vitamin E to children and adults for treating various conditions such as cardiovascular disease. The formulations may be in the form of tablets, capsules, food bars, or drinks. Morris discloses that the formulations comprise omega-6 fatty acids, such as linoleic acid, in dosages and amounts overlapping the dosages in Plaintiff's claims. Morris shows that the formulations comprise from about 50 mg to about 500 mg omega-6 fatty acids that may be administered once, twice, or three times daily, which would equal a dosage ranging from 50 mg to 1,500 mg of omega-6 fatty acids a day. There is further overlap where Morris shows that the formulation comprises Vitamin E in amounts and dosages that overlap the Plaintiff's claimed dosages.

The Board further found that Morris discloses packaged formulations comprising omega-6 fatty acids, Vitamin E, and polyphenols. Morris also discloses dosages of omega-6 and Vitamin E overlapping the claimed ranges. The Board determined the claimed dosages were obvious due to Morris's disclosure that dosages are a result-effective variable and may be optimized for

an individual. Morris also discusses preparing formulations based on an individual's age, weight, genetic makeup, etc., which equates to Plaintiff's Claim 99 limitation of preparing a formulation based on the diet cohort of an individual.

The only difference the Board found between Morris and the Plaintiff's claimed formulation was an explicit disclosure of using nutrients from different sources. However, this would have been obvious in light of another expert's teachings of oil blends from different sources.

Plaintiff brought this suit pursuant to 35 U.S.C. § 145 the Board affirmed the rejection of all pending claims of Plaintiff's Application.

A Section 145 appeal is a hybrid action because it is partially an appeal from an administrative body and partially a new evidentiary proceeding. See Hyatt v. Kappos, 625 F.3d 1320, 1322 (Fed. Cir. 2010); Halozyme, Inc. v. Iancu, 320 F. Supp. 3d 788, 801-02 (E.D. Va. 2018) (Hilton, J.). New evidence may be presented but the Board's decision remains at the center of the case. Hyatt, 625 F.3d at 1322. When a party presents new evidence not previously before the Board, the court makes a de novo finding on any disputed questions of fact. Kappos v. Hyatt, 566 U.S. 431, 433- 434 (2012). The issue of patent eligibility is a question of law for the court.

Under Federal Rule of Civil Procedure 56, a court should grant summary judgment if the pleadings and evidence show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In reviewing a motion for summary judgment, the court views the facts in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Once a motion for summary judgment is properly made, the opposing party has the burden to show that a genuine dispute of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

The Court finds there are no issues of material fact as to any of Plaintiff's claims and their patent ineligibility under 35 U.S.C. §§ 101 and 103.

The two-step framework for determining whether claims that are within a statutory category nevertheless fall within a patent-ineligible exception, is set out by the Supreme Court in Alice Corp. Pty. Ltd.v. CLS Bank Int'l, 573 U.S. 208 (2014). Step one is "whether the claims at issue are directed at one of [the] patent-ineligible concepts." Id. at 217. The patent-ineligible concepts include laws of nature, natural phenomena, and abstract ideas. If claims are directed at one of the patent-ineligible concepts, then the court moves to step two and

considers the elements of each claim "both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Id. at 217-218.

Each of Plaintiff's claims of the Application at issue deal with products of nature or abstract ideas that are patent ineligible under 35 U.S.C. § 101.

Plaintiff's claims 82-89, 91-104, 107-110, and 113-120 of the Application contain a recitation of the combination of nutrients naturally present in almonds and thus are a natural product. Further, the claims do not have any limitations that transform the natural product into patent-eligible subject matter.

Independent claims 82, 99, 115, and 116 recite nutritional formulations with a combination of nutrients in various specified dosages. These claimed nutrients are naturally present in almonds, making the claims about a natural product. Since almonds contain all of the claimed nutrients, the claims do not recite a product with any markedly different characteristics from those found in nature.

The court begins with step one to determine if the claims fit into a patent-ineligible statutory category. Independent claim 82 is a product claim, and its patentability depends on the product. The claim's recitation of the nutrients coming from

an intermixture process using different sources does not change the conclusion that it is a natural product. The patentability of a product claim depends on the product and not the process of making it.

Independent claim 82's dependent claims 95, 103, 109, and 110 clarify that the independent claim's formulation encompass nuts. Dependent claims 88, 91, 96-98, 102, and 104 do not make any attempt to further limit the nutrient composition. Dependent claims 83, 84, 100, and 115-118 merely recite the same nutrients which almonds comprise. Also, almonds contain the dosages of omega-6 fatty acids recited in claims 92, 107, 113, and 119, and the polyphenol dosage recited in claim 120. Almonds further comprise phytosterols as required by claim 85, in the dosages recited in claims 86, 93, 108, and 114.

Claim 94's requirement that one formulation provide omega-6 fatty acids in a dosage less than 1 g, but that a plurality collectively provide 1 to 40 g of omega-6 merely encompasses a product of 100 g of almonds broken into 5 g increments. Almonds also contain the phytochemicals, lipids, antioxidants, vitamins, minerals, and fiber recited in claims 87 and 101. Finally, claim 89 encompasses a mixture of one or more food items, which includes a mixture of 100 g of almonds with other nuts.

Having determined that the product and method claims of the Application are about a natural product under the first step of

the Alice inquiry, the court now moves to step 2 to determine if the additional claim elements transform the natural product into a patent-eligible application. Transformation of a natural product into eligible subject matter requires the additional features be more than "well-known understood, routine, conventional activit[ies]." See Alice at 225.

Plaintiff's independent product claim 82, simply recites well-known routing and conventional activity of packaging and labeling the formulations. This includes basic packaging such as in "a vial, a bottle, a pouch or a foil, or plastic and/or card-board box, and the like." This type of basic, common-place packaging is a conventional activity.

Claim 82's dependent claims, 91 and 95, fail to add any transformative claim limitations. Claim 91 limits the formulations into particular forms like powder. Unfortunately, it is well known that nuts can be crushed into a powder. Claim 95 recites that the formulation is in a "kit" which is nothing more than conventional packaging of the formulation.

Claims 83-87, 89, 92-94, 113-114, 117, and 119-120 are also dependent claims from claim 82, but do not recite any limitations beyond the natural product itself or additional natural products.

Independent claim 115 is also directed to just the natural product. Therefore, all of the product claims of the Application are patent ineligible.

Claims 88, 96-98, and 116 recite methods of administering the natural product. Beyond the natural product itself, the only limitation recited in claim 88 is the step of administering to an individual that belongs to a specified diet cohort. Administering, which includes eating or feeding, almonds to an individual is a conventional activity. The "diet cohort" limitation just identifies the intended recipient of the natural product and does so in a generic manner that all humans would qualify. Claims 96-98 and 116 are methods of treating either unspecified medical conditions or a long list of widely divergent conditions by administering the natural product and administering is still a routine and conventional activity.

Independent claim 99 and its dependent claims recite methods of preparing nutritional formulations for an individual which include "determining," "selecting," and "preparing" steps. Each step, however, is insufficient to transform the naturally-occurring nutritional formulation, almonds, into patent-eligible subject matter. First, the "determining" step simply groups the individuals into diet cohorts, which the Application explains broadly includes a grouping based on food preference, dietary habits, age, or gender. Grouping individuals on the basis of

these generic and broad categories is well-known and conventional. Second, the "selecting and preparing" step simply links the choice of nutritional formulation to the grouping. The additional limitations of claim 99 are therefore nothing more than post-solution activities related to preparing a natural product for consumption that do not transform the claims from being directed to the ineligible natural product.

Dependent claims 102, 104, 109, and 110 recite more limitations on the method of preparing but are not directed to anything more than the natural product itself.

Claim 112 deals with a computer system that implements the method of preparing the product from claim 99. It takes dietary preferences and guidelines to generate a nutrition program. This is a type of meal planning that is a method for organizing human activity and thus an abstract idea. Further, the additional elements given in claim 112 only add conventional computer components and are not sufficient to transform the claimed computer system into a patent-eligible invention.

Further showing the Application's patent-ineligibility, Plaintiff's claims of the Application are obvious under 35 U.S.C. § 103.

A claim is unpatentable under § 103 if the differences between the claims and the prior art would have been obvious to a person of ordinary skill in the art at the time of the

invention. A presumption of obviousness exists if the claims recite a range that overlap with what is disclosed in the prior art. Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006). Here, the prior art teaches all the claimed nutrients in dosages overlapping the claimed ranges, thereby establishing such a presumption.

As the Board correctly found, claims 82-89, 91-104, 107-110, and 113-120 of the Application would have been obvious given the teachings of Morris and inventors Joshua C. Anthony et al., US Published Patent Application Number 2007/0166411 A1 (hereinafter "Anthony"). The Board treated claim 82 as representative, finding Plaintiff did not separately argue the patentability of any dependent claims as required under 37 C.F.R. § 41.37(c)(1)(iv). As the party that "seeks to change an administrative result," Plaintiff bears the "burden" of showing error in that determination. Cal. Rsch. Corp. v. Ladd, 356 F.2d 813, 819 (D.C. Cir. 1966).

The Board further found that Morris teaches preparing and administering a packaged dietary formulation comprising omega-6 fatty acids, Vitamin E, and polyphenols. It also found that Morris teaches dosages of omega-6 fatty acids and Vitamin E overlapping the claimed range.

As Defendants' expert witness Dr. William S. Harris explained, in addition to being obvious over Morris and Anthony,

the benefits of consuming the claimed nutrients were well-known in the art as of 2010. This is reflected in an additional three combinations of references that also render claims 82-89, 91-104, 107- 110, and 113-120 obvious. These additional reference combinations disclose the claimed omega-6 fatty acid, antioxidant, and polyphenol dosages that have been the focus of Plaintiff's arguments throughout this proceeding. Plaintiff has not argued with particularity why this prior art does not disclose any additional limitations in the dependent claims.

Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids and its antioxidant range. However, Plaintiff fails to establish unexpected results to rebut the presumption of obviousness based on the overlapping ranges of the prior art and Plaintiff has not shown any additional teaching away to rebut the presumption of obviousness.

Lastly, Plaintiff attempts to argue the prior art is not relevant because it does not address the problem solved by her Application. However, the prior art is from the same field of endeavor in nutritional formulations as the Application and therefore is relevant art in this case.

For the foregoing reasons, Defendant's Motion for Summary Judgment should be granted.

An appropriate Order shall issue.

Alexandria, Virginia
March 30, 2023

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

ORDER

In accordance with the accompanying Memorandum Opinion, it is hereby

ORDERED that Defendant's Motion for Summary Judgment is GRANTED and Plaintiff's Motion Strike Motion for Summary Judgement or Stay Proceedings is DENIED. This case is hereby DISMISSED.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
March 30, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

ORDER

THIS MATTER comes before the Court on Plaintiff's Motion for Leave to File Second Amended Complaint. Summary judgment has been granted for Defendant and this case was dismissed. It is hereby

ORDERED that Plaintiff's Motion for Leave to File Second Amended Complaint is DENIED.

Alexandria, Virginia
March 31, 2023

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT, Plaintiff, v. THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL., Defendants.	)	Civil Action No. 1:20-cv-1515

ORDER

THIS MATTER comes before the Court on Defendants' Motion for Expenses pursuant to 35 U.S.C. § 145.

Defendants seek reimbursement in the amount of $4,185.58 for court reporter and transcription fees related to the deposition of Plaintiff's expert Dr. Undurti N. Das.

This case arises from Plaintiff filing this action under 35 U.S.C. § 145 against Defendants challenging the final decision of the United States Patent and Trademark Office's Patent Trial and Appeal Board affirming the examiner's rejection of all Plaintiff's pending claims as unpatentable. This Court then granted Defendants' Motion for Summary Judgment. Following entry of final judgment, Defendants requested reimbursement for these fees and Plaintiff denied the request.

A party initiating a civil action under 35 U.S.C. § 145 is responsible for "all expenses of the proceedings." The costs incurred with taking the deposition of a party's expert qualify as an expense under 35 U.S.C. § 145. Thus, Defendants' expenses related to the deposition of Plaintiff's expert Dr. Undurti N. Das shall be paid by Plaintiff in the amount of $4,185.58. It is hereby

ORDERED that Defendants' motion for expenses is GRANTED, and Plaintiff shall pay to the Defendants expenses in the amount of $4,185.58.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
May 31, 2023

ADDENDUM B

CLAIMS APPENDIX

1-81. (Canceled)

82. (Previously presented) A packaged product comprising one or more nutritional formulations for an individual including at least one formulation comprising an intermixture of omega-6 fatty acid(s) and antioxidant(s) from different sources; wherein the one or more formulations are so packaged and labeled indicating suitability for consumption that collectively provide a dosage from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols in the dosage of greater than 5mg; wherein the intermixture of omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

83. (Previously presented) The product according to claim 82, wherein:

- the omega-6 fatty acids comprise one or more fatty acids selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4), and/or

- the antioxidants are selected from the group consisting of flavonoids, flavones, isoflavones, catechins, anthocyanidins, isothiocyanates, carotenoids, allyl sulfides, terpenes, limonoids, phytosterols, beta carotene, ascorbic acid (vitamin C), folic acid, Se, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione and vitamin E.

84. (Previously Presented) The product according to claim 82, wherein the one or more polyphenols is selected from the group consisting of flavonoids, phenolic acids, lignans, stilbenes, punicalagins, hydroxycinnamic acids, and tyrosols.

85. (Previously presented) The product according to claim 82, wherein the antioxidants comprise one or more phytosterols selected from the group consisting of campesterol, sitosterol, gamma sitosterol, and stigmasterol.

86. (Previously presented) The product according to claim 82, wherein the antioxidants comprise one or more phytosterols wherein the dosage of the one or more phytosterols is greater than 150mg.

87. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals, lipids, antioxidants, vitamins, minerals, probiotics, prebiotics, microorganisms, and fiber.

88. (Previously presented) A method of using the product according to claim 82, the method comprising:

administering the dosage to an individual, wherein the individual belongs to a diet cohort selected from the group consisting of one or more of the following:

(i) a diet cohort based on primary dietary ingredients of the individual's daily or weekly diet which is determined by comparing levels of one or more of antioxidants, phytochemicals, vitamins, minerals, lipids, carbohydrates, and proteins from foods of the individual's diet with levels in a set of predetermined cohorts;

(ii) a diet cohort based on average daily consumption of one or more of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners, and beverages;

(iii) a diet cohort which is predominantly vegetable-based, meat-based or seafood-based; or

(iv) a diet cohort based on gender, age, genetic profile, family history, climactic temperature, or medical condition.

89. (Previously presented) The product according to claim 82, wherein the nutritional

formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise omega-9 fatty acids in an amount less than 60% by weight of total lipids.

90. (Canceled)

91. (Previously presented) The product according to claim 82, wherein at least one of the one or more formulations are in the form of a liquid, powder, topical cream, or patch.

92. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements-collectively comprise one or more of the following:

(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is 1:1 to 50:1;

(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 4:1;

(iii) monounsaturated and polyunsaturated fatty acids, wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 4:1;

(iv) omega-3 fatty acids, wherein the amount of omega-3 fatty acids is less than 20% by weight of total lipids;

(v) the dosage of omega-6 fatty acids is less than 30g; or

(vi) omega-3 fatty acids, wherein the dosage of the omega-3 fatty acids is less than 2g.

93. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise:

- folate in dosage 100-1000 mcg; and/or

- one or more phytosterols in dosage 150-1000 mg; and/or
- one or more carotenoids in dosage 100-14,000 mcg; and/or
- betaine and/or choline in dosage 25-600 mg; and/or
- Se in dosage 10-135 mcg; and/or
- one or more fibers in dosage 5-50g; and/or
- Vitamin E-alpha/gamma in dosage 0.01-0.30% by weight of total lipids.

94. (Previously presented) The product according to claim 82, comprising a plurality of formulations, food items and/or supplements wherein one formulation, food item and/or supplement thereof provides:

(i) one or more polyphenols in a dosage less than 5 mg, but collectively the formulations provide greater than 5mg of polyphenols; and/or

(ii) antioxidants in a dosage less than 25mg, but collectively the formulations provide from 25mg to 10g of antioxidants; and/or

(iii) omega-6 fatty acids in a dosage less than 1g, but collectively the formulations provide from 1 to 40g of omega-6 fatty acids.

95. (Previously presented) The product according to claim 82, comprising a kit comprising

plurality of the one or more formulations, food items, and/or supplements, wherein:

(i) the kit comprises formulation(s) which collectively provide an amount of nutrients from 0.0001 to 100 g/kg body weight; and/or

(ii) the kit comprises from 2-20 formulations for daily consumption by the individual, collectively comprising 40-80% of individual's daily calories; and/or

(iii) the kit comprises 10-50% calories from protein, 15-50% calories from lipids, and 35-85% calories from carbohydrates; and/or

(iv) the kit comprises 2-20 formulations for daily consumption by the individual, which collectively deliver at least 50% of daily micronutrients for the individual, and/or

(v) the kit comprises at least one of: vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, or seeds packs, meat or seafood packs, or herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder, puree, or yogurt packs.

96. (Previously presented) The method according to claim 97, wherein the dosage is administered to aid acid-base balance in the individual.

97. (Previously presented) A method of prophylaxis and/or treatment of a medical condition or disease in the individual, the method comprising:

administering a dosage of the product according to claim 82 to the individual.

98. (Previously presented) The method according to claim 97, wherein the medical condition or disease is selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases.

99. (Previously presented) A method for preparing a product comprising one or more nutritional formulations for an individual, the method comprising the steps of:

(a) determining for the individual a diet cohort based on diet and/or a demographic factor of the individual; and

(b) on the basis of the diet cohort, selecting and preparing one or more nutritional formulations for the individual, including at least one formulation comprising omega-6 fatty acid(s) and antioxidant(s);

wherein the one or more formulations collectively provide to the individual a daily dosage

from 1 to 40g of omega-6 fatty acids, and from 25mg to 10g of antioxidants comprising one or more polyphenols in a daily dosage of greater than 5mg;

wherein the omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed.

100. (Previously presented) The method according to claim 99, wherein:

- the antioxidants include one or more polyphenols selected from the group consisting of flavonoids, flavones, isoflavones, catechins, anthocyanidins, phenolic acids, lignans, stilbenes, punicalagins, hydroxycinnamic acids, and tyrosols; and/or

- the omega-6 fatty acids comprise one or more fatty acids selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4), and/or

- the antioxidant(s) further comprise one or more compounds selected from the group consisting of isothiocyanates, carotenoids, allyl sulfides, terpenes, limonoids, phytosterols, ascorbic acid (vitamin C), folic acid, Se, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione and vitamin E.

101. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements-collectively comprise phytochemicals, lipids, antioxidants, vitamins, minerals, probiotics, prebiotics, microorganisms, and fiber.

102. (Previously Presented) The method according to claim 99, wherein the individual belongs to a diet cohort selected from one or more of the following:

(i) a diet cohort based on primary dietary ingredients of the individual's daily or weekly diet which is determined by comparing levels of one or more of antioxidants, phytochemicals,

vitamins, minerals, lipids, carbohydrates, and proteins from foods of the individual's diet with levels in a set of predetermined cohorts;

(ii) a diet cohort based on average daily consumption of one or more of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners, and beverages;

(iii) a diet cohort which is predominantly vegetable-based, meat-based or seafood-based; or

(iv) a diet cohort based on gender, age, genetic profile, family history, climactic temperature, or medical condition.

103. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements provide one or more of:

(i) micronutrients to supplement the individual's diet;

(ii) less than 500 calories or less than 25% of daily calories; or

(iii) lipids from natural sources to supplement the individual's diet, wherein the natural sources include oils, butters, margarines, nuts, and seeds.

104. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements provide one or more of:

(i) supplement, balance, or replace the individual's daily food consumption based on the individual's diet cohort;

(ii) at least 25% of daily or weekly total caloric intake for the individual; or

(iii) satiety and diet dietary preference of the individual.

105. (Canceled)

106. (Canceled)

107. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise one or more of the following:

(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is 1:1 to 50:1;

(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 6:1;

(iii) monounsaturated and polyunsaturated fatty acids, wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 6:1;

(iv) omega-9 fatty acids, wherein the amount of omega-9 fatty acids is less than 60% by weight of total lipids;

(v) the amount of omega-6 fatty acids is greater than 20% by weight of total lipids

(vi) comprise omega-3 fatty acids, wherein the amount of omega-3 fatty acids is less than 20% by weight of total lipids;

(vii) the dosage of omega-6 fatty acids is less than 35g; or

(viii) omega-3 fatty acids, wherein dosage of the omega-3 fatty acids is less than 2g.

108. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise:

(i) one or more polyphenols in dosage less than 300mg; and/or

(ii) folate in dosage less than 1000mcg; and/or

(iii) one or more phytosterols in dosage less than 1000mg; and/or

(iv) one or more carotenoids in dosage less than 14,000mcg; and/or

(v) betaine and/or choline in dosage less than 600mg; and/or

(vi) Se in dosage less than 135mcg; and/or

(vii) one or more fibers in dosage less than 50g; and/or

(viii) Vitamin E-alpha/gamma in dosage 0.01-0.30% by weight of total lipids.

109. (Previously presented) The method according to claim 99, wherein a packaged kit comprises the one or more formulations, food items, and/or supplements, wherein a label is attached to the packaging of the kit, wherein one or more of the following apply:

(i) the kit comprises individual portions of food items for daily consumption;

(ii) the kit comprises individual portions of food items for supplementation of daily diet of the individual;

(iii) the kit comprises a label comprising at least one indication of the suitability of the formulations or packages for a consumer with a specific dietary profile or cohort;

(iv) the kit comprises an indication of the upper limit of average daily consumption of items in the kit; or

(v) the kit comprises at least one of: vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, or seeds packs, meat or seafood packs, or herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder, puree, or yogurt packs.

110. (Previously presented) The method according to claim 99, wherein a list is prepared for the individual, which provides:

(i) predetermined natural sources of lipids, the sources selected from oils, butters, margarines, nuts and seeds, and optionally one or more of nutrients selected from antioxidants, phytochemicals, vitamins and minerals in amounts that optimizes dietary nutrients such that the individual's lipid intake provides a beneficial effect to the individual; and/or

(ii) a recommended consumption of food items over at least one week; and/or

(iii) food items that should not be included in the individual's daily diet; food items that should be limited in the individual's daily diet; or food items that should be added to the individual's daily diet.

111. (Canceled)

112. (Withdrawn) A computer system configured to computationally implement a method according to claim 99, comprising:

(a) a computing device having a memory;

(b) an input device for entering information regarding the individual's dietary preferences into the memory;

(c) a database in the memory for storing the information;

(d) a first program module, for execution in the computing device, for determining a dietary cohort of the individual corresponding to the individual's dietary preferences, wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences; wherein the dietary cohort of the individual is

(i) predetermined and entered directly in the computing device; and/or

(ii) determined either manually or computationally in response to remote user inputs of dietary preferences via a web connection; and/or

(iii) selected from predominantly vegetable-based, seafood based and meat based;

(e) a nutrient database for storing dietary guidelines relative to dietary cohorts of an individual; wherein optionally the nutrient database comprises suitable ranges for average daily dietary consumption of nutrients corresponding to each dietary cohort, and/or suitable ranges for daily dietary consumption of carbohydrates, protein, vitamins, minerals and phytochemicals;

(f) a knowledge database having rules for manipulating the information in the database to provide a recommended future nutrition program for the individual, the nutrition program comprising one or more of nutrients selected from antioxidants, phytochemicals, lipids, vitamins and minerals in amounts that provide a beneficial effect to the individual, wherein a suitable daily dosage of omega-6 fatty acids and antioxidants including polyphenols is included in the program;

(g) a second program module, for execution in the computing device, for applying the rules in the knowledge database to the information in the database and to the guidelines in

the nutrient database and for generating a nutrition program for the individual in a result database; and

(h) means for outputting the contents of the result database, under the direction of the second program module,

wherein the nutrition program comprises a listing of formulations, optionally comprising food items, wherein from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants comprising at least 5mg of one or more polyphenols are included in the program for daily consumption by the individual.

113. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise one or more of

(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is from 6:1 to 25:1;

(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 2:1;

(iii) monounsaturated and polyunsaturated fatty acids, wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 2:1;

(iv) omega-9 fatty acids, wherein the amount of omega-9 fatty acids is less than 40% by weight of total lipids;

(v) omega-6 fatty acids in an amount greater than 35% by weight of total lipids;

(vi) omega 3 fatty acids, in an amount less than 10% by weight of total lipids;

(vii) omega-6 fatty acids in a dosage less than 20g; or

(viii) omega-3 fatty acids in a dosage less than 1g.

114. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise:

(i) one or more polyphenols in a dosage less than 140mg; and/or

(ii) folate in dosage less than 400 mcg; and/or

(iii) one or more phytosterols in dosage less than 550 mg; and/or

(iv) one or more carotenoids in dosage less than 3,000 mcg; and/or

(v) betaine and/or choline in dosage less than 200 mg; and/or

(vi) Se in dosage less than 35 mcg; and/or

(vii) one or more fibers in dosage less than 20g; and/or

(viii) Vitamin E-alpha/gamma in dosage 0.01-0.05% by weight of total lipids.

115. (Previously presented) A nutritional formulation comprising a mixture of:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10 g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

116. (Previously presented) A method for treating medical conditions or diseases selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep

disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases, the method comprising:

administering to a subject the nutritional formulation in a dosage sufficient to treat the medical condition or disease wherein the nutritional formulation comprises:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

117. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals selected from the group consisting of monophenols, phenolic acids, hydroxycinnamic acids, tyrosols, monoterpenes, saponins, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds.

118. (Previously presented) The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals selected from the group consisting of monophenols, phenolic acids, hydroxycinnamic acids,

tyrosols, monoterpenes, saponins, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds.

119. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise omega-6 fatty acids in an amount greater than 20% by weight of total lipids.

120. (Previously presented) The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements-collectively comprise one or more polyphenols in dosage less than 300mg.

ADDENDUM C

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(54) Title: OPTIMIZED NUTRITIONAL FORMULATIONS, METHODS FOR SELECTION OF TAILORED DIETS THEREFROM, AND METHODS OF USE THEREOF

(57) Abstract: Nutritional compositions and formulations that optimize nutritional contents are provided. Dietary compositions and methods for tailoring such compositions to optimize levels of nutrients that have beneficial effects within specific ranges are provided. Dietary plans, and formulations comprising dietary products that comprise optimized levels of nutrients derived from phytochemicals, antioxidants, vitamins, minerals, lipids, proteins, carbohydrates, probiotics, prebiotics, microorganisms and fiber. Diet plans and modular nutritional packages comprising food and drink items tailored according to consumer patterns typed by

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OPTIMIZED NUTRITIONAL FORMULATIONS, METHODS FOR SELECTION OF TAILORED DIETS THEREFROM, AND METHODS OF USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority of U.S. Provisional Patent Application Serial No. 61/393,235, filed October 14, 2010 and U.S. Provisional Patent Application Serial No. 61/415,096, filed November 18, 2010. The contents of these patent applications are incorporated herein in their entirety by reference.

TECHNICAL FIELD OF THE INVENTION

[0002] This invention relates to the field of nutritional compositions and formulations. In particular, the application relates to methods of selection of nutritional plans tailored to optimize benefits derived from nutrients. More particularly, the invention relates to formulations and dietary products that provide compositions comprising optimized levels of nutrients such as phytochemicals, antioxidants, vitamins, minerals, lipids, proteins, carbohydrates, probiotics, prebiotics, microorganisms and fiber.

BACKGROUND OF THE INVENTION

[0003] The requirements of phytochemicals, lipids, and some other nutrients for human health are rather sensitive. There are many nutrient interactions and their range of healthful effectiveness is narrow and changes with diet type and/or demographic factors.

[0004] Formulations comprising lipids, antioxidants, phytochemicals, vitamins, minerals, microorganisms or a combination thereof, are traditionally provided as supplements or randomly added to nutritional or topical formulations. The focus is often on suppressing oxidation or inflammation, which ignores the fact that both oxidation and inflammation have a necessary role in physiology. Further, selective, repetitive, and excessive suppression may lead to dysregulation of inflammation with greater health consequences. Therefore, current approaches have the dangers of mismanaged and/or excessive delivery, which may be harmful particularly in combination with natural "nutrient rich foods," including foods such as nuts, seeds, oils, grains, legumes, fruits, vegetables, seafood, herbs, and spices, packed with certain lipids, antioxidants, phytochemicals, vitamins, minerals, and microorganisms. Similarly, functional foods that are enriched with sterols, stanols, calcium, vitamin E, folic acid, omega-3, flavonoids, etc. can also be harmful out of context. The current approach leads to

imbalanced or excessive consumption of these nutrients. As a result the prevalent approaches do not alleviate the disease burden.

[0005] To date there are no methods for matching naturally occurring foods such as nuts, seeds, oils, grains, legumes, fruits, vegetables, seafood, herbs, and spices to achieve optimal results. Instead focus is on additives, often to counter excesses. Currently there are no methods for creating delivery system(s) designed to deliver nutrients in an optimal range, such that a consumer can reach for products within the system, knowing that cumulative nutrients in the delivery system will keep them in a safe range. There is a need for the development of such system(s).

[0006] Therefore, it is desirable to develop a tailored nutritional program(s) or delivery system(s) where consumers are guided to consume naturally-occurring foods that have been matched keeping interactions, amounts, and consumer preferences in perspective. Further, the program(s) need to caution consumers against food types and amounts that may disrupt the nutritional optimization provided by the program. Within the broad parameters of personalization and moderate compliance, consumers may be at a reduced risk for chronic diseases, and with narrower parameters in personalization and greater compliance, greater health benefits may be achieved. To date tailored programs have been difficult to devise, particularly with regards to phytochemicals and lipid interactions and amounts.

[0007] The programs may be component or module based to allow flexibility and convenience for consumers. The benefits may be incremental with greater adherence to selection of components within the program. For example, lipid types and amounts are critical to health and can vary due to a number of factors, thus making the calibration complex for consumers to manage every day. Both the composition and the amounts need to be managed. For example, lipid requirement can be as much as 80 grams or 720 calories more for one family member (a 25-year-old male) than another (a 3-year-old child). This is further complicated because lipids do not mix homogenously with food; as such, individual portions may contain a disproportionate amount of lipids. Consequently, when lipids are supplemented within a given food preparation, an individual member may consume too little or too much of the lipids. Similarly, men may have a greater need for a nutrient than women. A tailored dietary component system may provide an effective solution.

[0008] As such there is a need for component based nutritional formulations, tailored diets and diet plans that provide optimized levels of nutrients such as phytochemicals, antioxidants, vitamins, minerals, lipids, proteins, carbohydrates, probiotics, prebiotics,

microorganisms and fiber. Some of these nutrients are rarely the focus of diet plans, e.g. phytochemicals, yet too much or too little of such micronutrient can turn an otherwise beneficial micronutrient in the diet to have adverse effects.

SUMMARY OF THE INVENTION

[0009] This invention relates to novel strategies for developing component based dietary formulations, and programs. In particular, the invention relates to generating tailored diets for consumers, wherein the nutrient levels are balanced to provide optimal benefits.

[0010] In certain aspects, the invention categorizes individuals into diet cohorts, for example, based on high meat, high plant, and high seafood diets. Consumers generally have a specific preference for the main foods such as red meat, seafood, or plant food. For example, vegetarians typically consume more vegetables, grains, and legumes, as compared to high-meat or high-seafood consumers. These dietary habits can help establish basic nutrients around which effective diet programs may be developed. Instead of randomly adding nutrients to a diet, there is a need to identify a series of diet types, e.g. plant, meat, or seafood heavy, and a series of consumer patterns typed by diet, age, size, gender, medical conditions, family history, climate and the like and then tailor nutritional compositions tailored to each series.

[0011] Therefore, in one aspect, the invention provides a method for customizing or selecting a nutritional formulation or plan for an individual, preferably a human. The invention in this aspect comprises determining for the individual, or categorizing the individual with respect to, a diet type ("cohort"). For example, the cohort may be high plant food, high meat (e.g., high red meat), or high seafood. In certain embodiments, the cohort is determined by the relative amounts of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners and beverages consumed by the individual, with a focus on foods rich in phytochemicals, and certain minerals and nutrients described herein, for which delivery should be controlled. The cohort may be determined based on an average daily consumption of such foods (weight, volume, or percent of calories). A nutritional program is then selected to balance certain lipids and nutrients by providing one or more nutritional formulations comprising natural oils, butters, margarines, nuts, seeds, herbs, vitamins, and minerals. These formulations deliver particular nutrients, such as lipids, phytochemicals, and minerals, to keep the individual in a safe range and thereby prevent or ameliorate the symptoms of chronic disease.

[0012] In certain embodiments, the nutritional formulation is packaged and marked for diet cohort, with a coding system for matching formulations to deliver the proper level of

micronutrients, for the convenience of the individual in maintaining a balanced nutritional state. The formulations are marked to provide the frequency for consumption (e.g., three times daily, twice daily, or once daily, or a frequency of from one to five times per week). The individual's diet is balanced (by virtue of the nutritional formulation) with respect to lipids (C4:0, C22:6 omega 3, and others), carbohydrates, protein, vitamins, minerals, antioxidants, phytochemicals, prebiotics, probiotics, and fiber. In certain embodiments, the nutritional formulation is further customized based on the age, gender, size, climactic temperature, medical condition, or lipid tolerance of the individual. In some embodiments, the nutritional formulation is in the form of one or more of an oil blend, spread or dip, sauce or dressing, or small dessert, which may be for diurnal consumption in some embodiments.

[0013] In some embodiments, the diet is balanced by the delivery of one or more (e.g., from 2 to 10) nutritional formulations that collectively make up a nutritional program for an individual. The program may collectively meet the description of the nutritional plan of Tables 5, 6, 7, or 8. At least one formulation contains one or more of phytochemicals such as phytosterol or polyphenols non-limiting examples of which include, curcumin, coumarins, and rosemarinic acid. In these or other embodiments, the diet is also balanced by the nutritional formulation with respect to minerals such as selenium. That is, the individual's diet is characterized by the sufficiency of such nutrients, and customized nutritional formulations prepared to balance the individual's diet by delivering or withholding these nutrients and/or minerals. The formulation provides a balanced lipid profile for the individual leading to physiologically balanced levels of essential fatty acids, long chain polyunsaturated fatty acids (LCPUFA), saturated fatty acids, omega-3 fatty acids, including docosahexaenoic acid (DHA), arachidonic acid, linoleic acid, omega-6 fatty acid, and omega 6:omega-3 ratio. In these or other embodiments, the diet is balanced by the delivery or withholding of one or more of the following substances (or the oil thereof) in certain defined concentrations: peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter oil, and coconut meat. Other components for the nutritional formulations are disclosed herein.

[0014] In certain embodiments, the individual may exhibit signs or symptoms of a chronic medical condition selected from gout, diabetes (type 1 or type 2), heart disease, glycemia, insulinemia, metabolic syndrome, an age-related disease (e.g., macular degeneration), or an infectious disease, and such symptoms may be ameliorated by the balanced diet (via consumption of the nutritional formulation for a period of time). The

nutritional formulations of the instant invention are suitable for prophylaxis or treatment of a medical condition or disease selected from menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases. Other features and/or components of the nutritional plan and nutritional formulations are described herein. Thus, in some embodiments, the individual is exhibiting signs and symptoms of such disease, and by consuming a customized nutritional formulation in accordance with the invention (tailored to the individual's diet cohort as described herein) for at least one week, two weeks, or one month, such symptoms are ameliorated. In some embodiments, medicaments are formulated based on a subject's dietary habits around typical consumption of phytochemicals, antioxidants, and other nutrients which may be administered with the diet plan. Appropriate supplements, medications or pharmaceutical drugs are administered to/by such dietary cohorts because their requirements, biochemistry, and gene expression may be influenced in a certain predictable way.

[0015] In another aspect, the invention provides nutritional compositions that may be modular/component systems of prepared or unprepared food, e.g. drinks, snacks, meals, desserts, cereals, salad, side dish, sauces, desserts, spreads etc, such that consumers can safely select a specific food or drink item, such as a bottle of juice, bar, a salad, a meal knowing that the nutrients derived from the components on the whole will keep them in a safe range. In certain embodiments, such components are packaged and marked for a particular cohort described herein, such that individuals can conveniently maintain nutritional balance without frequent nutritional counseling. The delivery may be in the form of novel dietary lipid programs comprising phytochemicals, antioxidants, vitamins, minerals, microorganisms and fiber designed for specific cohorts, comprising mutually complementing daily variety dosages of spread, oil blend, sauce, dressing, and dessert to fit the daily schedules, which could be convenient, appealing, and fun. Such programs minimize the possibilities and magnitude of adverse effects from inappropriate intake of nutrients, particularly phytochemicals and lipids and interactions among them.

[0016] Fine-tuning the dietary programs can be achieved by further tailoring for age, size, gender, medical conditions, lipid tolerance, family history, and climactic temperature,

and the like. In some aspects, such tailored programs are developed utilizing computer modeling, which may be provided to the consumer through a user-friendly software or web interface, allowing the consumer to: identify their diet cohort (cohort's being described herein); select and/or design customized nutritional programs delivering optimal amounts of phytochemicals, minerals, and lipids, among others; and purchase/order the individualized nutritional compositions that make up the diet plan.

[0017] In one aspect, packages and kits of prepared or unprepared food are provided to support specific aspects of the nutritional plan. In some embodiments, the packages and kits comprise component or modular systems comprising vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume/grain/nuts and/or seed packs, meat/ seafood packs, herbs, lipids, desserts, milks, yogurts and the like, or a combination thereof. In some embodiments, the kits comprise from 2 to 20, or from 5 to 10 nutritional formulations, which collectively, balance the individual's diet within the parameters disclosed in one of Tables 5 to 8. The nutritional formulations may be designed to, collectively, comprise at least 40%, at least 50%, at least 60%, or at least 80% of the individual's caloric intake. In some embodiments, the kits and packages comprise food suitable for consumption by babies and include, but are not limited to soybean-based formula, milk formula, standard milk formula, follow-on milk formula, toddler milk formula, hypoallergenic milk formula, prepared baby food, dried baby food and other baby food.

[0018] In one aspect, food items recommended in a diet plan or contained in a specific component or module are selected based on the methods of cooking, processing or manufacturing used in preparing the food items such that optimal nutrient content is achieved, and/or desired activation or inactivation of nutrients particularly phytochemicals is achieved.

[0019] Further aspects and embodiments of the invention will be apparent from the following detailed description of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0020] Universal supplementation of monounsaturated, omega-6, omega-3, other fatty acids, antioxidants, phytochemicals, vitamins, or minerals, and microorganisms without regard to the context has not been effective. Sensitive requirements are materially altered by a number of nutritional and demographic factors. Further, while many nutritional systems focus on the protein and/or carbohydrate component of the diet, proteins and carbohydrates affect

health patterns mostly when consumed in large amounts, e.g. a gram or more. On the other hand, microgram amounts of nutrients such as some lipids, antioxidants, phytochemicals, vitamins, minerals, probiotics, prebiotics, and microorganisms, can have significant effect on health. Thus, an object of the present invention is to balance nutrition based on supplementation with lipids, antioxidants, phytochemicals, vitamins, minerals, probiotics, prebiotics, and/or microorganisms.

[0021] The present invention relates, in-part, to the surprising finding that, while phytochemicals, lipids, antioxidants, vitamins, minerals, and microorganisms have a narrow window of healthful effects, and that the requirements change based on the complement of nutrients, individualized diet plans can nevertheless be designed with surprising simplicity and accuracy. Therefore, the invention provides methods for preparing nutritional plans, and provides nutritional formulations (including complementing nutritional formulations), such that total consumption of these key nutrients is kept in a safe range. Further benefit can be derived by tailoring them to diet cohort defined at least in part by protein and carbohydrate consumption. Further benefit can be derived by tailoring these formulations to diet cohort defined at least in part by demographic factors including one or more of: age, gender, size, medical condition, family history, and climate. Such methods would lead to reduced risk for chronic diseases, and achieve greater health benefits.

[0022] The following description of example embodiments is, not to be taken in a limited sense. The scope of the present invention is defined by the appended claims.

[0023] Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications and patents specifically mentioned herein are incorporated by reference for all purposes including describing and disclosing the chemicals, cell lines, vectors, animals, instruments, statistical analysis and methodologies which are reported in the publications which might be used in connection with the invention. Nothing herein is to be construed as an admission concerning the content of the prior art, that the invention is not entitled to antedate any particular disclosure by virtue of prior invention.

[0024] Before the present materials and methods are described, it is understood that this invention is not limited to the particular methodology, protocols, materials, and reagents described, as these may vary. It is also to be understood that the terminology used herein is for

the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention.

Definitions

[0025] As used herein, the term "phytochemical" refers to any natural molecule of plant origin. They are found in fruits, vegetables, beans, grains, and other plants. The terms "phytochemical" and "phytonutrient" are used interchangeably to describe the active components of plants. Commonly known phytonutrients or phytochemicals include (but are not limited to) antioxidants, flavonoids, flavones, isoflavones, catechins, anthocyanidins, isothiocyanates, carotenoids, allyl sulfides, polyphenols, terpenes, limonoids, lipids, phytosterols, beta carotene, ascorbic acid (vitamin C), folic acid, and vitamin E. Phytochemicals that the nutritional plan may control, and exemplary sources, are listed in Table 1. These phytochemicals/sources are controlled in the construction of the diet plan, and their delivery substantially controlled by virtue of a one, two, or three complementing formulations of natural oils, butters, margarines, nuts, seeds, herbs, vitamins, and minerals. Optionally, these formulations may take the form of a conventional supplement, such as a capsule for oral administration, or alternatively a topical formulation.

[0026] As used herein, the term "lipid" refers to any fat-soluble (lipophilic) molecule. These include (but are not limited to) components of vegetable oils, components of seed oils, triglycerides, waxes of triglycerides, and phospholipids. As used herein, the term "lipid" comprises a source of lipids or fats comprising any suitable lipid or lipid mixture. For example, the lipid source may include, but is not limited to, vegetable fat (such as olive oil, peanut oil, corn oil, sunflower oil, rapeseed oil, soy oil, palm oil, coconut oil, canola oil, lecithins, walnuts, flaxseeds, and the like) and animal fats (such as milk fat), structured lipids or other modified lipids such as medium chain triglycerides. As used in the nutritional formulations disclosed herein, the lipid is a component of a dietary food item and/or added individually as a supplement.

[0027] In some embodiments, the compositions of the present disclosure include one or more of the following fatty acids: Saturated fatty acids: butyric (C4:0), lauric (C12:0), myristic (C14:0), palmitic (C16:0), stearic (C18:0), and arachidic (20:0); monounsaturated fatty acids: myristoleic (C14:1), palmitoleic (C16:1); omega-9 fatty acids: oleic (C18:1), gadoleic (C20:1), erucic (C22:1), and nervonic (C24:1); omega-6 fatty acids: linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and omega-3 fatty acids: alpha-linolenic (C18:3),

stearidonic (C18:4), eicosapentaenoic (C20:5), docosapentaenoic (C22:5), and docosahexaenoic (C22:6) fatty acids.

[0028] As used herein, a "prebiotic" is a food substance that selectively promotes the growth of beneficial bacteria or inhibits the growth or mucosal adhesion of pathogenic bacteria in the intestines. The prebiotic can be acacia gum, alpha glucan, arabinogalactans, arabinoxylans, beta glucan, dextrans, fructooligosaccharides, galactooligosaccharides, galactomannans, gentiooligosaccharides, glucooligosaccharides, guar gum, inulin, isomaltooligosaccharides, lactosucrose, lactulose, levan, maltodextrins, partially hydrolyzed guar gum, pecticoligosaccharides, resistant starches, retrograded starch, soy oligosaccharides, sugar alcohols, xylooligosaccharides, or their hydrolysates, or combinations thereof. For example, prebiotics are defined by Glenn R. Gibson and Marcel B. Roberfroid, "Dietary Modulation of the Human Colonic Microbiota: Introducing the Concept of Prebiotics," J. Nutr. 1995 125: 1401 -1412. Prebiotics are fermented by the gastrointestinal microflora and/or by probiotics.

[0029] As used herein, probiotic micro-organisms (hereinafter "probiotics") are preferably microorganisms (alive, including semi-viable or weakened, and/or non-replicating), metabolites, microbial cell preparations or components of microbial cells that could confer health benefits on the host when administered in adequate amounts, more specifically, that beneficially affect a host by improving its intestinal microbial balance, leading to effects on the health or well-being of the host. See, Salminen S, Ouwehand A. Benno Y. et al. Trends Food Sci. Technol. 1999: 10 107-10. The probiotic can be of bacterial, yeast, or fungal origin, including *Saccharomyces, Debaromyces, Candida, Pichia, Torulopsis, Aspergillus, Rhizopus, Mucor, Penicillium, Bifidobacterium, Bacteroides, Clostridium, Fusobacterium, Melissococcus, Propionibacterium, Streptococcus, Enterococcus, Lactococcus, Staphylococcus, Peptostrepococcus, Bacillus, Pediococcus, Micrococcus, Leuconostoc, Weissella, Aerococcus, Oenococcus, Lactobacillus* or a combination thereof.

[0030] As used herein, the term "protein" comprises a protein or polypeptide obtained from a source selected from dietary protein including, but not limited to animal protein (such as milk protein, meat protein or egg protein), vegetable protein (such as soy protein, wheat protein, rice protein, canola and pea protein), or a combination thereof. In another embodiment, the compositions or formulations include one or more amino acids selected from: Isoleucine, Alanine, Leucine, Asparagine, Lysine, Aspartate, Methionine, Cysteine, Cystine,

Phenylalanine, Glutamate, Threonine, Glutamine, Tryptophan, Citrulline, Glycine, Valine, Proline, Serine, Tyrosine, Arginine, Histidine, or a combination thereof.

[0031] As used herein, the term "carbohydrate" refers to a source of carbohydrates comprising any suitable carbohydrate, including, but not limited to, sucrose, lactose, glucose, fructose, corn syrup solids, maltodextrin, modified starch, amylose starch, tapioca starch, corn starch, isomalt, isomaltulose, or combinations thereof. As used in the nutritional formulations disclosed herein, the carbohydrate is a component of a dietary food item and/or added individually as a supplement.

[0032] As disclosed herein, the nutritional composition includes minerals, or supplements containing such minerals, in a form that promotes metabolic alkalinity versus acidity. The minerals are provided attached to various organic acids, amino or fatty acids, or naturally occurring as part of a real food. For example, different forms of magnesium, calcium or aluminum are suitable for affecting acid-base balance.

