APPENDIX A

NOTE: This disposition is nonprecedential.

United States Court of Appeals
for the Federal Circuit

IN RE: URVASHI BHAGAT,

Appellant

2016-2525

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 12/426,034

Decided: March 16, 2018

URVASHI BHAGAT, Palo Alto, CA, pro se.

NATHAN K. KELLEY, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for appellee Andrei Iancu. Also represented by THOMAS W. KRAUSE, AMY J. NELSON.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

NEWMAN, *Circuit Judge.*

Urvashi Bhagat ("the Applicant") appeals the decision of the Patent Trial and Appeal Board ("the

Board") affirming the examiner's rejection of claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90–102, 107, 116–122, 124, and 128–145 of U.S. Patent Application No. 12/426,034 ("the '034 application").[1] We affirm the Board's decision.[2]

BACKGROUND

The '034 application is directed to lipid-containing compositions comprising omega-6 and omega-3 fatty acids. The '034 application states that dietary deficiency or imbalance of these fatty acids may lead to a variety of illnesses, and that omega-6 and omega-3 fatty acids are naturally occurring in oils, butters, nuts, and seeds. The '034 application claims a range and ratios of these fatty acids and other limitations. Application claim 65 is the broadest claim:

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

> (1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or
>
> (2) omega-6 fatty acids are not more than 40 grams.

---

[1] *In re Bhagat*, Appeal No. 2016–004154 (P.T.A.B. Apr. 15, 2016) ("Board Op.").

[2] Applicant's motions to expedite are denied as moot.

Other claims add specificity of amounts or ratios, additional ingredients, sources of the lipids, and delivery methods. The examiner held all of the claims unpatentable as directed to products of nature, and also held most claims unpatentable as anticipated.

The Board sustained the rejection of the claims, leading to this appeal.

DISCUSSION

On review of the Board's decision on an examiner's rejection, the Board's legal determinations receive de novo review, and the Board's factual findings are reviewed for support by substantial evidence in the examination record. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1363 (Fed. Cir. 2004). Claims in pending applications receive their broadest reasonable interpretation during examination, for adjustment of claim scope or clarification of meaning may be achieved by amendment during examination.

I

ANTICIPATION

A. The Mark reference

The Board affirmed the examiner's rejection of claims 52, 61, 64, 65, 67–69, 73, 75, 77, 78, 80, 83, 90, 92–96, 98, 100, 129–131, 133, 135–137, 142 and 144 on the ground of anticipation by U.S. Patent No. 5,549,905 ("Mark"). Mark describes a nutritional composition for pediatric patients, including a protein source, carbohydrate source, and lipid source containing omega-6 and omega-3 fatty acids in a

ratio of "approximately 4:1 to 6:1." Mark, col. 2, ll. 32–38; col. 4, ll. 21–23. Mark states that the omega-6 fatty acid "is present in a range of approximately 4–6% of the total calories" of the pediatric composition, and the omega-3 fatty acid "is preferably present in the range of approximately 0.8–1.2% of the total calories." *Id.* at col. 4, ll. 27–31. Mark describes a specific composition containing 38.5 grams of total lipids, id. at col. 6, l. 9, administered intravenously in a "typical feeding regimen" of "50 mL/hour for 20 hours/day," *id.* at col. 5, ll. 7–8.

The Board agreed with the examiner that Mark discloses minimum and maximum amounts of omega-6 and omega-3 fatty acids within the claimed range, and also discloses a mixture of several types of oils as fatty acid sources. The Applicant argues that Mark does not "unequivocal[ly]" disclose the claimed omega-6 to omega-3 ratio because Mark does not clearly state whether its compositions are total omega-6 and omega-3 acids, or only alpha-linolenic and linoleic acids. The Board found that Mark expressly discloses an omega-6 to omega-3 fatty acid ratio of 5:1; Mark, col. 6, l. 15; which is within the ratios in all of the '034 application claims. Board Op. at *19.

The Applicant also argues that Mark does not meet the "dosage" limitation of claim 65 because Mark discloses concentrations of nutrients, rather than a dosage of omega-6 and omega-3 fatty acids. Responding to this argument, the Board found that Mark's "typical feeding regimen" of "50 mL/hour for 20 hours," a total of 1,000 mL/day, meets the claim 65 "dosage," for Mark's daily dosage may include

1,000 mL, as the table in column 4 refers to g/1,000 mL, teaching the daily amount fed to a child. Board Op. at *18. This finding is supported in the record, as is the Board's resulting finding of anticipation of claims 65, 92–93, and 95 based on Mark's feeding regimen within the dosage stated in these claims.