[0033] The compositions/formulations disclosed herein can be included in a nutritional or nutraceutical composition together with additional active agents, carriers, vehicles, excipients, or auxiliary agents identifiable by a person skilled in the art upon reading of the present disclosure.

[0034] Subject as used herein refers to humans and non-human primates and any other organisms which can benefit from the agents of the present disclosure. There is no limitation on the type of animal that could benefit from the presently described agents. A subject regardless of whether it is a human or non-human organism may be referred to as a patient, individual, animal, host, or recipient. In certain preferred embodiments, the subject is a human.

Abbreviations

[0035] The following abbreviations are used throughout the application: AA, arachidonic acid (20:4n-6); ADHD, attention deficit hyperactivity disorder; ALA, alpha-linolenic acid (18:3n-3); γT, alpha-tocopherol; COX, cyclooxygenase; D5D, delta-5-desaturase; D6D, delta-6-desaturase; DGLA, dihomo-gamma-linolenic acid (20:3n-6); DHA, docosahexaenoic acid (22:6n-3); HNF, hepatic nuclear factor; EFA, essential fatty acids; EPA, eicosapentaenoic acid (20:5n-3); GLA, gamma-linolenic acid (18:3n-6); GSHpx, glutathione peroxidase; γT, gamma-tocopherol; IL, interleukin; LA, linoleic acid (18:2n-6); LCPUFA, long-chain PUFA (DGLA, AA, EPA, and DHA); LPO, lipid peroxidation products; LT,

leukotriene; LXR, liver X receptor; MUFA, monounsaturated fatty acids; NFkB, nuclear factor kB; OA, oleic acid (18:1n-9); PG, prostaglandin; PPAR, peroxisome proliferator activated receptor; PUFA, polyunsaturated fatty acid; SCD, stearoyl CoA desaturase also known as delta-9-desaturase; Se-GSHpx, Se-dependent glutathione peroxidase ; SFA, saturated fatty acids; SOD, superoxide dismutase; SREBP, sterol regulatory element-binding proteins; TNF, tumor necrosis factor; TX, thromboxane; UCP, uncoupling proteins.

[0036] The invention disclosed herein relates to development of nutritional compositions and/or formulations tailored to individual preferences that balance phytochemicals, antioxidants, vitamins, minerals, acid-base, lipids, proteins, carbohydrates, probiotics, prebiotics, microorganisms, fiber, and the like. Nutritional plans are based primarily on consumption of food from preferred natural sources. Levels and types of nutrients in each food item are considered in developing a nutritional plan keeping interactions in perspective that provides nutrients at levels that have exemplary health benefits. Nutritional plans are tailored to fit the primary dietary preferences of consumers.

Nutritional plans and influencing factors

[0037] In one aspect, the invention provides a method for customizing or selecting a nutritional plan for an individual. The nutritional plan comprises from 2 to about 20 (or from 2 to about 10) nutritional formulations, which are mutually complementing to balance certain micronutrients described herein. In certain embodiments, the nutritional plan comprises from 4 to about 12 or from 4 to about 10 mutually complementing formulations (e.g., complementing with respect to micronutrients). In certain embodiments, one, two, or three of these formulations deliver (collectively) at least 50%, or at least 75%, or at least 90% of the set of micronutrients, with the remaining formulations balanced with respect to basic dietary considerations, such as protein intake, carbohydrate intake, and/or caloric intake, for example. Lipid intake is also balanced, but in-part the balance is achieved by the delivery of the micronutrient formulation. For the one, two, or three formulations comprising the substantial level of micronutrients, a subset of from 3 to about 10 formulations can be prepared for selection between individuals, thereby allowing for cost-effective individualization. For example, in a particular example, the formulations delivering the micronutrients may deliver polyphenols at about 5, 10, 15, 20, 45, 70, 95, 115, 140, or 165 mg/day; and (respectively) folate at about 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 mcg/day; phytosterols (at respectively) about 150, 200, 250, 300, 350, 450, 550, 650, 750, or 850 mg/day; and Se at

about 5, 10, 15, 20, 35, 55, 75, 95, 115, or 135 mcg/day (respectively). In some embodiments, these values may vary by up to 10% or 20%.

[0038] The invention in this aspect comprises determining for the individual, or categorizing the individual with respect to, a diet type or "cohort." For example, the diet type may be high plant food, high meat (e.g., high red meat), or high seafood. In certain embodiments, the diet type is determined by the relative amounts of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners and beverages consumed by the individual. A nutritional program is then selected to balance certain phytochemicals including lipids and other nutrients by the delivery of one or more nutritional formulations comprising one or more of natural oils, butters, margarines, nuts, seeds, herbs, vitamins, and minerals. For example, the nutritional formulation may be packaged and marked for diet type or cohort, for the convenience of the individual. In certain embodiments, the packaging of the nutritional formulations may comprise components or modules each comprising all or part of a dietary cohort's nutritional requirements. In certain embodiments, the nutritional formulation is further customized based on the age, gender, climactic temperature, medical condition, or lipid tolerance of the individual. Balancing diet plans based on certain demographics is described in WO 2009/131939, which is hereby incorporated by reference.

[0039] For example, diet plans and nutritional kits can be prepared as follows.

[0040] Dietary components (such as those described herein) are grouped as: legume, grain, vegetable, fruit, meat, seafood, herb, spice, nut, seeds, oil, or butter.

[0041] Food items from the list are selected that have a significant level of sensitive nutrients (see, e.g., Table 1), such as polyphenols, phytosterols, fat soluble vitamins/substances A,D,E,K, lipids, folate, and Se. These should be controlled. Food sources having significant levels of these micronutrients are described herein, and are known in the art. Where a layer or part of the sensitive food item can be removed (e.g. bran, husk, germ, or skin) to remove the significant levels of micronutrient, then the part is removed and the food item is regrouped with its basic category (e.g., legume or grain). In some embodiments, a method of processing as described later is used to arrive at optimal nutrient content or activity.

[0042] With like items grouped together, a combination of grains is created, as described herein and as shown in one of Tables 5 – 8 for example. In certain embodiments, grains with strong properties e.g. barley, spelt, quinoa, millet, spelt oats, and rye are controlled. For example, collectively, in certain formulations, these components may make up less than 70%, less than 50%, less than 40%, less than 30%, or less than 20% of carb calories. These steps

are repeated for legumes, vegetables, and fruits. The amounts of soy, pink lentils, black beans, and pigeon peas are also controlled, since these items are high in flavonoids. In various embodiments, these items make up less than 70%, less than 50%, less than 40%, less than 30%, or less than 20% of protein calories.

[0043] For meat and seafood items, these comprise less than 70%, less than 50%, less than 40%, less than 30%, or less than 20% of protein calories.

[0044] The remaining nutrients needed to balance the nutritional plan are supplied by one, two, or three or more formulations comprising herbs, spices, nuts, seeds, oils, butters, and sweeteners, which are described in detail herein. Thus, the entire nutritional plan in some embodiments meets the description in one of Tables 5 to 8. For example, for this micronutrient formulation, grains, legumes, vegetables, fruits, herbs, seeds, or a combination thereof; in whole, stripped-down, or processed form; are prepared to arrive at a healthful dosage of phytochemicals (polyphenols, sterols, coumarins, isoflavones (Daidzein, Genistein, Glycitein), flavonoids, bran, endosperm etc.).

[0045] The set of formulations can be fine-tuned by cohorts, such as for heavy meat, vegetarian, and heavy seafood. For each cohort, it is important to identify which phytochemicals, minerals, and/or nutrients are likely to be over- or underconsumed. For example, for the meat cohort: it is likely that consumption of phytosterols, polyphenols, and isoflavones is inadequate, and thus should be supplemented accordingly. If most protein calories are met by meat, then herbs, nuts and seeds can replace added fats. If there is room for additional protein calories, then legumes (black beans, kidney beans, peas, soy, pigeon peas, black gram, chickpeas) can be used. For heavy seafood diets, it will likely be necessary to avoid nuts, seeds, and certain whole grains. For vegetarians, the nutritional plan must guard against excess of phytochemicals particularly phytosterols, polyphenols, isoflavones, and make up for potential protein deficiency. The actual level for each phytochemical, mineral, or nutrient consumed too much or too little in each cohort, can be computed.

[0046] By classifying an individual as meat, plant, or seafood-base cohort, the following factors can be taken into account. In certain embodiments, cohorts are specifically defined by the amount or presence of the following factors.

[0047] In certain embodiments, the nutritional formulation is balanced, with respect to the individual, for essential fatty acids and their metabolites, long-chain polyunsaturated fatty acids (LCPUFA), eicosanoids, monounsaturated fatty acids, and saturated fatty acids, through the delivery of lipids, phytochemicals, nutrients, minerals, and other components.

[0048] In some embodiments, the individual's diet cohort is defined, at least in-part, by consumption of and requirement for essential fatty acids, and which may be implemented by the defining cohorts as plant-based, meat-based, or seafood-based, in some embodiments. For example, essential fatty acids (EFA) and their metabolites, long-chain polyunsaturated fatty acids (LCPUFA) and various eicosanoids play an important role in human health. Monounsaturated and saturated fatty acids also have a significant role in health. However, the latter can inhibit the activity and bioavailability of EFA and LCPUFA. Genders differ in their ability to metabolize lipids due to sex hormones and differential gene expression. Change in hormone status may also change lipid requirements with age. Further, of the macronutrients, lipids are the most susceptible to oxidative stress, which is one of the most likely causes of aging. Synergistic and managed use of different antioxidants is of benefit to human health. Sudden and wide fluctuations in fatty acids consumption can alter the immune response, which is dose-dependent, the excitability of neural and muscle cells and neurotransmission, and androgen production. Thus sudden and large alterations in fatty acids consumption may cause compromised immunity and physiological disturbances.

[0049] In some embodiments, the diet cohort is defined, at least in-part, by the individual's consumption of and requirement for omega-6, omega-3, and omega-9 fatty acids, including one or more of the omega-6:omega-3 ratio, the omega-9:omega-6 ratio, ratio of monounsaturated fatty acids to polyunsaturated fatty acids, and ratio of monounsaturated fatty acids to saturated fatty acids.

[0050] In these and other embodiments, the individual's diet cohort is defined at least in-part by the individual's consumption of antioxidants, phytochemicals, vitamins, and minerals, including particular antioxidants, phytochemicals, vitamins, and minerals described herein. In some of these embodiments, the cohort is further defined by gender, age, size, and climactic temperature for the individual, which will affect the individual's requirement for such nutrients. A number of factors can influence metabolism, including antioxidants, phytochemicals, vitamins, minerals, hormones, and microorganisms as well as the gender, genetics and age of the individual, and climactic temperature.

[0051] Nutritional programs are developed based on the observation that phytochemicals, antioxidants, vitamins and minerals, microorganisms significantly alter the sensitivity of lipid requirement and metabolism. Thus, the diet cohort may be defined in some embodiments by the requirement for omega-6, omega-3, and omega-9 fatty acids, including one or more of the omega-6:omega-3 ratio, the omega-9:omega-6 ratio, ratio of

monounsaturated fatty acids to polyunsaturated fatty acids, and ratio of monounsaturated fatty acids to saturated fatty acids; and this requirement used to supplement or withdraw one or more of phytochemicals, antioxidants, vitamins, minerals, and microorganisms from the individual's diet, using a customized nutritional composition.

[0052] While a number of factors can influence fatty acid metabolism such as the presence of other fatty acids, antioxidants, phytochemicals, vitamins, minerals, hormones, and microorganisms as well as the gender, genetics and age of the individual consumer, and climactic temperature, the present invention provides a simple yet accurate method for determining an individual's requirement for fatty acids, and a convenient and effective nutritional supplementation program. While in certain embodiments the individual's requirements are determined by identifying a basic diet cohort (e.g., meat, plant, or seafood, and optionally one or more of gender, size, age, and climactic temperature), additional influencing factors may optionally be considered in defining the diet cohort, and these influencing factors are described below.

Desaturase Modulators

[0053] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, desaturase modulators. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Desaturase modulators include essential fatty acids, vitamin A, curcumin, sesamin, and phytosterols.

[0054] The desaturases D6D and D5D are involved in the production of potent LCPUFA. Several nutritional, hormonal, and genetic factors can influence the activity of the desaturases. In response to increase or decrease of EFA levels, the desaturases may rapidly change in activity levels. Thus, a large and sudden increase in omega-6 fatty acids from deficient conditions may lead to sudden surge of LCPUFA, its metabolites, and inflammation. The limited desaturase activity in certain pathological states might be due to or exacerbated by other endogenous or exogenous factors rather than an enzymatic defect.

[0055] Males and females differ in their ability to synthesize long-chain omega-3 fatty acids from ALA as hormones play a role. Estradiol may increase, whereas testosterone may decrease the production of LCPUFA from LA and ALA. Omega-3 pathway is more responsive to hormonal treatment than omega-6 pathway. In females, the conversion from ALA to DHA may be as high as 9%, whereas for males it may be 0.5-4% resulting in higher DHA concentration in plasma lipids, without significant differences in their consumption of

protein, carbohydrate, total fat, alcohol, individual fatty acids and selected nutrients. Growth hormones have been found to increase the D6D activity and LCPUFA in animal models. Vitamin A has been shown to down regulate the expression of D5D. In addition, some phytochemicals, particularly curcumin and sesamin, have also been shown to influence D5D function. , D5-desaturation of omega-6 fatty acids was down regulated, whereas D5-desaturation omega-3 fatty acids was up regulated. Fujiyama-Fujiwara Y, et al. Effects of sesamin and curcumin on delta 5-desaturation and chain elongation of polyunsaturated fatty acid metabolism in primary cultured rat hepatocytes. J Nutr Sci Vitaminol (Tokyo). Aug 1992;38(4):353-363. 1995; 41(2), 217-225. Phytosterols have been shown to increase the activity of D6D, D5D, and SCD.

[0056] The most potent regulator of desaturase activity is the cellular LCPUFA availability. Under normal physiological conditions cellular LCPUFA is maintained in a narrow range by regulation of desaturase transcription.

Phytochemicals

[0057] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, phytochemicals. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Phytochemicals in certain embodiments are one or more of those in Table ~~2~~.1 In certain embodiments, the cohort is defined by the approximate level of consumption of the sources of such phytochemicals listed in Table ~~2~~. 1.

[0058] A key ingredient in optimizing dietary programs comprises providing the proper types and amounts of phytochemicals in the nutritional plan. Phytochemicals (phytoalexins, plant matter, natural molecules contained in plants) have powerful properties, but healthful effects are available within narrow ranges of amounts included in the diet particularly because they have cumulative effects.

[0059] In general, phytochemicals: (a) have antioxidant properties, change oxidation of lipids and other molecules; (b) may turn into prooxidants at high amounts or due to some interactions; (c) modulate gene expression; stimulate synthesis of adaptive proteins/genes for cytoprotective, detoxifying and antioxidant enzymes; (d) maintain genome integrity; (e) modulate cell signaling pathways and membrane, cytoplasmic, and nuclear enzymatic reactions; (f) dampen cellular hyperproliferation and hyperactivity, promote apoptosis of genetically unstable cells; (g) accumulate in cell membranes causing alterations of cell shape and modulation of the bilayer material properties (bilayer thickness, fluidity and elasticity) that

affect membrane proteins and ion channels; (h) inhibit inflammation, e.g. transcription of NFkB, which regulates broad range of cytokine genes involved in inflammation (e.g. sulforaphane, curcumin, zerumbone); or activate PPAR-gamma, which may modulate anti-inflammatory genes and inhibit NFkB (e.g. curcumin, capsaicin, ginsenosides, hesperidin, and resveratrol); (i) may excessively suppress oxidation and/or certain inflammatory molecules or pathways; body may then upregulate compensatory mechanisms; (j) may inhibit mitochondrial function; (k) may lead to acidosis particularly when consumed with omega-3 and unbalanced or inadequate lipids (xanthones have been shown to cause acidosis, there are quite likely other phytochemicals that cause acidosis); (l) may alter metabolism and activity of lipids and their metabolites; (m) may increase the requirement for Omega-6, and some other fatty acids; and (n) may reduce the requirement or tolerance for omega-3 (e.g. certain polyphenols enhance synthesis of long-chain omega-3 from its precursor, but may impede formation of long-chain omega-6).

Table 1: List of common/known phytochemicals and plant matter and their exemplary sources.

MONOPHENOLS:

Apiole (parsley)

Carnosol (rosemary)

Carvacrol (oregano, thyme)

Dillapiole (dill)

Rosemarinol (rosemary)

POLYPHENOLS: (flavonoids, phenolic acids, lignans, stilbenes)

Flavonoids

Flavonols: Quercetin (onions, tea, wine, apples, cranberries, buckwheat, beans), Gingerol (ginger), Kaempferol (strawberries, gooseberries, cranberries, peas, brassicates, chives), Myricetin (grapes, walnuts), Rutin (citrus fruits, buckwheat, parsley, tomato, apricot, rhubarb, tea). Isorhamnetin, Proanthocyanidins procyanidins, prodelphinidins and propelargonidins, apples, maritime pine bark, cinnamon, aronia fruit, cocoa beans, grape seed, grape skin, red wine

Flavones: Chrysin, Apigenin (chamomile, celery, parsley) Luteolin, Tricetin, Disometin etc Parsley, capsicum pepper

Flavanones: Naringenin (citrus), Hesperidin (citrus), Dihydroquercetin etc Orange juice, grape fruit, lemon peel & juice etc, Eriodictyol.

Flavan3ols: Catechins (white tea, green tea, black tea, grapes, wine, apple juice,

cocoa, lentils, black-eyed peas), Silymarin, Silibinin, Taxifolin, (+)- Catechin, (+)-Gallocatechin, (-)-Epicatechin, (-)-Epigallocatechin, (-)-Epigallocatechin gallate (EGCG) – green tea;

(-)-Epicatechin 3-gallate (ECG), Theaflavin – black tea; Theaflavin-3-gallate – black tea; Theaflavin-3'-gallate – black tea; Theaflavin-3,3'-digallate – black tea; Thearubigins etc Cocoa, chocolates, cocoa beverages, beans, cherry, grapes, red wine, cider, blackberry etc

Isoflavones: Daidzein (formononetin) – soy, alfalfa sprouts, red clover, chickpeas, peanuts, other legumes. Genistein (biochanin A) – soy, alfalfa sprouts, red clover, chickpeas, peanuts, other legumes. Glycitein – soy.

Chalcones:

Anthocyanins and Anthocyanidins: Pelargonidin – bilberry, raspberry, strawberry. Peonidin – bilberry, blueberry, cherry, cranberry, peach. Cyanidin – red apple & pear, bilberry, blackberry, blueberry, cherry, cranberry, peach, plum, hawthorn, loganberry, cocoa. Delphinidin – bilberry, blueberry, eggplant. Malvidin – bilberry, blueberry. Petunidin

Dihydroflavonols

Chalconoids

Coumestans (phytoestrogens) Coumestrol – red clover, alfalfa sprouts, soy, peas, brussels sprouts.

phloretin.

Phenolic acids

Ellagic acid – walnuts, strawberries, cranberries, blackberries, guava, grapes.

Gallic acid – tea, mango, strawberries, rhubarb, soy.

Salicylic acid – peppermint, licorice, peanut, wheat.

Tannic acid – nettles, tea, berries.

Vanillin – vanilla beans, cloves.

Capsaicin – chilli peppers.

Curcumin – turmeric, mustard. (Oxidizes to vanillin.)

Lignans (phytoestrogens) – seeds (flax, sesame, pumpkin, sunflower, poppy), whole grains (rye, oats, barley), bran (wheat, oat, rye), fruits (particularly berries) and vegetables.

Silymarin – artichokes, milk thistle.

Matairesinol – flax seed, sesame seed, rye bran and meal, oat bran, poppy seed,

strawberries, blackcurrants, broccoli.

Secoisolariciresinol – flax seeds, sunflower seeds, sesame seeds, pumpkin, strawberries, blueberries, cranberries, zucchini, blackcurrant, carrots.

Pinoresinol and lariciresinol – sesame seed, Brassica vegetables

enterolactone, enterodiol

Stilbenes

Resveratrol – grape skins and seeds, wine, nuts, peanuts, berries

Pterostilbene – grapes, blueberries

Piceatannol – grapes

Punicalagins – pomegranates

Hydroxycinnamic acids

Caffeic acid – burdock, hawthorn, artichoke, pear, basil, thyme, oregano, apple, rosemary, coffee

Chlorogenic acid – echinacea, strawberries, pineapple, coffee, sunflower, blueberries.

Cinnamic acid – cinnamon, aloe.

Ferulic acid – oats, rice, artichoke, orange, pineapple, apple, peanut.

Coumarin – citrus fruits, maize.

Tyrosol esters

Tyrosol – olive oil

Hydroxytyrosol – olive oil

Oleocanthal – olive oil

Oleuropein – olive oil

TERPENES (ISOPRENOIDS)

Carotenoids (tetraterpenoids)

Carotenes - orange pigments

α-Carotene – to vitamin A, in carrots, pumpkins, maize, tangerine, orange.

β-Carotene – to vitamin A, in dark, leafy greens and red, orange and yellow fruits and vegetables.

γ-Carotene

δ-Carotene

Lycopene – Vietnam Gac, tomatoes, grapefruit, watermelon, guava, apricots, carrots, autumn olive.

Neurosporene

Phytofluene – star fruit, sweet potato, orange.

Phytoene – sweet potato, orange.

Xanthophylls - yellow pigments.

Canthaxanthin – paprika.

Cryptoxanthin – mango, tangerine, orange, papaya, peaches, avocado, pea, grapefruit, kiwi.

Zeaxanthin – wolfberry, spinach, kale, turnip greens, maize, eggs, red pepper, pumpkin, oranges.

Astaxanthin – microalge, yeast, krill, shrimp, salmon, lobsters, and some crabs

Lutein – spinach, turnip greens, romaine lettuce, eggs, red pepper, pumpkin, mango, papaya, oranges, kiwi, peaches, squash, legumes, brassicates, prunes, sweet potatoes, honeydew melon, rhubarb, plum, avocado, pear.

Rubixanthin – rose hips.

Monoterpenes

Limonene – oils of citrus, cherries, spearmint, dill, garlic, celery, maize, rosemary, ginger, basil.

Perillyl alcohol – citrus oils, caraway, mints.

Saponins – soybeans, beans, other legumes, maize, alfalfa.

Lipids

Phytosterols – almonds, cashews, peanuts, sesame seeds, sunflower seeds, whole wheat, maize, soybeans, many vegetable oils.

Campesterol - buckwheat.

beta Sitosterol – avocados, rice bran, wheat germ, corn oils, fennel, peanuts, soybeans, hawthorn, basil, buckwheat.

gamma sitosterol

Stigmasterol – buckwheat.

Tocopherols (vitamin E)

omega-3, 6,9 fatty acids – dark-green leafy vegetables, grains, legumes, nuts.

gamma-linolenic acid – evening primrose, borage, blackcurrant.

Triterpenoid

Oleanolic acid - American pokeweed, honey mesquite, garlic, java apple, cloves, and many other Syzygium species.

Ursolic acid - apples, basil, bilberries, cranberries, elder flower, peppermint, lavender, oregano, thyme, hawthorn, prunes.

Betulinic acid - Ber tree, white birch, tropical carnivorous plants Triphyophyllum peltatum and Ancistrocladus heyneanus, Diospyros leucomelas a member of the persimmon family, Tetracera boiviniana, the jambul (Syzygium formosanum), and many other Syzygium species.

Moronic acid - Rhus javanica (a sumac), mistletoe

BETALAINS

Betacyanins

betanin - beets, chard

isobetanin - beets, chard

probetanin - beets, chard

neobetanin - beets, chard

Betaxanthins (non glycosidic versions)

Indicaxanthin - beets, sicilian prickly pear

Vulgaxanthin – beets

ORGANOSULFIDES

Dithiolthiones (isothiocyanates)

Sulphoraphane – Brassicates.

Thiosulphonates (allium compounds)

Allyl methyl trisulfide – garlic, onions, leeks, chives, shallots.

Diallyl sulfide – garlic, onions, leeks, chives, shallots.

INDOLES, GLUCOSINOLATES/ SULFUR COMPOUNDS

Indole-3-carbinol – cabbage, kale, brussels sprouts, rutabaga, mustard greens, broccoli.

sulforaphane - broccoli

3,3'-Diindolylmethane or DIM - broccoli family

Sinigrin - broccoli family

Allicin - garlic

Alliin - garlic

Allyl isothiocyanate - horseradish, mustard, wasabi

Piperine - black pepper

Syn-propanethial-S-oxide - cut onions.

PROTEIN INHIBITORS

Protease inhibitors – soy, seeds, legumes, potatoes, eggs, cereals.

OTHER ORGANIC ACIDS

Oxalic acid – orange, spinach, rhubarb, tea and coffee, banana, ginger, almond, sweet potato, bell pepper. Phytic acid (inositol hexaphosphate) – cereals, nuts, sesame seeds, soybeans, wheat, pumpkin, beans, almonds. Tartaric acid – apricots, apples, sunflower, avocado, grapes. Anacardic acid - cashews, mangoes.

[0060] See Dr. Duke's Phytochemical and Ethnobotanical Databases (available on the web at ars-grin.gov/duke/) for details on phytochemicals in natural foods and their known or presumed activities.

Lipids and metabolites

[0061] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, omega-3, omega-6, omega-9 fatty acids, and optionally, fat soluble vitamins including A, D, E, and K. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Optimal levels for basic dietary cohorts of meat, plant, and seafood heavy diets is disclosed herein (see Tables 6 to 8).

[0062] Lipids include a group of phytochemicals that include omega-3, -6, -9 fatty acids, other fatty acids, waxes, sterols, fat-soluble vitamins A, D, E and K. Phytosterols are a subgroup of lipids, more than 200 steroid compounds similar to cholesterol are found in plants.

[0063] A large part of the human sensitivity to lipids is due to the actions of essential fatty acids (EFA) and their metabolites. Eicosanoids, EFA metabolites, are involved in various physiological and pathological processes, including blood vessel constriction, dilation, blood pressure regulation, platelet aggregation, and modulation of inflammation. Generally, eicosanoids of AA origins produce a vigorous response, whereas eicosanoids of EPA origins produce a muted response. Additionally, AA, EPA, and DHA are precursors for lipoxins, resolvins, and neuroprotectins with anti-inflammatory properties. Though LCPUFA modulate a number of biological functions through eicosanoids, the fatty acids are highly active as components of cell membranes in pinocytosis, ion channel modulation, and gene regulation.

[0064] It is important to balance omega-6 and omega-3 fatty acids in human nutrition for optimal function of cellular membranes and for balance between eicosanoids produced from omega-6 and omega-3 fatty acids. The present consumption pattern, omega-6-to-omega-3 ratios of 15:1-17:1 in Western diets, has been cited as one of the dietary component

significantly associated with modern chronic diseases. Simopoulos AP. Evolutionary aspects of diet, the omega-6/omega-3 ratio and genetic variation: nutritional implications for chronic diseases. Biomed Pharmacother. Nov 2006;60(9):502-507.

[0065] In addition to the effects of ratios of fatty acids, plasma and/or serum lipids comprising high proportions of palmitic (16:0), palmitoleic (16:1), and DGLA, and a low proportion of LA and PUFA are associated with type-2 diabetes, myocardial infarction, stroke, left ventricular hypertrophy, and metabolic syndrome. High D6D and SCD (stearoyl CoA desaturase), and low D5D activity has been independently associated with cardiovascular disease risk markers, including insulin resistance and low-grade inflammation, and cardiovascular and total mortality. Altered endogenous desaturase levels might contribute to the mortality risks. Defect in D6D and D5D may be a factor in the initiation and progression of atherosclerosis and often associated diseases such as obesity, diabetes mellitus, and hypertension.

[0066] Omega-3 fatty acids of seafood origin include, but are not limited to, salmon, herring, mackerel, anchovies and sardines. Omega-3 fatty acids of botanical origin include, but are not limited to, chia, kiwifruit, perilla, flaxseed, lingonbeny, camelina, purslane, black raspberry, butternuts, hempseed, walnut, pecan nut, and hazel nut.

Non-essential Fatty Acids

[0067] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, non-essential fatty acids. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Optimal levels for basic dietary cohorts of meat, plant, and seafood heavy diets is disclosed herein (see Tables 6 to 8).

[0068] Non-essential fatty acids can be synthesized endogenously, however some of them are considered conditionally essential and they may influence EFA metabolism. For example, OA can have regulatory functions in addition to altering cellular fatty acid composition in select organs. Fatty acids contribute to many cellular functions including homeostasis, coordinating the expression of proteins involved in lipid synthesis, transport, storage, degradation, and elimination to maintain a normal physiological state. Subsequent to meal ingestion lipids in the duodenum regulate energy and glucose homeostasis through a feedback mechanism to the central nervous system which ultimately regulates food intake. This sensitive neuronal circuitry can become defective in response to high-fat or fat imbalance. Certain fatty acids, palmitic,

lauric, and stearic, have a role in stimulating the expression of mitochondrial uncoupling proteins, UCP2 and UCP3, which reduce oxidative stress and are associated with longevity.

[0069] Not only omega-6 and omega-3 fatty acids but most other fatty acids also compete in metabolic pathways such that dietary fat is reflected in tissue composition. Total amount of dietary fatty acids (low-fat versus high-fat diets) can also influence the fatty acid metabolism and tissue composition. For example, increased omega-3 fatty acid levels in plasma fatty acids from low fat diets have been observed, which is likely due to preferential metabolism of ALA. Other studies have shown that dietary fat quantity outweighs fat type in influencing blood pressure, a risk factor for vascular disease. Thus, omega-6 and omega-3 ratios and amounts should be considered in conjunction with the influencing factors.

Microorganisms, Prebiotics, Probiotics, Synbiotics

[0070] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, microorganisms, namely prebiotics, probiotics, and synbiotics. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement.

[0071] The nutritional program may include one or more prebiotics and/or fiber (soluble and/or insoluble). The nutritional program may include one or more probiotics. In general, it is believed that these micro-organisms inhibit or influence the growth and/or metabolism of pathogenic bacteria in the intestinal tract. Probiotics may also activate the immune function of the host.

[0072] The nutritional program or formulation may include one or more synbiotics, fish oils, and/or phytonutrients. As used herein, a synbiotic is a supplement that contains both a prebiotic and a probiotic that work together to improve the microflora of the intestine.

[0073] Gut microflora influences the capacity of an individual to obtain energy from diet. That microflora also influences lipogenesis and plasma lipopolysaccharide levels implicated in inflammation, obesity, and type-2 diabetes. A high-fat diet creates unfavorable gut microflora. Conversely, gut microorganisms influenced fat composition of host tissue. Oral administration of *Bifidobacterium breve* with linoleic acid increased the tissue composition of conjugated-linoleic acid and omega-3 fatty acids EPA and DHA.

Oxidation and Antioxidants

[0074] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, antioxidants. In these embodiments, the

individual is provided a nutritional supplement and/or program to balance the requirement. Optimal levels for basic dietary cohorts of meat, plant, and seafood heavy diets is disclosed herein (see Tables 6 to 8). In certain embodiments, the cohort is defined by, and the formulation designed to supplement or withdraw from the diet, one or more of vitamin C, vitamin E, and/or selenium, iron, copper, and/or zinc.

[0075] In relation to lipid metabolism, fatty acids may undergo any one of the following after ingestion: (1) primarily mitochondrial and peroxisomal ß-oxidation for energy production, (2) free-radical mediated oxidation (chain reactions where one free radical can oxidize many lipid molecules), (3) free-radical independent, non-enzymatic oxidation, or (4) enzymatic oxidation to produce bioactive lipid products such as long-chain fatty acids and eicosanoids. Specific products are formed from each type of oxidation and specific antioxidants are required to inhibit each type of reaction. The nutritional program may include antioxidants. Antioxidants are molecules capable of slowing or preventing the oxidation of other molecules. Non-limiting examples of antioxidants include preventative enzymes such as superoxide dismutase (SOD), catalase, and glutathione peroxidases (GSHpx),vitamin A, carotenoids, vitamin C, vitamin E, selenium, flavonoids, Lactowolfberry, wolfberry, polyphenols, lycopene, lutein, lignan, coenzyme Q10 (CoQ10), glutathione or combinations thereof.

[0076] Vitamin E and C work synergistically to protect lipids; vitamin C repairs the alpha-tocopheroxyl radical (vitamin E radical) enabling it to resume its antioxidant function. Vitamin E's antioxidant action can reverse age-associated increase in Cyclooxygenase-2 (COX-2) activity and associated increase in PGE2 synthesis by inhibiting the cofactors; this effect also increases T-cell-mediated immune function. Gamma-tocopherol (γT) form of vitamin E has been found to be a more effective inhibitor of PGE2, LTB4, and tumor necrosis factor-α (TNFα) an inflammatory cytokine than alpha-tocopherol (αT). Vitamin E requirements are partially dependent on PUFA consumption, because PUFA may reduce intestinal absorption of vitamin E while increasing the amount needed for PUFA protection.

[0077] Selenium, an important component of Se-dependent glutathione peroxidase (Se-GSHpx) and it functions synergistically with vitamin E as an antioxidant to protect cellular fatty acids and enzymes for eicosanoid production. The metal ions zinc, cadmium, silver, iron, and mercury are inhibitors of Se-GSHpx. GSHpx (both Se-dependent and non-Se-independent). Both copper and zinc play a role in SOD mediated protection of COX, and PG and TX synthetases. Copper status is also associated with Se-GSHpx status in liver and lungs.

[0078] Many of the antioxidants, phytochemicals, vitamins, and minerals suppress oxidation of PUFA (though some minerals, such as, iron and copper are pro-oxidants) and PG synthesis, thereby increasing the need for LA or omega-6 family of fatty acids, and reducing the need for or tolerance of omega-3 fatty acids. Reduced oxidation affects the omega-6 family more than the omega-3 family because of preferential metabolism of omega-3 family.

[0079] Antioxidants have powerful properties and therefore have a narrow window of healthful effects. Low levels of oxidation products (e.g. lipid peroxidation (LPO) products, free radicals) are necessary for cellular functions. Oxidation of molecules proceed by different pathways. Specific products are formed from each type of oxidation and specific antioxidants are required to inhibit each type of reaction. *See* Buettner G., Arch Biochem Biophys. 1993; 300: 535-543, incorporated herein by reference in its entirety. Droge W. Free radicals in the physiological control of cell function. Physiol Rev. Jan 2002;82(1):47-95.

[0080] LPO products in plasma of healthy human subjects are below 1 μM and the molar ratios of LPO products to the respective parent lipids are below 1/1000, that is, below 0.1%. Sublethal concentrations of LPO products induce cellular adaptive responses and enhance tolerance against subsequent oxidative stress through upregulation of antioxidant compounds and enzymes. Such opposite dual functions of LPO products imply that LPO, and oxidative stress in general, may exert both delcterious and beneficial effects in vivo. LPO as well as reactive oxygen and nitrogen species has been shown to play important roles as a regulator of gene expression and cellular signaling messenger. In order to exert physiologically important functions as a regulator of gene expression and mediator of cellular signaling, the formation of LPO products must be strictly controlled and programmed. Niki E. Lipid peroxidation: physiological levels and dual biological effects. Free Radic Biol Med. Sep 1 2009;47(5):469-484.

[0081] An excessive and/or sustained increase in reactive oxygen species production has been implicated in pathogenesis of many diseases including cancer, diabetes mellitus, atherosclerosis, neurodegenerative diseases, chronic inflammation, rheumatoid arthritis, ischemica/ reperfusion injury, obstructive sleep apnea. However, in a study of lipid and lipoprotein profiles, fatty acid composition, and oxidant-antioxidant status in pediatric attention deficit hyperactivity disorder (ADHD) patients, reduced lipid peroxidation was noted. Similarly, disturbances in the lipid profile, in lipoprotein concentrations and composition, and in oxidant-antioxidant status were observed in pediatric Crohn's disease patients.

Vitamins and minerals

[0082] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, vitamins and minerals. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Optimal levels for basic dietary cohorts of meat, plant, and seafood heavy diets is disclosed herein (see Tables 6 to 8). In certain embodiments, the cohort is defined by, and the formulation designed to supplement or withdraw from the diet, one or more of vitamin A, vitamin D, vitamin E, vitamin K, vitamin B12, folic acid or folate, selenium, copper, iron, calcium, magnesium, phosphorus, manganese, potassium, sodium, chloride, and zinc.

[0083] Some vitamins and minerals may also have powerful properties, i.e. a narrow window of healthful effects because of their prooxidants/antioxidant potential, and their ability to modulate the antioxidant enzyme expression, among other factors. Some of those are: Vitamin A, Vitamin E (tocopherols), Vitamin B9 (Folic acid, particularly food folate in natural form), Vitamin D, Vitamin E, Selenium, Copper, Zinc. Like phytochemicals, some minerals can act as antioxidants and pro-oxidant depending on levels and complement of other nutrients.

Dietary fiber

[0084] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's consumption of, and requirement for, dietary fiber. In these embodiments, the individual is provided a nutritional supplement and/or program to balance the requirement. Optimal levels for basic dietary cohorts of meat, plant, and seafood heavy diets is disclosed herein (see Tables 6 to 8). In certain embodiments, the cohort is defined by, and the formulation designed to supplement or withdraw from the diet, one or more of cellulose, starch, glucans, cereal bran, and hydrocolloids.

[0085] As used herein, "dietary fiber" refers to indigestible and non-metablizable organic material contained in food. Low calorie bulking agents, such as cellulose, starch, glucans, cereal bran, and hydrocolloids (e.g., xanthan, guar, and alginate), generally are indigestible polymers that can be used in food products. These agents, often referred to as "fiber" or "roughage," pass through the digestive system for the most part intact and have been shown to have a number of actual and potential health benefits.

[0086] Dietary fiber may be divided into predominantly soluble or insoluble fibers (depending on solubility in water). Both types of fiber are present in substantially all plant foods, with varying degrees of each depending on the plant. Water soluble dietary fiber, or "soluble fiber", refers to dietary fiber that is water soluble or water swellable. Water soluble

dietary fibers include, for example, oligosaccharides, psyllium, beta glucan, oat bran, oat groat, pectin, carrageenan, guar, locust beau gum, gum acacia, and xanthan gum, and the like and combinations thereof. Dietary fiber typically consists of non-starch polysaccharides, for example, cellulose and other plant components including dextrins, inulin, lignin, waxes, chitins, pectins, beta-glucans and oligosaccharides.

[0087] Dietary fibers affects nutrition by changing the nature of the contents of the gastrointestinal tract, and by changing how other nutrients and chemicals are absorbed. The addition of such indigestible fiber materials to food stimulates the intestine to peristalsis, resulting in increased digestion of accompanying food materials. Due to its effect on digestion, increased consumption of dietary fiber has been linked to decreases in the incidence of gastrointestinal diseases, including bowel cancer. Prebiotic soluble fiber products, like those containing inulin or oligosaccharides, may contribute to relief from inflammatory bowel disease, as in Crohn's disease, ulcerative colitis, and *Clostridium difficile*, due in part to the short-chain fatty acids produced with subsequent anti-inflammatory actions upon the bowel. Consistent intake of fermentable fiber through foods like berries and other fresh fruit, vegetables, whole grains, seeds and nuts is now known to reduce risk of several diseases—obesity, diabetes, high blood cholesterol, cardiovascular- disease, bowel cancer, and numerous gastrointestinal disorders including irritable bowel syndrome, diarrhea, and constipation.

Gender

[0088] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's gender. In these embodiments, the individual is provided a nutritional supplement and/or program customized for gender.

[0089] While sex hormones can alter metabolism of dietary fats, dietary fats can alter synthesis of sex hormones and the associated receptor organization. Increasing amount of dietary fat increases the androgen production, depending on the fatty acids administered. Higher PUFA administration resulted in lower activity of steroidogenic enzymes and lower levels of androgens as compared to MUFA or SFA administration. Omega-3 fatty acids, particularly DHA caused less androgen production than omega-6 fatty acids; and omega-6 fatty acids caused less androgen production than MUFA or SFA. The period over which the dietary fat was fed to an animal also altered androgen levels; initially sharp increases correlated with the dietary levels after 3 weeks, followed by significant reductions after 6 weeks, demonstrating an adaptation mechanism. The response may be a homeostatic adjustment possibly due to LCPUFA's similar actions and benefits as sex hormones. Though

the relationship is not well understood yet, parallels have been drawn to estrogen. Both estrogen and PUFA enhance nitric oxide synthesis, suppress the production of pro-inflammatory cytokines, show antioxidant-like and anti-atherosclerotic properties, and have neuroprotective actions. The relationship of fatty acids with androgens also has significance for men. High levels of androgens may be associated with carcinogenesis, while low levels may be deleterious to semen quality. Men and women also differ in storage, mobilization, and oxidation of fatty acids, and gene expression relevant to fatty acid metabolism.

Genetics

[0090] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's genetic polymorphisms, and/or consumption and requirement for methyl donor compounds. In these embodiments, the individual is provided a formulation tailored to the individual's genetics, or requirement for methyl donor nutrients. In certain embodiments, the cohort is defined by, and the formulation designed to supplement with one or more of folate, vitamin B-12, vitamin B-6, choline, methionine, genistein, coumesterol, and polyphenol. Taking into account the known existence of genetic polymorphisms, the individual's diet may be supplemented with or restricted of certain phytochemicals including one or more of curcumin, capsaicin, ginsenosides, hesperidin, and resveratrol.

[0091] Genetic code, the sequence of nucleotides in our DNA, can influence health status. But there is another set of instructions that affect gene expression, and this set of instructions can be altered by diet. Epigenetics, the study of heritable changes in gene function that occur independent of a change in DNA sequence, represents a new frontier in biomedical science that has important implications for dietetics practice. For example, one way in which gene expression is modulated is through DNA methylation— the degree to which methyl groups are present or absent from certain regions of our genes. Depending on the circumstances, hypomethylation or hypermethylation can be beneficial or harmful depending on which genes are turned on or off, at what point in time, and in which tissues. DNA methylation can be affected by intake of folate, vitamins B-12 and B-6, choline, and methionine because these nutrients are involved in the generation of methyl groups through one carbon metabolism. Other dietary factors, such as genistein, coumesterol, and polyphenols also influence DNA methylation. Stover PJ, Caudill MA. Genetic and epigenetic contributions to human nutrition and health: managing genome-diet interactions. J Am Diet Assoc. 2008;108:1480-1487. Barnes S. Nutritional genomics, polyphenols, diets, and their impact on dietetics. J Am Diet Assoc. 2008; 108:1888-1895.

[0092] Genetic variations can also influence the metabolism and therefore requirement of lipids. Polymorphisms in apolipoprotein E and peroxisome-proliferator-activated receptor-gamma (PPARγ) genes may influence response to dietary fats. However, dietary fats can alter many genes. PUFA suppress lipogenic, glycolytic, and choelsterolgenic genes, but increase expression of genes for enzymes needed in the β-oxidation pathway. Simopoulos AP. The role of fatty acids in gene expression: health implications. Ann Nutr Metab. 1996; 40:303-311. Sampath H, Ntambi JM. Polyunsaturated fatty acid regulation of genes of lipid metabolism. Annu Rev Nutr. 2005; 25:317-340. PUFA modulate gene expression by interacting with nuclear receptor hepatic nuclear factor (HNF-4), liver X receptors (LXR), and PPAR α, β, δ, and γ, and by regulating the transcription factor sterol regulatory element-binding proteins (SREBP) 1 & 2. SREBP, suppressed by PUFA, are key regulators of cholesterol, fatty acid, and triglyceride synthesis. LA and AA are potent PPAR ligands, producing rapid increase in expression of genes involved in lipid oxidation.

[0093] Phytochemicals may also influence the expression of a range of genes. Several phytochemicals can bind to cell surface and nuclear receptors as ligands. Curcumin, capsaicin, ginsenosides, hesperidin, and resveratrol are known PPARγ ligands, believed to attenuate cytokine production and inflammation. Phytosterols can also alter intestinal and liver gene expression. Since nutrients can change gene expression, it is more effective to design nutrition (fewer variables, greater control, and easier implementation) for optimum gene-expression, rather than nutrition for disease states caused by unhealthy nutrition.

Aging

[0094] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's age. In these embodiments, the individual is provided a formulation tailored to the individual's age. In certain embodiments, the cohort is defined by, and the formulation designed to supplement with one or more antioxidants, fatty acids, and phytosterols.

[0095] Aging brings about a decline in sex hormones, increased oxidative stress, and decreased homeostatic regulation and immunity. Oxidative stress is currently one of the most accepted theories of aging, where aging is the result of lifelong and progressive damage to molecules from oxidation products and the consequential deterioration of physiological functions. Hulbert AJ, Pamplona R, Buffenstein R, Buttemer WA. Life and death: metabolic rate, membrane composition, and life span of animals. Physiol Rev. Oct 2007;87(4):1175-1213. Since fatty acids are the molecules most vulnerable to oxidation, membranes with fatty acid compositions least prone to lipoxidative damage are associated with longevity. Fatty

acids differ dramatically in their susceptibility to peroxidation. Birds, who have exceptionally long lifespan relative to their body mass favor lower unsaturation index of omega-6 PUFA to higher unsaturation index of omega-3 PUFA in membranes.

[0096] PUFA and unsaturation index have been shown to increase with advancing age in most tissue except for brain where they decline; but membrane fluidity declines uniformly with age because of peroxidation and possibly altered fatty acid chain composition . Unsaturated fatty acids are said to contribute to fluidity. Oxidized lipids and LPO are greater cause for membrane rigidity than low unsaturation index. Antioxidants are unable to increase the maximum life span of a species, but they have been shown to increase mean life span in select populations.

[0097] A decline in brain PUFA, particularly DHA, with age has been shown to be associated with increased lipid peroxidation. A decline in cognitive function along with neuronal apoptosis of cerebral cortex and hippocampus has also been found to be associated with age or hyperoxia, and prevented by vitamin E. Since an aging brain has been shown to have lower DHA, fish oils have been suggested to increase tissue DHA levels because they bypass D6D and D5D and directly provide long-chain omega-3 fatty acids in form of EPA and DHA. However, dietary fish oils rich in DHA and EPA strongly suppress D6D, with implications for other LCPUFA levels. Cho HP, Nakamura M, Clarke SD. Cloning, expression, and fatty acid regulation of the human delta-5 desaturase. J Biol Chem. Dec 24 1999; 274(52):37335-37339.