The Applicant argues that even if the broadest claims are deemed anticipated by Mark, the other claims are not anticipated. The Applicant argues that Mark teaches a composition for children ages 1–10, and does not anticipate claim 137 which states "the formulation is for a human infant, or adult." The Board found this argument did not distinguish claim 137 because "Mark teaches pediatric patients which necessarily encompasses human infants and children." Board Op. at *26. We discern no error in the finding that claim 137, which includes "human infants," is anticipated by Mark's reference to children ages 1–10.

The Board received argument of the general unpredictability of components of natural products, and deemed this argument irrelevant because "the Examiner relies upon evidence of particular compositions of walnut oil or olive oil that satisfy the requirements of claim 65." Board Op. at *11. This is a correct application of the law of anticipation, for compositions containing the components and ratios in claim 65 are shown in Mark for uses that include the pediatric use described in Mark. The Applicant's claims are all directed to formulations and compositions, not to any asserted new use.

The Board also found that while "casing" and "dosage" are not expressly defined, the specification

states that any "orally accepted form" of delivery is within the scope of the claims. Board Op. at *9. The specification states that "the compositions comprising the lipid formulation disclosed herein may be administered to an individual by any orally accepted form." J.A. 65 ¶34. The Board found that the "casing" and "dosage" terms do not impart patentability to the claimed compositions, and we agree, for the specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations.

The Applicant also argues that Mark does not teach "steady delivery" as required by claim 78. Claim 78 states "the formulation provides gradual and/or steady delivery so that any omega-3 withdrawal is gradual, and/or any omega-6 and/or other fatty acid increase is gradual." The Board found that claim 78 does not recite a patentably significant difference from Mark's typical feeding regimen of 50 mL/hour for 20 hours. Board Op. at *24. The Applicant does not provide any distinction in claim 78 from Mark's typical feeding regimen, and does not overcome the Board's finding of prima facie anticipation of claim 78 by Mark.

The PTO concedes that the Board incorrectly included claim 134 in the claims found to be anticipated by Mark. However, the PTO argues that claim 134 is anticipated by the Walnut Nutrient Analysis on the same basis as for the other claims, and also is unpatentable under Section 101.

B. *The Olive and Walnut Nutrient Analyses*

The examiner rejected claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90, 92–94, 96–98, 100, 129–131, 133, 136, 137, 142, and 144 as anticipated by the nutrient profile of a serving of olives, whose fatty acid composition is shown in "Olive Nutrient Analysis," http://web.archive.org/web/20060314112106/http://www.whfoods.com/genpage.php?tname=nutrientprofile&dbid=111 (Mar. 14, 2006).

The Olive Nutrient Analysis describes a one cup serving of olives as containing omega-6 and omega-3 fatty acids in a 12:1 ratio. The Board agreed with the examiner's finding that the Olive Nutrient Analysis shows a serving size within the claimed dosage, and shows that olives contain a combination of lipids within the scope of the claims. The Olive Nutrient Analysis shows 1.14 grams of omega-6 fatty acids in a one cup serving, which is within the limitation in all the claims that "omega-6 fatty acids are not more than 40 grams."

The Board affirmed the examiner's rejection except for claim 136, which the Board reversed with respect to the Olive Nutrient Analysis. Board Op. at *38. The Board held that the examiner had not established that olives contain the claimed combination with "one or more carriers selected from starches, sugars, granulating agents, binders and disintegrating agents." Board Op. at *13–14, 32. However, the Board sustained the examiner's rejection of claim 136 with respect to the Walnut Nutrient Analysis as that reference "teaches that walnuts contain sugars including disaccharides as required." Board Op. at *37. On this appeal the PTO

does not discuss claim 136 with regard to olives, but argues that claim 136 is anticipated by the Walnut Nutrient Analysis and invalid under Section 101.