[0098] As noted before, LCPUFA increase in tissue other than the brain with age, which may be a compensation for decline in hormones because of similarities in actions. Studies with rats have demonstrated lower desaturase activity with age, which may be reversed with GLA. However, GLA was significantly more effective on DHA than on AA restoration. Therefore, reduced AA levels with age may be of concern, particularly in women and vegetarian women. The solution might lie in optimal mix of fatty acids and antioxidants with phytosterols, which increase desaturase activity and have antioxidant properties and hormone-like actions, such that greater membrane fluidity and lower unsaturation index can be achieved.

Temperature

[0099] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's climactic temperature. In these embodiments, the individual is provided a formulation tailored to the individual's climactic temperature. In certain embodiments, the

cohort is defined by, and the formulation designed to supplement with optimal dietary lipids and phytochemicals.

[00100] In general, a greater unsaturation index of fatty acids occurs in tissues at lower temperatures in order to maintain homeoviscosity and optimal membrane and cellular functions. Increased unsaturation preserves function at low temperature and decreased unsaturation preserves function at high temperature, but excessively low PUFA levels also reduce heat tolerance. Although membrane lipid composition is the main acclimatory response to changes in climactic temperature, other responses may include altered expression of membrane proteins, altered composition of bilayer stabilizing versus destabilizing lipids, and altered proportions of plasmalogens compared to diacyl phospholipids. Phytochemicals can also alter membrane properties including fluidity. Thus, while the body adapts to changes in temperature, benefit can be derived by customizing dietary lipids and phytochemicals with respect to temperature, such that raw materials conducive to self-regulation are present in optimal quantities.

Inflammatory pathways - relationship with nutrients

[00101] In certain embodiments, the individual's diet cohort is defined, at least in-part, by the individual's inflammatory state. In these embodiments, the individual is provided a formulation tailored to the individual's inflammatory state. In certain embodiments, the cohort is defined by, and the formulation designed to supplement or withdraw, dietary phytochemicals, antioxidants, vitamins, and minerals, such as one or more of flavonoids, sulforaphane, curcumin, and zerumbone, capsaicin, ginsenosides, hesperidin, and resveratrol, omega-3, omega-6 (including the omega-6:omega-3 ratio), In some embodiments, the phytochemicals include one or more of procyanidins, epigallocatechin gallate, epicatechin 3-gallate, resveratrol, apigenin, luteolin, quecetin, anthocyanins and hydrocinnamic acids, curcumin, hesperidin, diosmin, amentoflavone, bilobetin, morelloflavone, ginkgetin, and yuccaols A, B, C, D and E. In some embodiments, the phytochemicals are as defined in Table 1 and 3. The diet cohort may be defined by the level of consumption of the sources disclosed in Table 1 and 3, and the nutritional program may be tailored by supplementation or withdrawal of these sources. Some phytochemicals, antioxidants, vitamins and minerals interactions can lead to harmful health effects. Phytochemicals and antioxidants can suppress a number of inflammatory pathways. Excessive suppression may be problematic in that some inflammation may be necessary, and that compensatory mechanisms may be put in motion. Phytochemicals, particularly flavonoids have been found to have antimicrobial, antiviral, anti-

ulcerogenic, cytotoxic, antineoplastic, mutagenic, antioxidant, antihepatotoxic, antihypertensive, hypolipidemic, anti-aging, antiplatelet and anti-inflammatory activities. They also have biochemical effects, which inhibit a number of enzymes such as aldose reductase, xanthine oxidase, phosphodiesterase, Ca+2-ATPase, lipoxygenase, cycloxygenase, etc. Additionally, they also have a regulatory role on different hormones like estrogens, androgens and thyroid hormone.

[00102] Excessive phytochemicals, inadequate or imbalanced lipids and/or their impaired metabolism, and/or their interactions may dysregulate cytokines involved in inflammation: TGF-βl, TNF-α, IL- lβ, IL4, IL5, IL6, IL8, IL10, IL13, and γ-IFN. Particular diseases that may be implicated are disorders of the immune system, for example systemic lupus erythematosus (SLE), allergy, asthma, Crohn's disease and rheumatoid arthritis, but particularly multiple sclerosis, and also neurodegenerative diseases such as sequelae of stroke, head trauma, bleeds, Alzheimer's and Parkinson's disease, and sepsis, coronary heart disease (CHD), and infant abnormalities.

[00103] LCPUFA play an important role in inflammation and immunity. At low levels AA augments or is neutral to certain immune function, but at high levels it has an inhibitory effect. Intakes of long-chain omega-3 appear to be inhibitory on a wide range of immune functions: autoantibody production, T-lymphocyte proliferation, apoptosis of autoreactive lymphocytes, and cytokines and leukotrienes. Many of the effects of long-chain omega-3 appear to be due to the inhibition of transcription factor, NFkB, which regulates broad range of cytokine genes involved in inflammation. Calder PC. Polyunsaturated fatty acids and inflammatory processes: New twists in an old tale. Biochimie. Jun 2009;91(6):791-795. Long-chain omega-3 also activate transcription factor PPARγ, which can modulate anti-inflammatory genes and inhibit NFkB. Therefore, in the short run omega-3 may ameliorate the symptoms of diseases associated with low-grade inflammation; but in the long run they may compromise host immunity. Further, the effects may be compounded by certain phytochemicals which also inhibit NFkB (e.g. sulforaphane, curcumin, and zerumbone) or activate PPARγ (e.g. curcumin, capsaicin, ginsenosides, hesperidin, and resveratrol). Sudden and wide fluctuations in phytochemicals and or fatty acids intake can change the immune response and rest of the physiology. Withdrawing a phytochemical or Omega-3 or any immunosuppressive/ inflammation suppressive nutrient may unleash excessive inflammation.

[00104] Depending upon fatty acids and phytochemical tissue stores, a sudden withdrawal of a habitual high long-chain omega-3 fatty acids or immunosuppressive or antiinflammatory

phytochemical supply from the host, or a sudden increase in omega-6 fatty acids or other fatty acids may result in unrestrained cytokine response, with severe consequences involving systemic inflammatory response (capillary leakage, pyrexia, tachycardia, tachypnoea), multi-organ dysfunction (gastrointestinal, lungs, liver, kidney, heart), and joint tissue damage. In addition to sudden increases in cytokine action, other factors such as sudden change in excitability of neural and muscle cells may be another complicating factor. At such instances the host may become vulnerable to infections, myocardial infarction, stroke, and induction of psoriasis depending upon the rest of the body chemistry and the presence of infectious agents. In less severe manifestations, due to moderate fluctuations in fatty acids and in otherwise salubrious condition, the host may experience sleep disturbances, headaches, muscle cramps, confusion, melancholia, and rage resulting from changes in neurotransmission, excitability of muscle and neural cells, and fluctuating eicosanoids and androgens. As a nutritional strategy, cumulative effects of all dietary inflammation modulation should be below the threshold where self-regulation of the immune system is materially blunted or inflammation is dysregulated.

[00105] Different flavonoids display anti-inflammatory mechanisms of action. For example (from Rathee et al. Mechanism of Action of Flavonoids as Anti-inflammatory Agents: A review. Inflammation & Allergy-Drug Targets, 2009, 8, 229-235.)

[00106] Procyanidins — Inhibits transcription and secretion of IL-1

[00107] Epigallocatechin gallate — Inhibits the expression of iNOS - Reducing the activity of NF-kB and AP-1.

[00108] Epicatechin 3-gallate — Attenuates adhesion and migration of peripheral blood CD8+T cells.

[00109] Resveratrol — Inhibits stimulation of caspase-3 and cleavage of PARP induced by IL-1alpha. Suppressing the expression of iNOS mRNA and protein by inhibiting the activation of NF-kB Inhibiting NO generation. Upregulating MAP kinase phosphatase-5

[00110] Apigenin — Blocks the expression of intercellular adhesion molecule-1 (ICAM-1), VCAM-1, and E-selectin. Inhibiting prostaglandin synthesis and IL-6, 8 production.

[00111] Luteolin — Inhibits the upregulation of THP-1 adhesion and VCAM-1 expression. Inhibiting the activity of the NF-kB.

[00112] Quercetin — Inhibits NO production and iNOS protein expression. Inhibits both cyclooxygenase and lipoxygenase activities.

[00113] Anthocyanins & Hydroxycinnamic acids — Localizes into endothelial cells. Reducing the upregulation of IL-8, MCP-1, and ICAM-1

[00114] Curcumin — Decreases MPO activity and TNF-alpha on chronic colitis. Reducing nitrites levels and the activation of p38 MAPK. Downregulating COX-2 and iNOS expression.

[00115] Hesperidin, Diosmin — Inhibits prostaglandin formation.

[00116] Amentoflavone, Bilobetin, Morelloflavone, Ginkgetin — Inhibits phospholipase C1 and A2.

[00117] Yuccaols A, B, C, D and E — Inhibit the nuclear transcription factor NF-kB.

[00118] The activities of the nutrients may be mediated by interactions with one or more of cell-derived mediators (listed in Table 2, from Rathee et al.).

Table 2: Cell-derived mediators

Name	Type	Source	Description
Lysosome granules	Enzymes	Granulocytes	contain a large variety of enzymes which act as inflammatory mediators
Histamine	Vasoactive amine	Mast cells, basophils, platelets	Stored in preformed granules, histamine is released in response to a number of stimuli
IFNgamma	Cytokine	T-cells, NK cells	Antiviral, immuno-regulatory, and anti-tumour properties. This interferon was originally called macrophage-activating factor, and is especially important in the maintenance of chronic inflammation
IL-8	Chemokine	Macrophages	Activation and chemo-attraction of neutrophils, with a weak effect on monocytes and eosinophils
Leukotriene B4	Eicosanoid	Leukocytes	Mediates leukocyte adhesion and activation. In neutrophils, it is also a potent chemo-attractant, and induces the formation of reactive oxygen species and the release of lysosome enzymes by these cells.
Nitric oxide	Soluble gas	Macrophages, endothelial cells, some neurons	Potent vasodilator, relaxes smooth muscle, reduces platelet aggregation, aids in leukocyte recruitment, direct antimicrobial activity in high concentrations.
Prostaglandins	Eicosanoid	Mast cells	A group of lipids which cause vasodilation, fever, and pain.
TNFalpha & IL-1	Cytokines	Macrophages	Affect a wide variety of cells to induce inflammatory reactions: fever,

			production of cytokines, endothelial gene regulation, chemotaxis, leukocyte adherence, activation of fibroblasts.

[0119] Several nutrients are known to have cardiovascular disease (CVD) related activities as shown in Table 3 (from M. Massaro et al., Nutraceuticals and Prevention of Atherosclerosis; Cardio vascular Therapeutics; 28 (2010), Table 2)

Table 3: Known CV disease related actions of different nutrients

Bioactive compound	Examples	Sources	Putative effects
Flavonols	Quercetin, kaempferol, catechin	Onion, apple, tea, berries, olives, broccoli, lettuce, red wine, cocoa/chocolate	↓TC, ↓LDL-C oxidation↑HDL-C, AOx, ↓platelet aggregation, ↓eicosanoid synthesis, ↓athero-ELAMs, ↓angiogenesis, ↓MMPs
Flavonols	Epicatechin, epigallocatechin, epicatechin-3-gallate, epigallocatechin-3-gallate	Green/black tea, cocoa/chocolate	AOx, ↓apoptosis, ↓LDL-C oxidation, ↓platelet aggregation, ↓athero-ELAMs, ↓angiogenesis, ↓MMPs
Lignans	Enterolactone, enterodiol	Flaxseed oil, lucerne, clover	↓LDL-C, AOx, estrogen/antiestrogen; ↓atherosclerosis in vivo but may show adverse CVD effect (pro-oxidant activity with partially defatted flaxseed)
Isoflavones	Genistein, daidzein	Soybeans, legumes	↓TC and LDL-C, ↓LDL-C oxidation, ↓TG, ↑HDL-C, ↓thrombosis, AOx, estrogen/antiestrogen, ↓athero-ELAMs, ↓angiogenesis, ↓atherosclerosis in vivo, ↓MMPs
Stilbenoids	Resveratrol	Grapes, red wine, peanuts	↓LDL-C oxidation, ↓platelet aggregation/thrombosis, ↓eicosanoid synthesis, AOx, ↓athero-ELAMs, ↓angiogenesis but promotes angiogenesis in the ischemic heart, ↓atherosclerosis in vivo, ↓MMPs
Carotenoids	Lycopene	Tomatoes, tomato products	↓LDL-C and LDL-C oxidation, AOx, ↓athero-ELAMs, ↓MMPs, but no effects was shown in animal models of ATS and dietary intervention studies using well-defined subjects population did not provided a clear

			evidence of lycopene in the prevention of CVD
Carotenoids	α-Carotene, β-carotene, γ-carotene, δ-carotene	Carrots, pumpkins, maize, tangerine, orange and yellow fruits and vegetables	Inconsistent data. β-carotene has shown adverse CVD effect because its prooxidant activity
Organosulfur compounds	Allicin, diallyl sulfide, diallyl disulfide, allyl mercaptan	Garlic, onion, leek	↓TC and LDL-C, ↓TG, ↓cholesterol and FA synthesis, ↓BP, ↓thrombosis, AOx, ↓athero-ELAMs, ↓angiogenesis, ↓atherosclerosis in vivo, ↓MMPs
Soluble dietary fibers	Glucan, pectin	Psyllium, oats, barley, yeast, fruit, vegetables, psyllium seed, fortified cereals and grains	↓TC, ↓TG, ↓LDL-C
Isothiocyanates	Phenethyl (PEITC), benzyl (BITC), sulforaphanes	Cruciferous vegetables (e.g., watercress, broccoli)	no relevant effects
Monoterpenes	d-Limonene, perillic acid	Essential oils of citrus fruit, cherries, mint, herbs	↓TC and LDL-C, ↓HMGCoAR, ↓angiogenesis
Plant sterols	Sitostanol, stigmasterol, campesterol	Tall oil, soybean oil, rice bran oil	↓TC and LDL-C, AOx, ↓cholesterol absorption; adverse effect: ↓carotenoid absorption
Phenolic acids	Tyrosol, hydroxytyrosol, oleoeuropeine, caffeic acid, cumaric acid	Extra virgin olive oil	↓LDL-C oxidation, ↓platelet aggregation/thrombosis, ↓eicosanoid synthesis, AOx, ↓athero-ELAMs, ↓atherosclerosis in vivo, ↓MMPs
ω-3 PUFA	DHA, EPA, αLA	Fish and fish oil, green leaves	↓TC, suppression of cardiac arrhythmias, ↓BP ↓platelet aggregation, ↓eicosanoid synthesis, ↓athero-ELAMs, ↓angiogenesis; ↓MMPs
Prebiotics	Inulin-type fructans	Fruit and vegetable, purified extract from chicory root	↓TC and ↓TG
Probiotics	Selected strains of *Lactobacillus acidophilus, Bifidobacterium bifidum* and *Lactobacillus*	Fermented milk products	↓TC, LDL-C and BP

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AOx, antioxidant activity; BP, blood pressure; CVD, cardiovascular disease; HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides; MMPs, metalloproteinases; ELAMs, endothelial leukocyte adhesion molecules.

Health effects of whole/natural food items

[0120] Whole foods have different health effects than one would predict from the sum of the parts. Nutrients have different properties in one form versus another, e.g. conjugated versus free. This is due to alteration in metabolism, presence and/or composition of other nutrients and/or absorption; nature of connection between nutrients and context is crucial. Flavonoids which are mainly present as glycosides in food (with the exception of catechins) are expected to be poorly absorbed, but quercetin glycosides are absorbed in appreciable amounts in the small intestine. For instance, the flavonoid quercetin was shown to be more bioavailable as an aglycone than quercetin glucosides when ingested as onion flesh, while quercetin glycosides where more available when ingested as dried onion skin. Beneficial or harmful effects of nutrients including phytochemicals can be explained by additive and synergistic effects, as vegetables and fruits contain multiple different phytochemicals which seem to influence and potentiate each other. Synergistic effects increase bioavailability. For example quercetin is an inhibitor of resveratrol sulfation in the liver and small intestine and increases the bioavailability of resveratrol. The synergistic effect of piperine on curcumin is driven by its inhibiting effect on curcumin conjugation. Further, absorption of phytochemicals can be enhanced by complexing with lipids or by nanoparticles that increase the water solubility of hydrophobic drugs.

Development of novel dietary programs

[0121] The invention relates to development of nutritional compositions and/or formulations that balance phytochemicals, antioxidants, vitamins, minerals, acid-base, lipids, proteins, carbohydrates, probiotics, prebiotics, microorganisms, fiber, and the like. Levels and types of nutrients in each food item are considered in developing a nutritional plan that provides nutrients at levels that have exemplary health benefits. In some aspects, nutritional plans are tailored to fit the primary dietary preferences of consumers.

[0122] To be effective, the nutritional plans are designed such that at least 25%, 50%, 60%, 70%, 80% or 100% of calories in the diet are provided by the foods specified in the plan over an extended period of time.

[0123] In one aspect, packages and kits are provided to support specific aspects of the nutritional plan. In some embodiments, the packages and kits comprise component or modular

systems comprising vegetable, fruit, grains, cereals, legumes, meats, seafood, nuts, seeds, herbs, lipids, milks, yogurts and the like, and any combination thereof. In some embodiments, the packages and kits comprise unprepared, or ready to cook foods, such as fruit, vegetable, legume, dry grain, meat, seafood, herbs, fat, nuts and seeds, milks, yogurts, and the like. In some embodiments, the packages and kits comprise processed or cooked foods such as a nutritional bar; a bakery food product such as a bread, a dessert, a pastry, a truffle, a pudding or cake; a salad, a drink, a yogurt, a milk, a side dish, a snack, a meal; a gel, a puree, a sauce, a dressing, a spread, a butter, drops, or the like; a sealed single dosage packet or resealable packaging containing a liquid, semi-liquid, semi-solid, or a solid. In some embodiments, they may be unsealed and taken orally, or added as part of a cooking ingredient to previously cooked or uncooked food preparation with or without added fat. For example, they can be made into an oil blend, or a special cooking oil such as a frying oil, a pan-frying oil, a parting oil or the like. The components of the compositions or formulation may be delivered in one-part or multiple parts as various components of a meal or to complement a meal, for example.

[0124] In some embodiments, the kits and packages comprise food suitable for consumption by babies and include, but are not limited to soybean-based formula, milk formula, standard milk formula, follow-on milk formula, toddler milk formula, hypoallergenic milk formula, prepared baby food, dried baby food and other baby food.

[0125] In some embodiments, the compositions / formulation disclosed herein may be administered to an individual in any orally accepted form. In some embodiments, they may be part of an enteral or parenteral formula, or a combination thereof. In some embodiments, they may be administered topically via a liquid, cream or patch formulation. The formulations may be packaged in one, two, three, four or more mutually complementing daily dosages. In some embodiments, they may be contained in any one or more of, but not limited to, a single dosage or sustained and controlled release capsule, soft-gel capsule, hard capsule, tablet, powder, lozenge, or pill prepared in some instances with carriers such as starches, sugars, diluents, granulating agents, lubricants, binders, disintegrating agents, a granule, and the like. In some embodiments, the compositions may be delivered using a gelatinous case, a vial, a bottle, a pouch or a foil, or plastic and/or card-board box, and the like, or a combination thereof for containing such compositions. In some embodiments a one-day, one-week, two-week, bi-weekly, bi-monthly, or monthly diet plan may be formulated comprising various formulations described herein, with varying compositions administered each day.

[0126] In some embodiments, each pack contains specific nutritional content suitable for a balanced and optimized diet. For example, a grain or cereal pack may contain polyphenols, antioxidants, omega fatty acids and/or saturated fatty acids within specific ranges wherein each range is suitable for a specific dietary cohort. Likewise, a fruit, legume or vegetable pack or drink package may be similarly classified. In some embodiments, each pack comprises identification of the ranges of specific critical nutrients and nutrients. In some embodiments, each pack or module is identified by the specific dietary cohort it is suitable for. In some aspects, each module can effectively fit into a nutritional plan when each component or module individually provides less (or greater) than 100, 200, 300, 400, or 500 calories and/or less (or greater) than 10%, 20%, 25%, 30%, or 40% percent of an individual's daily caloric need.

[0127] In some aspects, the formulations described herein have high antioxidant and phytochemical content and properties that render extra omega-3 unnecessary, or enhance bioavailability, and/or endogenous synthesis of long-chain omega-3. In specific embodiments, nuts, legumes, grains, sweeteners (such as honey), and herbs/spices (such as curcumin) included in the compositions can render extra omega-3 unnecessary.

[0128] In one aspect, food items recommended in a diet plan or contained in a specific component or module are selected based on the methods of processing or manufacturing used in preparing the food items such that optimal nutrient is achieved, and/or desired activation or inactivation of nutrients is achieved. Such processes include steps in preparing the food items such as hulling, removing a layer or part, peeling, drying versus providing fresh or frozen, and method of cooking such as soaking, sprouting, grinding, roasting, baking, grilling, heating, sautéing, fermenting, and the like. Method of processing (removing a layer, cooking, grinding, roasting, soaking, dry versus fresh) is selected to arrive at a formulation from different sources wherein nutrients complement each other. Different parts of plants may contain different strengths of phytochemicals and antioxidants. For example, seed (ovule of flowering plant or part thereof), leaves, stems, flowers or fruits; and skin versus flesh. Seeds include edible kernel, endosperm, germ, and bran or husk. Removing a layer, cooking, grinding, roasting, soaking, dry versus fresh or frozen can change the strength of nutrients.

[0129] In one aspect, the invention relates to developing a tailored dietary program and optimizing levels of dietary nutrients therein. Different programs are developed according to general dietary preferences. In general, individual consumers have specific preference for the main foods they like to consume, for example, high or low plant foods versus high or low red meats versus high or low seafood. Henson S, Blandon J, Cranfield J, Herath D. Understanding

the propensity of consumers to comply with dietary guidelines directed at heart health. Appetite. 2010;54:52-61. Diets rich in legumes, fruits, vegetables, whole grains, herbs, nuts and seeds are inherently high in antioxidants and phytochemicals. Grains, vegetables, fruits, legumes, herbs, nuts and seeds are the richest source of phytochemicals and antioxidants. (Halvorsen et al. J Nutr. 2002; 132:461-471). Mazur W. Phytoestrogen content in foods. Baillieres Clin Endocrinol Metab. 1998;12:729-742. Consumers are categorized into dietary cohorts according to average amount of the main foods consumed. Commonly consumed foods are not that many. There are a limited number of grains, vegetables, fruits, herbs, meats, seafoods, drinks, and sweeteners. Commonly consumed foods are so because of their nutritive value, safety proven over centuries, and ease of cultivation.

[0130] In some aspects, dietary cohorts are based on basic dietary habits and amount of plant foods, meats, and/or seafood in diet. These preferences determine bulk of the food consumption. For example vegetarians are predisposed to eating a lot of and certain kinds of phytochemicals and antioxidants. They may depend on legumes to meet their protein requirement, which inherently increases consumption of flavonoids, and certain kinds of proteins, which affects their requirement for other nutrients. Similarly, seafood inherently includes significant amounts of omega-3, and selenium. Similarly, high meat consumers are inherently and consistently consuming certain kinds of proteins and are deficient in certain phytochemicals and antioxidants. Basic dietary habits can help establish average nutrients consumed from the most commonly consumed major foods. Diet plans may be developed for and around such cohorts. Once the bulk of foods consumed or should be consumed by such cohorts is established, then complementing lipids, phytochemicals, antioxidants, vitamins, minerals, and microorganism programs/ formulations are determined based on what achieves the best outcomes. Such a program may reduce the probability of overconsumption or under consumption of critical nutrients. Once nutrient requirement is met and balanced satiety may be achieved. Morton GJ, Cummings DE, Baskin DG, Barsh GS, Schwartz MW. Central nervous system control of food intake and body weight. Nature. 2006;443:289-295.

[0131] A method for developing a tailored dietary nutrition program can comprise the following steps: (a) classifying dietary cohorts based on the primary source of calories in a preferred diet of the cohort, or the most common food group in a weekly diet or the types of nutrients in a diet, or inclusion sensitive foods such as seafood; (b) computing the typical range of major nutrients and nutrients in each dietary cohort; (c) preparing a list of food items that fit the dietary preference of the cohort and provide optimized and balanced levels of nutrients; and

(d) generating a nutritional plan for consumption over an extended period of time of at least 1, 3, 5 days or 1, 2, 4, 6, 8, or 12 weeks. The plan may be developed for the entire diet or a component thereof, such as lipids. A schematic is provided in Table 4.

[0132] In one embodiment, the tailored dietary program is developed by first classifying a subject into a dietary cohort. The range of nutrients in the dietary cohort of the subject is then determined. Finally, a tailored recommended dietary program is developed by determining the dietary nutrients that need to be supplemented or replaced in the diet in order to complement the regular dietary intake of the cohort and achieve optimized nutritional levels.

[0133] The method comprises the steps disclosed in Table 4.

Table 4: Schematic representation for developing tailored dietary programs and for optimizing dietary nutrients

Step 1. Develop dietary cohorts[a,b]								
	High phytochemicals		High meat		High seafood			
Grains								
Brown Rice	--to--	cups/g	--to--	cups/g	--to--	cups/g		
Whole Wheat	--to--	cups/g	--to--	cups/g	--to--	cups/g		
Other	--to--	cups/g	--to--	cups/g	--to--	cups/g		
Vegetables	Develop	ranges	as	above				
Fruits	Develop	ranges	as	above				
Legumes	Develop	ranges	as	above				
Dairy	Develop	ranges	as	above				
Meats	Develop	ranges	as	above				
Seafood	Develop	ranges	as	above				
Herbs	Develop	ranges	as	above				
Sweeteners	Develop	ranges	as	above				
Beverages	Develop	ranges	as	above				
Step 2. Compute range of nutrients								
Lipids								
C4:0	--to--	mg	--to--	mg	--to--	mg		
C22:6 Ω3	--to--	mg	--to--	mg	--to--	mg		
Other	--to--	mg	--to--	mg	--to--	mg		

Carbohydrates	Compute	ranges	as	above
Protein	Compute	ranges	as	above
Vitamins	Compute	ranges	as	above
Minerals	Compute	ranges	as	above
Phytochemicals	Compute	ranges	as	above
Antioxidants	Compute	ranges	as	above

Step 3. Develop nutritional programs/formulations

Develop programs /formulations to complement the nutrients above, from natural oils, nuts, seeds, and herbs; additional vitamins and minerals may be used. Deliver as diurnal mutually complementing individual dosages; daily variety may strengthen compliance.

Monday	Oil blend-A	+	sauce-A	+	spread-A	+	dessert-A	
Tuesday	Oil blend-B	+	sauce-B	+	spread-B	+	dessert-B	
Other days	Oil blend-X	+	sauce-X	+	spread-X	+	dessert-X	

[a]Based on average daily consumption.

[b]Further customizations may address age, gender, climactic temperature, and medical conditions/ lipid tolerance.

[0134] Similar cohorts can be defined by age, gender, genetic profile, climactic temperature, and medical conditions such as lipid tolerance. In case of infants, formulations and diet plans may be defined based on mother's diet, genetic profile, and/or medical conditions. In some embodiments, a feedback system is used to fine tune the dietary program according to results achieved.

[0135] Dietary cohorts can be based on main foods preferred in the diet of an individual or a group. For example: (a) vegetable based comprising 2, 3, 4, 6, or more servings per day of herbs, legumes, fruits, and vegetables; (b) seafood based comprising 1, 2, 3, 4, 6, or more servings per week of seafood; (c) meat based comprising 3, 4, 6, 8, 10, 12, 14 or more servings per week of meat (red meat) and less than 2, 3, 4 or 6 servings per day of herbs, legumes, fruits, and/or vegetables.

[0136] Dietary cohorts can also be defined based on folate, polyphenols, phytosterols, antioxidants, vitamin A, E, Se in the diet. For example, one or more polyphenols greater (or less) than 5, 10, 15, 20, 45, 70, 95, 115, 140, or 165 mg/day; and/or folate greater (or less) than

100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 mcg/day; and/or one or more phytosterols greater (or less) than 150, 200, 250, 300, 350, 450, 550, 650, 750, or 850 mg/day; and/or Se greater (or less) than 5, 10, 15, 20, 35, 55, 75, 95, 115, or 135 mcg/day can be used to classify dietary cohorts.

[0137] In one embodiment, the tailored dietary program is presented as a diet plan for an individual; infant, child, teen, adolescent, adult, mature, senior; 0-1, 1-3, 2-5, 4-8, 7-12, 13-15, 14-20, 18-30, 25-45, 40-50, 45-60, 60-70, 70+ years of age, male or female.

[0138] In one embodiment, the tailored dietary program is prepared according to climatic condition and ambient temperature range. Temperature ranges may be classified as hot (90°-135°), warm (70°-99°), cool (50°-75°), cold (33°-55°), below freezing (0°-37°), arctic (-50°-5°), or polar (-100°--45°).

[0139] In one aspect, the tailored dietary program is manifested in packages, kits or modular food components that are used to complement the diet of the cohort or replace the caloric intake of the subject. The daily consumption of food according to plan may vary, but over a period of 1, 2, 4, 6, 8, 12, or more weeks, or as a lifestyle change, the tailored plan according to the invention provides at least 25, 50, 60, 70, 80, 90 or 100% of the total caloric intake of an individual.

[0140] Although it is important to deliver balanced complete diets balanced with respect to lipids, antioxidants, phytochemicals, vitamins, minerals, carbohydrates, microorganisms, fiber, and proteins, the perishability of certain essential fresh products may raise difficulties. However, some pre-formulated products such as lipids, nuts, seeds, dry herbs or herbal extracts, grains, and legumes have greater shelf life, and are less cumbersome to tailor. Some vegetable, fruit, meat, and seafood packs can also be developed, which require similar processing facilities and storage, i.e. produce/meat/seafood processing facilities with refrigeration. In addition to manufacturing and production advantages and industrial utility, this approach also retains a level of flexibility and gratification for the consumer in selecting the main dietary components.

[0141] Nutrients are selected from foods such as vegetables, fruits, grains, legumes (including lentils, peas, beans), herbs, spices, teas, cocoa, coffee, sweeteners, nuts, seeds, and oils; grains are selected from wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, and quinoa; the vegetables are selected from asparagus, bell peppers, cucumber, eggplant, green beans, green peas, kale, romaine, spinach, squash summer and winter, tomato, carrots, romaine lettuce, radish, bitter gourd, okra, fenugreek leaves, broccoli, brussels sprout, cabbage, chard,

cauliflower, mustard greens, collard greens, turnip greens, turnip, beets, potatoes, fungi, yams and sweet potatoes; the fruits are selected from apple, apricot, orange, pear, plum, banana, cantaloupe, grapes, grapefruit, papaya, mango, pineapple, blueberries, cranberries, figs, kiwi, prune, raspberries, pomegranate, strawberries and watermelon; the legumes are selected from black beans, dried peas, mung beans, garbanzo, kidney beans, lentils, lima beans, navy beans, pinto beans, pigeon peas, and soybeans; the herbs or spices are selected from asafetida, basil, bishop's weed, black pepper, cayenne pepper, chili pepper, cinnamon, cloves, coriander, cumin, dill, ginger, mustards seeds, oregano, peppermint, rosemary, sage, thyme, turmeric, fennel, garlic, onion, leeks, parsley, celery, cardamom, saffron, lime, lemon, tamarind, and mint, and the sweeteners are selected from molasses, cane juice, honey, maple syrup, dates, raisins, dried berries, figs, and sugar.

[0142] In some embodiments, the nutrients from the foods are extracted, and incorporated in a nutritional formulation in liquid, dry powder, or in topical cream or patch. Thus, formulations that provide the micronutrients to complement the remaining diet, may be oral compositions or topical in some embodiments.

[0143] In one aspect, the disclosure provides compositions that include seeds, nuts, and/or oils. In one embodiment the composition can include one or more edible oils, culinary nuts and/or seeds in their whole form or their oils such as, but not limited to acai oil, amaranth oil, apple seed oil, apricot kernel oil, argan oil, artichoke oil, avocado oil, babassu oil, ben oil, blackcurrant seed oil, borage seed oil, borneo tallow nut oil, bottle gourd oil, buffalo gourd oil, butter oil (anhydrous), canola oil (rapeseed), cape chestnut oil, carob pod oil, cocklebur oil, cocoa butter oil, cohune oil, coriander seed oil, corn oil, cottonseed oil, dika oil, evening primrose oil, false flax oil (camelina sativa), fish oil (cod liver), fish oil (herring), fish oil (menhaden), fish oil (salmon), fish oil (sardine), grapeseed oil, household lard, kapok seed oil, lallemantia oil, marula oil, meadowfoam seed oil, mustard oil, nutmeg butter, okra seed oil, palm oil, papaya seed oil, pequi oil, perilla oil, prune kernel oil, quinoa oil, ramtil oil, rice bran oil, royle oil, sacha inchi oil, safflower oil, sheanut oil, soybean lecithin oil, tea oil, thistle oil, tomato seed oil, ucuhuba butter oil, wheat germ oil, acorns, almonds, beech nuts, brazilnuts, breadnuts, candlenuts, chestnuts, chilacayote nuts, chilean hazel nuts, coconuts, cashews, colocynth nuts, filberts, hazelnut, hickory, kola nut, macadamia, mamoncillo, melon seeds, mongongo, obongo nut, olives, peanuts, pecans, pili nuts, pine nuts, pistachios, soya nuts, poppy seeds, pumpkin seeds, hemp seeds, flax seeds, sesame seeds, sunflower seeds, walnuts, and watermelon seeds.

[0144] In some embodiment, general formulations use sensitive/ nutrient rich food items sparingly and with concern for adverse interactions: all nuts and seeds; oils and butters; eggs; some fruits: berries, papaya, apricot, fig, kiwi, pineapple; some vegetables: beets, yams, mustard greens, avocados; some legumes: soybeans and their products, pink lentils; some grains: barley, millet, buckwheat, oats; fungi (all kinds of mushrooms and yeasts); microorganisms (all kinds of probiotics, in excess they can cause problems, e.g. digestive issues and they can modulate metabolism of many foods); seafood including sea vegetables; herbs and spices in general: cinnamon, cloves, sage, turmeric; sweeteners: cane juice, honey, maple syrup; generally food folate, polyphenols, phytosterols, vitamin A, E, Se and fat containing foods. Ortolani C, Pastorello EA. Food allergies and food intolerances. Best Pract Res Clin Gastroenterol. 2006;20:467-483. Lessof MH. Food intolerance and allergy--a review. Q J Med. 1983; 52:111-119.

[0145] Typical interactions that are monitored comprise: seafood with nuts and seeds; seafood with phytochemicals; nuts and seeds, with berries, avocados, kiwi, papaya.

[0146] In one aspect, the total daily nutrients from all foods are within the ratios and ranges described herein and the compositions described herein are administered to an individual that falls within the age and calorie intake range as recommended. In a related embodiment, a 1-day, a 1-week, a 2-week, or a 1-month or more diet formulation or plan is provided.

[0147] In some embodiments, the nutritional formulations and diet plans are designed such that they provide greater (or less) than 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, calories from protein, greater (or less) than 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50% calories from lipids, and greater (or less) than 35%, 45%, 55%, 65%, 75%, 85% calories from carbohydrates.

[0148] In another aspect the diet comprises proteins, which proteins are from one or more of but not limited to legumes, eggs, cheese, milk, yogurt, poultry, seafood, and meat.

[0149] In some embodiments, carbohydrates are from greater (or less) than 40%, 50%, 70% intake of grains in calories, greater (or less) than 20%, 30%, 40% intake of vegetables in calories, and greater (or less) than 20%, 30%, 40% intake of fruits in calories. In a related aspect the calories from carbohydrates are additionally from one or more of spices, sweeteners, and beverages. In a further aspect the carbohydrates from grains are supplied by one or more of wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, quinoa, and other grains.

[0150] In some embodiments, polyphenols, folate, phytosterols, alpha carotene, beta carotene, beta cryptoxanthin, betaine, choline, lycopene, and lutein/zeaxanthin are included in the formulations. For example, one or more polyphenols greater (or less) than 5, 10, 15, 20, 45, 70, 95, 115, 140, 165, 200, or 300 mg/day; and/or folate greater (or less) than 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 mcg/day; and/or one or more phytosterols greater (or less) than 150, 200, 250, 300, 350, 450, 550, 650, 750, 850, or 1000 mg/day; and/or one or more carotenoid greater (or less) than 100, 300, 500, 1000, 3000, 5000, 8000, 10000, 12000, or 14000 mcg/day; and/or betaine and/or choline greater (or less) than 25, 50, 100, 200, 400, 500, or 600 mg/day. In some embodiments, these ranges represent limits for certain cohorts.

[0151] In some embodiments, antioxidants, and vitamins and minerals, e.g. Se are included in the formulations. For example, antioxidants greater (or less) than 25, 50, 100, 200, 400, 500, 600, or 1000 mg per day, or 1, 2, 4, 6, 8, or 10g per day; and/or Se greater (or less) than 5, 10, 15, 20, 35, 55, 75, 95, 115, or 135 mcg/day can be used.

[0152] In some embodiments, one or more fibers are included in the formulations. For example, greater (or less) than 1, 5, 10, 20, 30, 40, 50g per day.

[0153] Omega-6 to Omega-3 fatty acid ratios, depending on the cohort range from 1:1-50:1. In certain embodiments, the ratio is greater (or less) than 1:1, 5:1, 6:1, 7:1, 8:1, 10:1, 15:1, 20:1, 25:1, 30:1, 40:1, or 50:1.

[0154] Omega-9 to Omega-6 fatty acid ratios, depending on the cohort, range from 0.5:1-6:1. In various embodiments, the ratio is greater (or less) than 0.5:1, 1:1, 2:1, 3:1, 4:1, 5:1, or 6:1.

[0155] Total Fatty Acids to Monounsaturated fatty acid ratios, depending on the cohort, range from 1:1-15:1. In various embodiments, the ratio is greater (or less) than 1:1-2:1, 2:1-4:1, 4:1-6:1, 6:1-8:1, 8:1-10:1, 10-1:12:1, 12:1-15:1.

[0156] Monounsaturated to Polyunsaturated fatty acid ratios, depending on the cohort, range from 0.25:1-6:1. In various embodiments, the ratio is greater (or less) than 0.25:1, 1:1, 2:1, 3:1, 4:1, 5:1, or 6:1.

[0157] Monounsaturated to Saturated fatty acid ratios, depending on the cohort, range from 0.25:1-7:1. In various embodiments, the ratio is greater (or less) than 0.25:1, 1:1, 1.5:1, 2:1, 3:1, 5:1, 6:1 or 7:1.

[0158] Total Fatty Acids to Polyunsaturated fatty acid ratios, depending on the cohort, range from 1:1-15:1. In various embodiments, the ratio is greater (or less) than 1:1, 2:1, 3:1, 5:1, 7:1, 10:1, 12:1 or 15:1.

[0159] Total Fatty Acids to Saturated fatty acid ratios, depending on cohort, range from 1:1-15:1. In various embodiments, the ratio is greater (or less) than 1:1, 2:1, 3:1, 5:1, 7:1, 10:1, 12:1 or 15:1.

[0160] In some embodiments, the diet formulation calls for specific percentages of omega-9, omega-6, and omega-3 fatty acids within the following ranges (w/w, w/v, or v/v of total lipids). Omega-9 fatty acid, depending on the cohort, ranges from 10-90%. In some embodiments, omega-9 fatty acids comprise more (or less) than 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 80% or 90% of total lipids.

[0161] Omega-6 fatty acid, depending on the cohort, ranges from 4-75%. In some embodiments, omega-6 fatty acids comprise more (or less) than 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, or 70% of total lipids.

[0162] Omega-3 fatty acid, depending on the cohort, ranges from 0.1-30%. In some embodiments, omega-3 fatty acids comprise more (or less) than 0.25%, 0.5%, 1%, 5%, 10%, 15%, 20%, 25% of total lipids. In some embodiments, from about 25 % to about 100% by weight of the omega-3 fatty acids are long chain co-3 fatty acids. In some embodiments, from about 50% to about 100% by weight of the omega-3 fatty acids are long chain omega-3 fatty acids. For example, from about 60% to about 80%, or from about 70% to about 90%.

[0163] Vitamin E-alpha/gamma, depending on the cohort, ranges from 0.001-0.5%. In some embodiments, vitamin E-alpha/gamma comprise more (or less) than 0.01%, 0.05%, 0.10%, 0.15%, 0.20%, 0.25% or 0.30% of total lipids.

[0164] In some embodiments the average daily amount of omega-6 fatty acid according to the nutritional program ranges between 1-40 g. In embodiments, the daily amount of omega-6 fatty acid is more (or less) than 1, 2, 5, 10, 15, 20, 25, 30, 35, or 40g.

[0165] In some embodiments the average daily amount of omega-3 fatty acid according to the nutritional program ranges between 0.1-15g. In some embodiments, the daily amount of omega-3 fatty acid is more (or less) than 0.1, 0.2, 0.5, 1, 2, 5, 7, 10, 12, or 15g.

[0166] In some embodiments, method of selection of foods for the seafood cohort comprises following steps: a) formulate a dietary protein component utilizing seafood, and meats, b) compute the range of micronutrients, proteins and lipids contained, c) select legumes, and grains to obtain additional proteins and desired carbohydrates, d) select vegetables and fruits to meet micronutrient requirements, e) select probiotics and prebiotics, and f) select oils and other foods to meet remaining lipid, protein, phytochemical, antioxidants and vitamins and minerals

requirements. In some embodiments, for a seafood based cohort hulled grains may be preferred, for example, white rice may be used instead of brown rice, a less intense variety of wheat may be used, and lesser than 10% of grain calories on the average may be used from spelt, barley, oats, rye, buckwheat, millet and quinoa. Similarly, use of mustard greens, yams, fungi, winter squash, and berries may be restricted because of their nutrients density and interaction potential with nutrients in seafood. In a related aspect, preferable ratio of omega-6 to omega-3 may be, 2:1-4:1, 4:1-10:1, 10:1-15:1. In a related aspect, seafood cohorts may consume relatively high amounts of one or more of long-chain omega-3, and Se, which may limit tolerance for certain phytochemicals, for example flavonoids and folate. In some embodiments, diets high in long-chain omega-3 and/or Se are complemented with low phytochemicals, particularly flavonoids, and folate.

[0167] In some embodiments, method of selection of foods for the meat (red) based cohort comprises following steps: a) formulate a dietary protein component utilizing meats, b) compute the range of micronutrients, proteins and lipids contained, c) select legumes and grains to obtain additional proteins and desired carbohydrates, d) select vegetables and fruits to add micronutrients, e) select probiotics and prebiotics, and f) select herbs, nuts, seeds, and oils to meet remaining lipid, phytochemical particularly flavonoids and sterols, antioxidants and vitamins and minerals requirements. In some embodiments, for a meat based cohort whole grains are utilized preferentially. Similarly, mustard greens, yams, fungi, winter, squash, and berries may be utilized preferentially because of their nutrient density. In a related aspect, preferable ratio of omega-6 to omega-3 may be 0.5:1-4:1, 4:1-10:1. In a related aspect, meat cohorts may consume relatively high amounts of one or more of long-chain omega-6, and certain saturated fatty acids, and their diet may be inherently low in certain phytochemicals, for example flavonoids and folate. In some embodiments, diets high in long-chain omega-6 are complemented with high antioxidants, such as Vitamin E, and phytochemicals, particularly flavonoids, and folate.

[0168] In some embodiments, method of selection of foods for the plant based ovo-lacto vegetarian cohort comprises following steps: a) formulate a dietary protein component utilizing legumes and dairy products, b) compute the range of micronutrients, proteins, and lipids contained, c) select grains to obtain desired carbohydrate and proteins , d) select vegetables and fruits to add micronutrients, e) select probiotics and prebiotics, and f) select herbs, nuts, seeds, and oils to meet remaining lipid, phytochemical, antioxidants and vitamins and minerals requirements. In some embodiments, for a plant based cohort some of the grains are hulled, for

example, white rice may be used instead of brown rice, a less intense variety of wheat may be used, and lesser than 15% of grain calories on the average may be used from spelt, barley, oats, rye, buckwheat, millet and quinoa. Similarly, use of mustard greens, yams, fungi, winter, squash, and berries may be restricted because of their nutrients density and interaction potential with nutrients in legumes. In a related aspect, preferable ratio of omega-6 to omega-3 may be, 4:1-10:1, 10:1-15:1, 15:1-20:1. In a related aspect, ovo-lacto cohorts may consume relatively high amounts of one or more polyphenols, particularly isoflavones, which may limit tolerance for certain other phytochemicals, for example folate and/or phytochemicals found in whole grains. In some embodiments, diets high in legumes are complemented with low phytochemicals, from whole grains.

[0169] In some aspects, the nutritional/diet plan or food compositions developed therefrom can serve as a medicaments or compositions for use in prophylaxis or treatment of certain diseases or medical conditions. Medicaments can be based on a subject's dietary habits around typical consumption of phytochemicals, antioxidants, and other nutrients. Appropriate supplements, medications or pharmaceutical drugs can also be administered to/by such dietary cohorts because their requirements, biochemistry, and gene expression may be influenced in a certain predictable way.

[0170] In some aspects, the nutritional/diet plan or food compositions developed therefrom can serve as a medicaments or compositions for use in prophylaxis or alleviation of one or more symptoms associated with a disease or condition selected from: menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases.

[0171] Potential benefits of the tailored dietary or nutritional programs include: a) lipid, antioxidant, phytochemical, vitamin and mineral delivery within the optimal range considering main food preferences, age, gender, size, medical condition, family history, and climatic temperature; b) synergistic use of different natural sources to deliver an array of nutrients; c) reduction of some potential harmful interactions; d) managed expression of oxidation products; e) optimization of gene expression; f) steady delivery of lipids and phytochemicals to stabilize

immunity and physiology; g) satiety and its perception, since nutrient requirements are balanced; and h) caloric restriction.