The examiner rejected claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 83, 90–101, 116–118, 120–22, 124, 128–140, and 141–145 as anticipated by the nutrient profile of a serving of walnuts as reported in the Walnut Nutrient Analysis, http://web.archive.org/web/20061109221127/http://whfoodw.com/genpage/php?tname=nutrientprofile&dbid=132 (Nov. 9, 2006). The Walnut Nutrient Analysis states that a 25 gram serving of walnuts contains omega-6 and omega-3 fatty acids in a 4.2:1 ratio. The Walnut Nutrient Analysis shows 9.52 grams of omega-6 fatty acids in a quarter-cup serving, which is within the limitation that "omega-6 fatty acids are not more than 40 grams." The Board agreed with the examiner that the reference's serving size of walnuts contains a dosage of lipids within the scope of the claims. The Board affirmed all of the claim rejections on this Walnut reference.

The Applicant states that the Board erroneously ignored a prosecution disclaimer of all compositions containing products from single sources such as olives and walnuts. The Applicant points out that all the claims are directed to formulations containing mixtures of omega-6 and omega-3 fatty acids, and that the Walnut and Olive Nutrient Analyses do not describe the specific mixtures that limit all the claims; for example, the Claim 65 requirement that "omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids." The Applicant also argues that the

total lipids in these formulations are not described in the Walnut and Olive Nutrient Analyses. The Board found that all of the rejected claims include fatty acid quantities and ratios within the "dosages" in the Nutrient Analysis references. The Board's finding that the references' serving sizes of olives and walnuts meet the "dosages" in the claims is supported by substantial evidence in the record.

The Applicant argues that a "serving" of olive oil or walnut oil, as reported in the Olive and Walnut Nutrient Analyses, is not a "dosage," but merely a way to measure nutrient density. The Board found that the Applicant's dosage is limited only in that the maximum content of omega-6 fatty acids is "not more than 40 grams," Claim 65, ante. The Board found that this is not a patentable distinction from the prior art, which shows omega-6 fatty acids in this range. We discern no error in this conclusion.

The Board also considered the Applicant's separate arguments of patentability of several of the dependent claims. The Applicant argues that the Olive Nutrient Analysis does not show the vitamin E ratio in claim 130 ("vitamin E-alpha/gamma less than 0.5% by weight of total lipids"). However, the Board found that the Olive Nutrient Analysis states that the measured serving of olives contains 4.03 mg of "vitamin E alpha equiv" and 14.35 g of total fat (lipids). Board Op. at *30. These amounts are within the scope of claim 130. The Applicant does not show error in the Board's finding that the reference shows a Vitamin E presence within the claimed range.

For claims 67 and 68 the Board found that the protein in walnuts and olives meets the "protein

source" designated in these claims. The Board found that the Walnut Nutrient Analysis includes protein and carbohydrates as recited in claim 67, and "the protein in walnuts is not derived from the prohibited sources of claim 68." Board Op. at *35–36. Claim 78 recites "steady" delivery, e.g., "[t]he formulation of claim 65, whereby the formulation provides gradual and/or steady delivery so that any omega-3 withdrawal is gradual, and/or any omega-6 and/or other fatty acid increase is gradual." Claims 73, 74, 98, 118, 122, 137 and 140 add limitations directed to intended use. Claims 96 and 97 include limitations of additional nutrients and polyphenols.

The Board found that all of the additional limitations are known aspects used in known conditions, as shown in Mark or in the Olive or Walnut Nutrient Analysis. These findings are supported by substantial evidence in the cited references. The examiner's prima facie case of anticipation by these known fatty acid compositions and uses was not rebutted by the Applicant. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (the burden of presenting an initial prima facie case of unpatentability is on the examiner, after which the burden of coming forward with rebuttal evidence shifts to the applicant; the ultimate burden of proof of unpatentability is with the examiner).

II

SECTION 101

The examiner and the Board also held that all of the claims are directed to non-statutory subject matter under Section 101, because the claimed fatty

acid mixtures occur naturally in walnut oil and olive oil. The examiner found that the claimed "intermixture of lipids from different sources" is "structurally indistinct" from lipid formulations derived from a single source, as shown in the prior art. The examiner also found that the claims are directed to natural products of walnut oil and olive oil, and that the additional limitations in the claims do not change the characteristics of the products, or add "significantly more" to the claims.