[0172] In one aspect, the invention relates to a computer program storage device readable by a machine or processor and containing a set of instructions which, when read by the machine, causes execution of a bioinformatics method for generating a compilation of dietary ingredients comprising a nutritional plan. In some embodiments, the method may be stored on a computer-readable medium having computer-executable instructions for performing the method. A computer- readable medium may include, but is not limited to, a compact disc (CD), a USB thumb drive, an optical drive, or a magnetic drive. Other types of computer-readable media may be used as well, such as those presently known in the art and those yet to be discovered. The method is executed on a computational device comprising a processor, at least one memory and optionally, a display and a measuring device. Stored in the memory are parameters that allow classification of an individual's dietary pattern input into the memory into at least one predetermined dietary cohort by the processor. Also stored in the memory are modules of nutritional plans that have been developed as appropriate for each dietary cohort. In some aspects, the device is connectable to other devices by wired or wireless connection or over LAN or WAN. The computer program operates in response to user inputs, which in some embodiments include dietary habits for an individual (e.g., approximate daily consumption values in step 1 of Table 4). User inputs may be remote, via web connection. The computer program is configured to identify dietary cohort and/or calculate ranges in step 2 of Table 4, and develop complementing nutritional supplements in accordance with this disclosure, and such nutritional supplements may be based upon culinary preferences for the individual, which may also be input into the system.

[0173] As defined herein, a therapeutically effective amount of the nutrient (i.e., an effective amount) may range from about 0.0001 to 100 g/kg body weight, or other ranges that would be apparent and understood by artisans without undue experimentation. The skilled artisan will appreciate that certain factors can influence the dosage and timing required to effectively treat a subject, including but not limited to the severity of the disease or disorder, previous treatments, the general health or age of the subject, and other diseases present.

[0174] According to another aspect, one or more kits of parts can be envisioned by the person skilled in the art, the kits of parts to perform at least one of the methods herein disclosed, the kit of parts comprising two or more compositions, the compositions comprising alone or in

combination an effective amount of the compositions disclosed herein according to the at least one of the above mentioned methods.

[0175] The kits possibly include also compositions/ formulations comprising active agents, identifiers of a biological event, or other compounds identifiable by a person skilled upon reading of the present disclosure. The kit can also comprise at least one composition comprising an effective amount of the compositions disclosed herein or a cell line. The compositions and the cell line of the kits of parts to be used to perform the at least one method herein disclosed according to procedure identifiable by a person skilled in the art.

[0176] According to one aspect, complementary modules or packages are provided that suit a particular diet plan. Such modules or packages may be embodied as vegetable/ vegetable juice packs, fruit/fruit juice packs, dry grain packs, cereal packs, legume/grain/ nuts and/or seeds packs, meat/seafood packs, herbs, lipids, desserts, milks, yogurts and the like, or a combination thereof in cooked, uncooked, processed or unprocessed form.

[0177] Each module is marked or is otherwise associated with indication that it is suitable for consumption by an individual with a specific dietary profile or a dietary cohort or further sub-sections thereof based on additional factors such as gender, age, location, climate, medical condition and the like. Consumption of a suitable module ensures an optimized pattern of nutrient profile in the consumer, in particular nutrients that are sensitive to narrow fluctuations.

EXAMPLES

[0178] The following examples are included to demonstrate preferred embodiments of the invention. It should be appreciated by those of skill in the art that the techniques disclosed in the examples which follow represent techniques discovered by the inventor to function well in the practice of the invention, and thus can be considered to constitute preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

EXAMPLE 1: General Diet Formulations

[0179] In one embodiment, a diet plan is provided which includes the 25%-45% of calories from fat, which are supplied by the lipid compositions described herein. In an exemplary general diet plan, macronutrients provide 35-65% of calories from carbohydrates, 10-45% of calories from proteins and 15-45% of calories from lipids. The general diet formulation comprises one or more of the components listed in Table 5 below, wherein the upper limits are set on the basis of

levels of the micronutrients present in the each food item and the sensitivity of the food item. Thus, nutritional formulations are provided to the individual to balance the individual's diet within the following ranges shown in Table 5, with listed ingredients being alternatives for use individually or together (e.g., in one or more nutritional formulation disclosed herein).

[0180] In one aspect, one or more of the food items are provided in individual modules or packages of food or drink. In one aspect, each package comprises a label indicating its suitability for consumption according to a general diet plan and optionally, maximum amounts for average daily consumption to maintain a health benefit according to the invention.

Table 5: General Diet Formulation

Grains (one or more of)		**50-70% of carbohydrate calories**		**Upper limit of Avg. Daily Amounts (uncooked, Grams/ Calories)**	**Upper limit of Avg. Daily Servings (cups)**
1	Wheat	<50%	of grains	114	3.5
2	Rice	<50%	of grains	114	2.5
3	Corn	<20%	of grains	46	1
4	Barley	<20%	of grains	46	1
5	Spelt	<20%	of grains	46	1
6	Oats	<20%	of grains	46	1
7	Rye	<20%	of grains	46	1
8	Buckwheat	<15%	of grains	34	0.75
9	Millet	<15%	of grains	34	0.75
10	Quinoa	<15%	of grains	34	0.75
11	Other Grains	<10%	of grains	23	0.5
Vegetables (one or more of)		**15-40% of carbohydrate calories**			
1	Bell Peppers, Cucumber, Eggplant, Green beans, Green peas, Spinach, Squash summer, Tomato, Okra, Potatoes	<50%	of vegetables		5
2	Asparagus, Broccoli, Brussels Sprout, Cabbage, Carrots, Chard, Cauliflower, Kale, Collard Greens, Fenugreek Leaves, Romaine Lettuce	<40%	of vegetables		4
3	Turnip, Turnip Greens, Beets, Yams, Sweet Potatoes, Winter squash, Bitter Gourd, Radish, Mustard Greens	<35%	of vegetables		2
4	Fungi includes all mushrooms	<25%	of vegetables		1
5	Other Vegetables	<15%	of		0.5

			vegetables		
Fruits (one or more of)		**10-30% of carbohydrate calories**			
1	Apple, Orange, Pear, Banana, Cantaloupe, Grapes	<75%	of fruits		2
2	Apricots, Grapefruit, Papaya, Mango, Pineapple	<50%	of fruits		1
3	Blueberries, Cranberries, Figs, Kiwi, Prune, Raspberries, Pomegranate, Strawberries, Watermelon, Plum	<35%	of fruits		1
4	Other fruits	<15%	of fruits		0.5
Spices (one or more of)		**<7% of carbohydrate calories**			
	Basil, Black pepper, Cayenne pepper, Chili Pepper, Cinnamon, Cloves, Coriander seeds and leaves, Cumin, Dill, Ginger, Mustard Seeds, Oregano, Peppermint leaves, Rosemary, Sage, Thyme, Turmeric, Fennel, Garlic, Onion, Leeks, Parsley, Celery, Cardamom, Saffron, Lime, Lemon, Tamarind, Mint, Vinegar, other				3 tsp.
Sweeteners (one or more of)		**<7% of carbohydrate calories**			
	Molasses, Cane Juice, Honey, Maple Syrup, Dates, Raisins, Dried Berries, Figs, Sugar, other				2 tbs.
Beverages (one or more of)		**<5% of carbohydrate calories**			
	Green tea, Black tea, cocoa, coffee, alcohol, other				3
Proteins (one or more of)		**10-45% of calories**			
	Legumes: Black beans, Dried Peas, Mung beans, Garbanzo, Kidney beans, Lentils, Lima beans, Navy beans, Pinto beans, Soybeans	<75%	of protein calories	675	3
	Meat	<60%	of protein calories	540	2
	Poultry	<60%	of protein calories	540	2
	Seafood	<50%	of protein calories	450	1
	Milk	<35%	of protein calories	315	2
	Cheese	<20%	of protein calories	180	1

	Eggs	<15%	of protein calories	135	1
	Yogurt	<15%	of protein calories	135	1
	Other	<15%	of protein calories	135	1
Lipids (one or more of)		**15-45% of calories**			
	Peanut oil, olive oil, sunflower oil, safflower oil, corn oil	<75%	of lipid calories	675	
	Coconut Oil, Butter or butter oil	<45%	of lipid calories	405	
	Olives, Walnuts, flaxseeds	<45%	of lipid calories	405	
	Almonds, cashews, pistachios, peanuts	<30%	of lipid calories	270	
	Sesame seeds, flaxseeds, pumpkin seeds, sunflower seeds	<25%	of lipid calories	225	
	Other	<10%	of lipid calories	100	
Lipid Ratios:					
	Omega-6:omega-3	0.5:1-20:1			
	Omega-9:omega-6	1:1-3:1			
	Mono:Poly	1:1-3:1			
	Mono:Sat	1:1-5:1			
Omega fatty acids:					
	Omega-6	1-40 g			
	Omega-3	0.1-20g			

EXAMPLE 2: Diet Formulation for Cohort: Seafood

[0181] In one embodiment, a diet plan is provided for a cohort who derives 2%-40% of calories from seafood per day/week/month. Such individuals can generally be classified as seafood-heavy.

[0182] A 1-day, a 1-week, a 2-week, or a 1-month diet plan is provided which includes the 2%-40% of calories from seafood, and the remaining 60%-98% of calories are supplied by a diet including the following components, ranges specified in calories. The components in Table 6 are selected such that levels of sensitive nutrients are optimized. Thus, nutritional formulations are provided to the individual to balance the individual's diet within the following ranges shown in Table 6, with listed ingredients being alternatives for use individually or together (e.g., in one or more nutritional formulations described herein).

[0183] The seafood cohort diet formulation comprises one or more of the components listed in Table 6 below, wherein the upper limits are set on the basis of levels of the micronutrients

present in the each food item, and the sensitivity of the food item. In one aspect, one or more of the food items are provided in individual modules or packages of food or drink. In one aspect, each package comprises a label indicating its suitability for consumption according to a seafood cohort diet plan and optionally, maximum amounts for average daily consumption to maintain a health benefit according to the invention.

Table 6: Seafood Cohort Diet Formulation

Grains (one or more of) (hulled grains preferred)		**50-70% of carbohydrate calories**		**Upper limit of Avg. Daily Amounts (uncooked, Grams/ Calories)**	**Upper limit of Avg. Daily Servings (cups)**
1	Wheat	<50%	of grains	114	3.5
2	Rice	<50%	of grains	114	2.5
3	Corn	<10%	of grains	23	0.5
5	Spelt	<10%	of grains	23	0.5
6	Oats	<10%	of grains	23	0.5
10	Quinoa	<10%	of grains	15	0.5
11	Other Grains	<10%	of grains	23	0.5
Vegetables (one or more of)		**15-40% of carbohydrate calories**			
1	Bell Peppers, Cucumber, Eggplant, Green beans, Green peas, Spinach, Squash summer, Tomato, Okra, Potatoes	<50%	of vegetables		5
2	Asparagus, Broccoli, Brussels Sprout, Cabbage, Carrots, Chard, Cauliflower, Kale, Collard Greens, Fenugreek Leaves, Romaine Lettuce	<30%	of vegetables		3
3	Turnip, Turnip Greens, Beets, Yams, Sweet Potatoes, Winter squash, Bitter Gourd, Radish, Mustard Greens	<10%	of vegetables		0.5
4	Fungi includes all mushrooms	<10%	of vegetables		0.5
5	Other Vegetables	<15%	of vegetables		0.5
Fruits (one or more of)		**10-30% of carbohydrate calories**			
1	Apple, Orange, Pear, Banana, Cantaloupe, Grapes	<75%	of fruits		2
2	Apricots, Grapefruit, Papaya, Mango, Pineapple	<30%	of fruits		0.5

3	Blueberries, Cranberries, Figs, Kiwi, Prune, Raspberries, Pomegranate, Strawberries, Watermelon, Plum	<15%	of fruits		0.25
4	Other fruits	<15%	of fruits		0.25
Spices (one or more of)		**<5% of carbohydrate calories**			
	Basil, Black pepper, Cayenne pepper, Chili Pepper, Cinnamon, Cloves, Coriander seeds and leaves, Cumin, Dill, Ginger, Mustard Seeds, Oregano, Peppermint leaves, Rosemary, Sage, Thyme, Turmeric, Fennel, Garlic, Onion, Leeks, Parsley, Celery, Cardamom, Saffron, Lime, Lemon, Tamarind, Mint, Vinegar, other				2 tsp.
Sweeteners (one or more of)		**<7% of carbohydrate calories**			
	Molasses, Cane Juice, Honey, Maple Syrup, Dates, Raisins, Dried Berries, Figs, Sugar, other				2 tbs.
Beverages (one or more of)		**<5% of carbohydrate calories**			
	Green tea, Black tea, cocoa, coffee, alcohol, other				3
Proteins (one or more of)		**10-45% of calories**			
	Legumes: Black beans, Dried Peas, Mung beans, Garbanzo, Kidney beans, Lentils, Lima beans, Navy beans, Pinto beans, Soybeans	<50%	of protein calories	450	2
	Meat	<60%	of protein calories	540	2
	Poultry	<60%	of protein calories	540	2
	Seafood	<50%	of protein calories	450	1
	Milk	<35%	of protein calories	315	2
	Cheese	<20%	of protein calories	180	1
	Eggs	<15%	of protein calories	135	1
	Yogurt	<10%	of protein calories	135	1
	Other	<15%	of protein calories	135	1
Lipids (one or more of)		**15-45% of calories**			

	Peanut oil, olive oil, sunflower oil, safflower oil, corn oil	<75%	of lipid calories	675	
	Coconut Oil, Butter or butter oil	<45%	of lipid calories	405	
	Other	<10%	of lipid calories	100	
Lipid Ratios:					
	Omega-6:omega-3	2:1-15:1			
	Omega-9:omega-6	1:1-3:1			
	Mono:Poly	1:1-3:1			
	Mono:Sat	1:1-5:1			
Omega fatty acids:					
	Omega-6	1-35 g			
	Omega-3	0.1-20g			

EXAMPLE 3: Diet Formulation for Cohort: Meat

[0184] In one embodiment, a diet plan is provided for a cohort who derives 10%-50% of calories from meat per day/week/month. Such individuals can generally be classified as meat-heavy.

[0185] A 1-day, a 1-week, a 2-week, or a 1-month diet plan is provided which includes the 10%-50% of calories from meat, and the remaining 50%-90% of calories are supplied by a diet including the following components, ranges specified in calories. Thus, nutritional formulations are provided to the individual to balance the individual's diet within the following ranges shown in Table 7, with listed ingredients being alternatives for use individually or together (e.g., with one or more nutritional formulations described herein).

[0186] The components in Table 7 are selected such that levels of sensitive nutrients are optimized.

[0187] The meat cohort diet formulation comprises one or more of the components listed in Table 7 below, wherein the upper limits are set on the basis of levels of the micronutrients present in the each food item, and the sensitivity of the food item. In one aspect, one or more of the food items are provided in individual modules or packages of food or drink. In one aspect, each package comprises a label indicating its suitability for consumption according to a meat cohort diet plan and optionally, maximum amounts for average daily consumption to maintain a health benefit according to the invention.

Table 7: Meat Cohort Diet Formulation

Grains (one or more of)		50-70% of carbohydrate calories		Upper limit of Avg. Daily Amounts (uncooked Grams/ Calories)	Upper limit of Avg. Daily Servings (cups)
1	Wheat	<50%	of grains	114	3.5
2	Rice	<50%	of grains	114	2.5
3	Corn	<20%	of grains	46	1
4	Barley	<20%	of grains	46	1
5	Spelt	<20%	of grains	46	1
6	Oats	<20%	of grains	46	1
7	Rye	<20%	of grains	46	1
8	Buckwheat	<15%	of grains	34	0.75
9	Millet	<15%	of grains	34	0.75
10	Quinoa	<15%	of grains	34	0.75
11	Other Grains	<10%	of grains	23	0.5
Vegetables (one or more of)		**15-40% of carbohydrate calories**			
1	Bell Peppers, Cucumber, Eggplant, Green beans, Green peas, Spinach, Squash summer, Tomato, Okra, Potatoes	<50%	of vegetables		5
2	Asparagus, Broccoli, Brussels Sprout, Cabbage, Carrots, Chard, Cauliflower, Kale, Collard Greens, Fenugreek Leaves, Romaine Lettuce	<40%	of vegetables		4
3	Turnip, Turnip Greens, Beets, Yams, Sweet Potatoes, Winter squash, Bitter Gourd, Radish, Mustard Greens	<35%	of vegetables		2
4	Fungi includes all mushrooms	<25%	of vegetables		1
5	Other Vegetables	<15%	of vegetables		0.5
Fruits (one or more of)		**10-30% of carbohydrate calories**			
1	Apple, Orange, Pear, Banana, Cantaloupe, Grapes	<75%	of fruits		2
2	Apricots, Grapefruit, Papaya, Mango, Pineapple	<50%	of fruits		1
3	Blueberries, Cranberries, Figs, Kiwi, Prune, Raspberries, Pomegranate, Strawberries, Watermelon, Plum	<35%	of fruits		1
4	Other fruits	<15%	of fruits		1

Spices (one or more of)		**<7% of carbohydrate calories**			
	Basil, Black pepper, Cayenne pepper, Chili Pepper, Cinnamon, Cloves, Coriander seeds and leaves, Cumin, Dill, Ginger, Mustard Seeds, Oregano, Peppermint leaves, Rosemary, Sage, Thyme, Turmeric, Fennel, Garlic, Onion, Leeks, Parsley, Celery, Cardamom, Saffron, Lime, Lemon, Tamarind, Mint, Vinegar, other				3 tsp.
Sweeteners (one or more of)		**<7% of carbohydrate calories**			
	Molasses, Cane Juice, Honey, Maple Syrup, Dates, Raisins, Dried Berries, Figs, Sugar, other				2 tbs.
Beverages (one or more of)		**<5% of carbohydrate calories**			
	Green tea, Black tea, cocoa, coffee, alcohol, other				3
Proteins (one or more of)		**10-45% of calories**			
	Legumes: Black beans, Dried Peas, Mung beans, Garbanzo, Kidney beans, Lentils, Lima beans, Navy beans, Pinto beans, Soybeans	<75%	of protein calories	675	3
	Meat	<60%	of protein calories	540	2
	Poultry	<60%	of protein calories	540	2
	Seafood	<50%	of protein calories	450	1
	Milk	<35%	of protein calories	315	2
	Cheese	<20%	of protein calories	180	1
	Eggs	<15%	of protein calories	135	1
	Yogurt	<15%	of protein calories	135	1
	Other	<15%	of protein calories	135	1
Lipids (one or more of)		**15-45% of calories**			
	Peanut oil, olive oil, sunflower oil, safflower oil, corn oil	<50%	of lipid calories	675	
	Coconut Oil, Butter or butter oil	<45%	of lipid calories	405	
	Olives, Walnuts, flaxseeds	<50%	of lipid calories	405	

	Almonds, cashews, pistachios, peanuts	<30%	of lipid calories	270	
	Sesame seeds, flaxseeds, pumpkin seeds, sunflower seeds	<25%	of lipid calories	225	
	Other	<10%	of lipid calories	100	
Lipid Ratios:					
	Omega-6:omega-3	0.5:1-10:1			
	Omega-9:omega-6	1:1-3:1			
	Mono:Poly	1:1-3:1			
	Mono:Sat	1:1-5:1			
Omega fatty acids:					
	Omega-6	1-40 g			
	Omega-3	0.1-20g			

EXAMPLE 4: Diet Formulation for Cohort: Legumes, Vegetables and fruits

[0188] In one embodiment, a diet plan is provided for a cohort which derives 20%-80% of calories from legumes, vegetables and fruits per day/week/month. Such individuals are generally considered to have a vegetable heavy diet.

[0189] A 1-day, a 1-week, a 2-week, or a 1-month diet plan is provided which includes the 20%-80% of calories from legumes, vegetables and fruits , and the remaining 80%-20% of calories are supplied by a diet including the following components, ranges specified in calories. The components in Table 8 are selected such that levels of sensitive nutrients are optimized. Thus, nutritional formulations are provided to the individual to balance the individual's diet within the following ranges shown in Table 8, with listed ingredients being alternatives for use individually or together (e.g., in one or more nutritional formulations described herein).

[0190] The legumes, vegetables and fruits cohort diet formulation comprises one or more of the components listed in Table 8 below, wherein the upper limits are set on the basis of levels of the micronutrients present in the each food item, and the sensitivity of the food item. In one aspect, one or more of the food items are provided in individual modules or packages of food or drink. In one aspect, each package comprises a label indicating its suitability for consumption according to a legumes, vegetables and fruits cohort diet plan and optionally, maximum amounts for average daily consumption to maintain a health benefit according to the invention.

Table 8: Legumes, Vegetables and Fruits Cohort Diet Formulation

Grains (one or more of) (selectively hulled grains preferred)		**50-70% of carbohydrate calories**		**Upper limit of Avg. Daily Amounts (Uncooked Grams/Cal)**	**Upper limit of Avg. Daily Servings (cups)**
1	Wheat	<50%	of grains	114	3.5
2	Rice	<50%	of grains	114	2.5
3	Corn	<20%	of grains	46	1
4	Barley	<15%	of grains	34	0.75
5	Spelt	<15%	of grains	34	0.75
6	Oats	<15%	of grains	34	0.75
7	Rye	<15%	of grains	34	0.75
8	Buckwheat	<10%	of grains	23	0.5
9	Millet	<10%	of grains	23	0.5
10	Quinoa	<10%	of grains	23	0.5
11	Other Grains	<10%	of grains	23	0.5
Vegetables (one or more of)		**15-40% of carbohydrate calories**			
1	Bell Peppers, Cucumber, Eggplant, Green beans, Green peas, Spinach, Squash summer, Tomato, Okra, Potatoes	<50%	of vegetables		5
2	Asparagus, Broccoli, Brussels Sprout, Cabbage, Carrots, Chard, Cauliflower, Kale, Collard Greens, Fenugreek Leaves, Romaine Lettuce	<40%	of vegetables		4
3	Turnip, Turnip Greens, Beets, Yams, Sweet Potatoes, Winter squash, Bitter Gourd, Radish, Mustard Greens	<35%	of vegetables		2
4	Fungi includes all mushrooms	<25%	of vegetables		1
5	Other Vegetables	<15%	of vegetables		0.5
Fruits (one or more of)		**10-30% of carbohydrate calories**			
1	Apple, Orange, Pear, Banana, Cantaloupe, Grapes	<75%	of fruits		2
2	Apricots, Grapefruit, Papaya, Mango, Pineapple	<25%	of fruits		0.5
3	Blueberries, Cranberries, Figs, Kiwi, Prune, Raspberries, Pomegranate, Strawberries, Watermelon, Plum	<25%	of fruits		0.5
4	Other fruits	<15%	of fruits		0.5
Spices (one or more of)		**1% of carbohydrate calories**			

	Basil, Black pepper, Cayenne pepper, Chili Pepper, Cinnamon, Cloves, Coriander seeds and leaves, Cumin, Dill, Ginger, Mustard Seeds, Oregano, Peppermint leaves, Rosemary, Sage, Thyme, Turmeric, Fennel, Garlic, Onion, Leeks, Parsley, Celery, Cardamom, Saffron, Lime, Lemon, Tamarind, Mint, Vinegar, other				3 tsp.
Sweeteners (one or more of)		**<7% of carbohydrate calories**			
	Molasses, Cane Juice, Honey, Maple Syrup, Dates, Raisins, Dried Berries, Figs, Sugar, other				2 tbs.
Beverages (one or more of)		**<5% of carbohydrate calories**			
	Green tea, Black tea, cocoa, coffee, alcohol, other				3
Proteins (one or more of)		**10-45% of calories**			
	Legumes: Black beans, Dried Peas, Mung beans, Garbanzo, Kidney beans, Lentils, Lima beans, Navy beans, Pinto beans, Soybeans	<75%	of protein calories	675	3
	Milk	<35%	of protein calories	315	2
	Cheese	<20%	of protein calories	180	1
	Eggs	<15%	of protein calories	135	1
	Yogurt	<15%	of protein calories	135	1
	Other	<15%	of protein calories	135	1
Lipids (one or more of)		**15-45% of calories**			
	Peanut oil, olive oil, sunflower oil, safflower oil, corn oil	<75%	of lipid calories	675	
	Coconut Oil, Butter or butter oil	<45%	of lipid calories	405	
	Olives, Walnuts, flaxseeds	<45%	of lipid calories	405	
	Almonds, cashews, pistachios, peanuts	<30%	of lipid calories	270	
	Sesame seeds, flaxseeds, pumpkin seeds, sunflower seeds	<25%	of lipid calories	225	
	Other	<10%	of lipid calories	100	

Lipid Ratios:					
	Omega-6:omega-3	4:1-20:1			
	Omega-9:omega-6	1:1-3:1			
	Mono:Poly	1:1-3:1			
	Mono:Sat	1:1-5:1			
Omega fatty acids:					
	Omega-6	1-40 g			
	Omega-3	0.1-15g			

EXAMPLE 5: Packaging and labeling of a dietary module

[0191] In one embodiment, dietary module according to a diet plan for a specific cohort or dietary profile comprises vegetable/ vegetable juice packs, fruit/fruit juice packs, dry grain packs, cereal packs, legume/grain/ nuts and/or seeds packs, meat or seafood packs, herbs, lipids, desserts, milks, yogurts and the like, or a combination thereof. The appropriate cohort or dietary profile for who the package is designed is indicated in association with the package. Each package is designed to provide less than 25% of calories per day/week/month which is indicated in association with the package.

[0192] Other nutritional information optionally indicated in association with package comprises information about ingredients, consumption limits, list of nutrients, and the like.

EXAMPLE 6: Case Study on Hypercholesterolemia, Cardiovascular Disease

[0193] The host subject experienced hypercholesterolemia on a vegetarian diet low in fat, mostly olive oil (75% monounsaturated fat), a daily fish oil supplement of 1 gram, and a daily total essential fatty acids (EFA) supplement of 1 gram. As part of the treatment, the fish oil and EFA supplements were discontinued. The subject was then administered a daily nutritional composition supplement comprising 11 grams of omega-6 and 1.2 grams of omega-3, made up primarily from a combination of vegetable oils, nuts and seeds which supplied effective amounts of phytochemicals. Administration of the lipid-containing nutritional composition resulted in a reduction of LDL from 160 mg to 120 mg. Very low levels of blood pressure were observed, 90/55 mmHg, when omega-3 was increased to 1.8 grams; blood pressure levels normalized at 105/70 mmHg at 11 grams of omega-6 and 1.2 grams of omega-3. When omega-3 was reduced from 1.8 grams to 1.2 grams per day, the subject experienced an irregular heartbeat, which subsided over a period of 2-3 weeks. However, when omega-3 was further reduced to 0.5 grams per day, it resulted in an ongoing arrhythmia. This demonstrated that supplementation with phytonutrients derived from vegetable oils, nuts and seeds, wherein the omega-6 to omega-3 ratio was about 9:1, resulted in a significant decrease in LDL cholesterol blood levels

(dyslipidemia which is associated with atherosclerosis). This case study also demonstrated that the nutritional compositions and ratios described herein may be useful in moderating blood pressure and arrhythmia.

[0194] In another human subject, intense muscle spasms arising from the left thoracic cavity/wall were observed upon withdrawal of habitual coumarin consumption from asafetida. It is hypothesized, that sudden withdrawal of phytochemicals, particularly ones that have blood thinning effect may be harmful.

EXAMPLE 7: Case Study on Mood Swing, Mental Function

[0195] The subject host was placed on a trial of varying ratios of omega-6 and omega-3 using various oils and nut combinations. Each time omega-3 was reduced or omega-6 was increased the subject became depressed and was given to crying at the slightest provocation. When omega-3 was increased, it elevated the subject's mood, immediately noticeable. However, within certain ranges of omega-6 and omega-3, the effect was self-adjusting, e.g., over a period of 3-6 weeks the moods normalized. It was also observed that within that range of omega-6 and omega-3, over a period of 3-6 weeks the subject in fact was more grounded at higher levels of omega-6; and was euphoric at higher levels of omega-3. Omega-3 increase enhanced cognitive function, which was immediately noticeable. Omega-3 reduction caused confusion, dyslexia, and a decline in cognitive function but these symptoms subsided with time, again within certain omega-6 and omega-3 ranges. The subject also displayed greater attention span and concentration after omega-6 and omega-3 were optimized over a period of 3-6 weeks, with greater reading speeds and comprehension. Thus, the subject performed better at a lower level of omega-3, which suggests that an adaptation mechanism was activated to compensate for the required level of omega-6 metabolites. There may be a similar adaptation mechanism for required level of omega-3. The cumulative effects of such adaptations could pose a threat to the individual. Since phytochemicals have a significant role in this equation, steady delivery of phytochemicals may also be critical.

EXAMPLE 8: Case Studies on Neural Disorders

1. Progressive Supra-nuclear Palsy

[0196] The subject host was a 50-year old woman whose symptoms included dental sensitivity, deteriorating muscle mass, occasional breathing difficulty, easy bruising, mild arrhythmia, and difficult bowel movement. A dentist, as a solution to her sensitive teeth, had extracted and replaced her teeth with dentures at 50. Each of her other symptoms was treated as a stand-alone symptom and treated with non-lipid medications. At 60 she developed loss of

balance, diplopia (double vision), and slurry speech. Eventually when she started having bone-shattering falls, she was diagnosed with Progressive Supra-nuclear Palsy (PSP), a neurological disease mainly characterized by loss of neural tissue in the brainstem. The subject then lost ambulation and speech, and developed dysphagia. She passed away at 67 from pneumonia.

[0197] The woman had had four healthy deliveries, a healthy life until 50, and had no incidence of neural disease in her family. Closer examination of changes in her life around 50 revealed that around that time the fats in her diet had been significantly cut back because of the prevalent doctrine in the 1980s that fats cause heart-disease, and that all fats are deleterious. Both of the woman's parents in their early 70s, and a brother at 48, had died of heart attacks. Hence, the fat reduction was a precautionary measure to avoid cardiac disease, which was then believed to have a strong genetic component. However, it is hypothesized in the present disclosure that the fats were cut to a point where she became severely deficient in both omega-6, and omega-3 fatty acids. The woman was a postmenopausal vegetarian with high antioxidant and phytochemical intake, and the little fat that was in her diet was either saturated fat (less than 20% of total fat) or monounsaturated fat (70-90% of total fat), mostly olive oil following the then doctrine that held olive oil above all others. 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 appeared to be the culprit. The deficiency of omega-6 is also evident from her early symptoms: muscle mass requires a balance of omega-6 and omega-3, lack of omega-6-derivative leukotrienes would lead to asthma-like breathing issues (conversely excessive leukotrienes can also lead to asthma like symptoms), deficiency of omega-3 has been linked with arrhythmia, and deficiency of omega-6 derived thromboxanes would lead to easy bruising, and lack of omega-6 derived prostaglandins will impede smooth muscle activity and therefore the bowel movement. The fact that she was post-menopausal made the requirement of omega-6 and omega-3 more critical, since estrogen and androgens, as hypothesized in the present disclosure, have similar actions and benefits as polyunsaturated fats. When the reproductive hormones decline, the body increasingly depends on omega-6 and omega-3 for the physiological functions. Excess phytochemicals, particularly polyphenols also may have contributed to the illness.

2. Amyotrophic Lateral Sclerosis

[0198] The subject was a vegetarian woman in her mid-30s, on a low fat diet using primarily olive oil and nuts. She had developed Amyotrophic Lateral Sclerosis (ALS)-like symptoms:

muscle weakness in hands, arms, legs, and the muscles of speech, twitching and cramping of muscles, shortness of breath, and difficulty in swallowing. The left side of her body was affected more than the right side. Upon administration of a nutritional composition and changes in diet plan that increased omega-6 to about 12 grams, her symptoms disappeared and the muscle tone improved, better than before the onset of symptoms. It is hypothesized that in this instance, the amount of omega-3 relative to omega-6 in the tissue had exceeded the ratio tolerated by the body. Since the vegetarian diet and nuts contributed plenty of antioxidants and phytochemicals, the subject became deficient in omega-6, despite moderate levels of omega-3. The symptoms could be reversed by increase in omega-6 and/or withdrawal of nuts and seeds, and certain phytochemicals.

EXAMPLE 9: Case Study on Weight Gain, Obesity

[0199] In a vegetarian host subject it was discovered that there was a band of optimal quantity and ratio of omega-6 and omega-3, beyond which the subject gained weight. At omega-6 of 11 grams and omega-3 of 2 grams, the subject was at 134 lbs. When the inventor gradually reduced omega-3 to 1.2 grams, the subject initially gained 6 lbs., and then after 6 weeks, lost 12 lbs. for an ending weight of 128 lbs. Obesity often has been linked to slow metabolism. In turn, metabolic rate has been linked to cell-membrane composition. High polyunsaturated membrane composition may be linked with fast membrane associated processes. Membrane composition influences all aspects of the energy balance equation: electrolyte gradient balance, neuropeptide regulation, gene regulation and glucose regulation.

EXAMPLE 10: Case Study on Digestive System Disorders

[0200] In the host subject, incidences of acid reflux disease, irritable bowels, indigestion, and dyspepsia were observed. Each time omega-6 was increased or omega-3 was decreased the following symptoms appeared: stomach pain, bloating, heartburn, nausea (upset stomach), and burping; but they all disappeared as the body adjusted to increased omega-6. Omega-6 was tested up to 11 grams. It is hypothesized that beyond that point in the particular host the symptoms would persist. Increasing omega-3 beyond 2 grams caused tight dark pellet-like stools. In the optimal omega-6 and omega-3 balance, bile production was optimal as determined by the yellowish brown color of the stools. It was also observed that mucus production in the alimentary canal was optimal with the proper omega-6 and omega-3 quantities and ratio, using mucus production in the oral cavity as an indicator. Halitosis was also observed with 2 grams of omega-3, and got worse when omega-3 was reduced, and then normalized over a period of 3-6

weeks. Arachidonic acid plays a pivotal role in protection and integrity of the intestinal mucosa. Excessive omega-3 can displace arachidonic acid leading to gastro-intestinal mucosal damage.

EXAMPLE 11: Case Study on Ovulation, Reproductive Disorders

[0201] In a host subject, a 35-year old female, cessation of ovulation (as indicated by watery pale menstrual cycles), intense ovulation-related pains and anovulatory menstruation at extremely low omega-6 in diet were observed; olive oil being the main fat source. It is hypothesized herein that this was due to deficiency of omega-6 derived prostaglandins, which aid ovulation. The same phenomenon was observed when the subject was put on Advil, which blocks cyclooxygenase activity and therefore the prostaglandin synthesis.

EXAMPLE 12: Case Study on Dental Diseases

[0202] In a vegetarian host subject, less dental sensitivity, reversal of gum receding, brightening of tooth enamel, and lessening of dental spots and plaque may be exhibited when omega-3 was reduced from 2 grams to 1.2 grams while holding omega-6 constant at 11 grams. Dietary compositions comprising nuts and oils were the source of phytochemicals, omega-6 and omega-3 fatty acids. There was an adjustment period of 3-6 weeks, when the symptoms got worse in the host subjects before getting better. Longer-term intervention studies should be able to test a hypothesis by studying tooth loss during the intervention period. Bioactivity of lipids may explain the linkage between periodontitis/tooth loss and coronary heart disease.

EXAMPLE 13: Case Study on Myofascial Pains and Thoracic Outlet Syndrome

[0203] In a 35-year old vegetarian female, on a low-fat diet using olive oil as the main fat in the diet, the development of episodes of acute myofascial pains were observed. The subject experienced severe muscle tightness in several areas of the body, neck shoulders, para-spinal muscles, thighs, hands, and arms.

[0204] The host was diagnosed with Myofascial Pain Syndrome (MFS) and Thoracic Outlet Syndrome (TOS). TOS consists of a group of distinct disorders that affect the nerves in the brachial plexus (nerves that pass into the arms from the neck) and the subclavian artery and vein blood vessels between the base of the neck and axilla (armpit). For the most part, these disorders are produced by compression of the components of the brachial plexus (the large cluster of nerves that pass from the neck to the arm), the subclavian artery, or the subclavian vein. Neurogenic form of TOS accounts for 95-98% of all cases of TOS, hence neural disease was suspected. The host subject went through numerous examinations including: MRIs of the entire CNS, X-rays, blood work, drug therapies, massage therapies, and chiropractic treatment.

The symptoms would go away and then reappear a few months or a year later. It was observed that the symptoms appeared upon increase of omega-6 fatty acids and/or saturated fatty acids, and/or withdrawal of certain plant matter, for example celery and brown rice. After fatty acids in the subject's diet were optimized by administration of the disclosed lipid compositions, the episodes of TOS and myofascial pains subsided. It is hypothesized herein that these episodes were the result of the body being severely deficient in certain fatty acid metabolites. Each time there was an inadvertent increase in fatty acids, more particularly omega-6 fatty acids and/or their metabolites, which can occur by any incidental changes in diet/withdrawal of a modulating nutrient, there may have been a sudden surge in prostaglandins, thromboxanes, and leukotrienes, and excitability of neural and muscle cells, resulting in severe muscular tightening. Other mechanisms related to the lipids may be involved that are not yet understood.

EXAMPLE 14: Case Studies on Immunity, Autoimmune and Infectious and Inflammatory Diseases

[0205] In a vegetarian host subject, a 48-year old menopausal woman, on 11 g of LA and 1.8 g of ALA, from oils and nuts, spinal burning sensation, heat in the body, skin and feet, and delayed wound healing were observed. The subject also developed vaginal yeast infection. Symptoms disappeared upon reducing ALA to 1.2 g after an initial adjustment period. It is hypothesized that omega-6 and omega-3 and plant matter imbalance leads to inflammation, compromised immunity, and infection. It is further suspected that both omega-6 and omega-3 are anti-inflammatory in small doses and inflammatory in large doses.

[0206] All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

[0207] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

[0208] The Abstract is provided to comply with 37 C.F.R. §1.72(b) to allow the reader to quickly ascertain the nature and gist of the technical disclosure. The Abstract is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

CLAIMS

We claim:

1. A method for selecting a nutritional formulation or plan for an individual, comprising:

determining for the individual a diet cohort, the cohort being high plant food, high meat, or high seafood; and

supplementing the individual's diet with one or more nutritional formulations comprising one or more of natural oils, butters, margarines, nuts, seeds, herbs, vitamins, and minerals, so as to balance the individual's nutritional state.

2. The method of claim 1, wherein the nutritional state is balanced with respect to the ranges of nutrients shown in Tables 5, 6, 7, or 8.

3. The method of claim 1 or 2, wherein the individual has signs or symptoms of a chronic disease.

4. A nutritional formulation comprising at least one module for consumption by a consumer, the formulation comprising:

at least one food item comprising one or more nutrients and/or nutrients in each module,

wherein the nutritional formulation comprises amounts and types of phytochemicals, antioxidants, vitamins, minerals, acid-base, lipids, proteins, carbohydrates, probiotics, prebiotics, microorganisms, fiber and other nutrients that are optimized and balanced to provide a health benefit when one or more servings of the nutritional formulation is used to provide at least 80% of the average daily calories to the consumer.

5. The nutritional formulation of claim 4, wherein at least one module comprises food items sufficient to supplement the consumer's diet.

6. The nutritional formulation of claim 4, wherein the module comprises at least one of vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, seeds packs, meat and/or seafood packs, herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder or puree and yogurt.

7. The nutritional formulation of claim 4, wherein the module comprises one or more nutrients selected from phytochemicals, lipids, antioxidants, vitamins, minerals, synbiotics, probiotics, prebiotics, microorganisms and fiber.

8. The nutritional formulation of any one of claims 4 through 7, wherein the module comprises one or more nutrients selected to supplement a dietary cohort.

9. The nutritional formulation of claim 8, wherein the dietary cohort is selected from vegetable-based, meat-based and seafood-based.

10. The nutritional formulation of claim 8, wherein the dietary cohort is selected based on gender, age, genetic profile, family history, climactic temperature, or medical condition.

11. The nutritional formulation of claim 4, wherein the module comprises food with less than 500 calories or 25% of daily calories

12. Use of the nutritional formulation of claim 4, wherein the module comprises a medicine for prophylaxis or therapy of a medical condition.

13. The nutritional formulation of claim 4, wherein the medical condition or disease is selected from menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases.

14. The nutritional formulation of claim 4, wherein the module comprises part of the subject's dietary intake of nutrients and nutrients.

15. The nutritional formulation of claim 4, comprising a plurality of modules that, in combination, provide the subject's entire daily dietary intake of nutrients and nutrients.

16. The nutritional formulation of claim 4, wherein the module consists essentially of whole food items from natural sources.

17. The nutritional formulation of claim 4, wherein food items in the module are selected based on the methods of processing employed to prepare the food item.

18. A process for developing a nutrient consumption program, the process comprising:

providing one or more lists of food items for average daily consumption by a subject,

wherein the food items comprise at least 80% of the subject's average daily caloric intake over at least one week,

wherein the food items further comprise a plurality of nutrients selected from phytochemicals, antioxidants, vitamins, minerals, synbiotics, probiotics, prebiotics, microorganisms and fiber in amounts that optimizes and balances the subject's total dietary intake of the nutrients such that a beneficial effect is provided to the subject.

19. The process of claim 18, further comprising:

determining a dietary cohort of the subject based on a primary dietary ingredient of the subject's daily or weekly diet by comparing levels of one or more of antioxidants, phytochemicals, vitamins, minerals, lipids, carbohydrates, and proteins from foods comprising the subject's diet with levels in a set of predetermined dietary cohorts.

20. The process of claim 19, wherein the dietary cohort is selected from vegetable-based, meat-based and seafood-based.

21. The process of claim 19, wherein the dietary cohort is selected based on gender, age, genetic profile, climactic temperature, or medical condition, family history.

22. The process of claim 18, further comprising: selecting a food item based on the methods of processing employed to prepare the food item.

23. The process of claim 22, wherein the processing is selected from hulling, removing a layer, drying, providing fresh, roasting and grilling.

24. The process of claim 18, wherein the nutrient consumption program supplements the subject's daily food consumption based on the subject's dietary cohort.

25. The process of claim 18, wherein the nutrient consumption program replaces the subject's daily food consumption based on the subject's dietary cohort.

26. The process of any one of claims 18-25, wherein the nutrient consumption program balances the subject's dietary intake based on the subject's lipid consumption.

27. The process of claim 26, wherein the nutrient consumption program provides a list of predetermined natural sources of lipids, the sources selected from oils, butters, margarines, nuts and seeds.

28. The process of claim 27, wherein the nutrient consumption program provides a list of one or more of nutrients selected from antioxidants, phytochemicals, vitamins and minerals in amounts that optimizes dietary nutrients such that the subject's lipid intake provides a beneficial effect to the subject.

29. A computer system for computationally implementing the method according to any one of claims 1 to 3, or any one of claims 18 to 28, comprising:

(a) a computing device having a memory;

(b) an input device for entering information regarding the subject's actual dietary intake into the memory;

(c) a data base in the memory for storing the information;

(d) a first application program, for execution in the computing device, for determining a dietary cohort of the subject corresponding to the subject's actual dietary intake;

(e) a nutrient database in the memory of the device for storing dietary guidelines relative to dietary cohorts of a subject;

(f) a knowledge base in the memory having rules for manipulating the information in the data base to provide a recommended future dietary program for the user, the program comprising one or more of nutrients selected from antioxidants, phytochemicals, phytosterols, vitamins and minerals in amounts that optimize dietary nutrients to provide a beneficial effect to the subject, when at least 70% of the subject's average daily calories are obtained from food listed in the program;

(g) a second application program, for execution in the computing device, for applying the rules in the knowledge base to the information in the data base and to the guidelines in the nutrient base and for generating a nutrition program for the user in a result base; and

(h) means for outputting the contents of the result base, under the direction of the application program,

wherein the nutrition program contents comprise a listing of particular foods suggested for daily consumption by the subject.

30. The system of claim 29, wherein the dietary cohort of the subject is predetermined and entered directly in the computing device.

31. The system of claim 29, wherein the dietary cohort is determined either manually or computationally.

32. The system of claim 29, wherein the predetermined dietary cohort is selected from vegetable-based, seafood based and meat based.

33. The system of claim 29, wherein the nutrient database comprises suitable ranges for average daily dietary consumption of nutrients corresponding to each dietary cohort.

34. The system of claim 29, wherein the nutrient database comprises suitable ranges for daily dietary consumption of carbohydrates, protein, vitamins, minerals and phytochemicals

35. The process according to any of claim 18, wherein a micronutrient is derived entirely or partly from natural sources.

36. Use of a formulation developed according to the process of claim 18 for preparation of a medicament for prophylaxis or therapy of a medical condition based on phytochemicals, lipids, and antioxidants comprising the subject's diet.

37. The use according to claim 36, wherein the medical condition or disease is selected from menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases.

38. The process according to claim 18, wherein the nutrient consumption program provides a recommendation for consumption of food items over at least one week.

39. The process according to claim 18, wherein the dietary cohort is determined based on average daily consumption of one or more of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners and beverages.

40. The process according to claim 18, wherein the food items listed in the nutrient consumption program are optimized to suit satiety and dietary preferences of the subject.

41. The process according to claim 18, wherein the nutrient consumption program comprises list of food items that should not be included in the subject's daily diet.

42. The process according to claim 18, wherein the nutrient consumption program comprises list of food items that should be limited in the subject's daily diet.

43. The process according to claim 18, wherein the nutrient consumption program comprises list of food items that should be added to the subject's daily diet.

44. A kit comprising modules or packages of food items in compliance with the recommendations of nutrient consumption program.

45. The kit of claim 44, comprising individual portions of food items for daily consumption.

46. The kit of claim 44, comprising individual portions of food items for supplementation of daily diet of a subject.

47. The kit of claim 44, further comprising a label comprising at least one indication of the suitability of the modules or packages for a consumer with a specific dietary profile or cohort.

48. The kit of claim 44, further comprising a label comprising at least one indication of the suitability of the modules or packages for a consumer with a specific dietary profile or cohort.

49. The kit according to claims 44, further comprising an indication of the upper limit of average daily consumption of items in the kit or module.

50. The kit according to claim 44, wherein the label is attached to the packaging of the kit or module.

51. A diet plan comprising from two to ten nutritional formulations that collectively meet the description of Table 5, 6, 7, or 8.

52. A method for providing nutritional balance in a subject, comprising, providing the diet plan of claim 51 to the individual.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and Federal Circuit Rule 32(b)(3), the undersigned hereby certifies that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(A) as modified by Federal Circuit Rule 32(b)(1).

1. Exclusive of the exempted portions provided in Federal Circuit Rule 32(b)(2), this brief contains 14,000 words.

2. This brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman Font in compliance with the typeface and type styles requirements set forth in Federal Rule of Appellate Procedure 32(a)(5)-(6). As permitted by Federal Rule of Appellate Procedure 32(g)(1), the undersigned has prepared this certificate using this word processing system's word count feature.

Date: December 17, 2023,

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2024, I electronically filed the foregoing **Corrected Opening Brief of The Appellant** with the Court's CM/ECF filing system, which constitutes service, pursuant to Fed. R. App. P. 25(c)(2) and Fed. Cir. R. 25(e)(1).

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