The Applicant argues that it "disclaimed" the claim scope of compositions from a single source, thus avoiding not only anticipation, but also Section 101. The Applicant states that the Board erred in rejecting all of the claims as directed to a product of nature, arguing that the claimed "intermixture of lipids from different sources" does not occur in nature, and that the properties of the claimed formulations from different lipid sources are different from the properties of single source natural products.

The Applicant also argues that the claimed limitations of "dosage" and "casings providing controlled delivery" do not exist as natural products. The Applicant states that natural products cannot provide a controlled delivery or dosage because lipid profiles in nature are unpredictable. The Applicant also states that walnut oil and olive oil are not "natural products," for they can be obtained only by treatment of natural products.

Claim 128

The Applicant also argues that claim 128 is distinguished from natural products, and is not anticipated based on the limitation that the compositions contain "nuts or their oils" obtained from "almonds, peanuts, and/or coconut meat." The Board held that admixture with other natural products of known composition was not shown or stated to change the nature of the compositions, citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) ("The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. . . . They serve the ends nature originally provided and act quite independently of any effort of the patentee.").

The Board correctly held that claim 128 does not avoid the rejection on the ground that the claims are directed to known natural products.

Claims 102, 107, and 119

The examiner and the Board did not specifically include claims 102, 107, and 119 in the rejection for anticipation, as the PTO recognizes, stating that "Bhagat advances arguments regarding olives and walnuts for claims 102, 107, and 119. Bhagat Br. 77–78. The Board did not issue a rejection for these claims based on either olives or walnuts." PTO Br. 38 n.10. However, the PTO states that these claims were properly rejected under Section 101.

Claim 102 recites specific ratios of polyunsaturated, monounsaturated, and saturated fatty acids. Claims 107 and 119 present the fatty acid content recited in claims 98 and 91, respectively, in Tables in the specification. The

Board observed that the servings of olive oil and walnut oil shown in the references contain omega-6 and omega-3 fatty acids in amounts within the Applicant's claimed ranges. Thus the Board held that the "intermixture of lipids from different sources" does not distinguish the claims from natural products because the 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, nor that a different source would necessarily impart characteristics to the formulation which were absent when a single source was used." Board Op. at *8.

The Applicant argues that the Board erred, and that the claimed mixtures of fatty acids from different sources are "structurally different" from the single-source walnut oil and olive oil. The Applicant points to the '034 specification's statements that the claimed mixtures provide benefits of "synergy" and "avoid concentrated delivery of specific phytochemicals that may be harmful in excess,"

J.A. 62 ¶30. The Board held that these arguments do not overcome the identity of the claimed products and the naturally occurring lipid profiles of walnut oil and olive oil. The Board cited the references showing the lipid content of natural walnut oil and olive oil, and pointed out that the claims include this lipid content. The Board pointed out that the specification does not distinguish the claimed omega-3 and omega-6 fatty acids, from the omega-3 and omega-6 fatty acids that exist in nature, and that the Applicant has not provided evidence of such distinction.

The Applicant argues that while naturally occurring plants or their isolated lipids may be natural products, extracts and composites or mixtures are not natural products because the extraction processes required to obtain edible oils from olives and walnuts transform the claimed lipids from natural products. The Board found, and we agree, that the Applicant has not shown that the claimed mixtures are a "transformation" of the natural products, or that the claimed mixtures have properties not possessed by these products in nature.

The Board concluded that the claims are directed to the omega-6 and omega-3 fatty acids that occur in nature, and that the asserted claim limitations do not distinguish the claimed products and compositions from those shown in the cited references. We have considered all of the Applicant's arguments, and conclude that substantial evidence supports the Board's findings, and the rulings of unpatentability.

AFFIRMED

No costs.

APPENDIX B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte URVASHI BHAGAT

Appeal 2016–004154

Application 12/426,034

Technology Center 1600

Before DAVID P. RUSCHKE,
Chief Administrative Patent Judge

DECISION ON PETITION

This is a Decision dismissing Appellant's "Petition Under 37 C.F.R. § 41.3 and § 1.181 for Review of PTAB Decision and Denial of Request for Rehearing" filed July 5, 2016 ("Petition"). Pursuant to 37 C.F.R. § 41.3(c), no fee is required for a petition seeking supervisory review.

FINDINGS OF FACT ("FFs")

1. The present application was filed on April 17, 2009.

2. Appellant filed a Notice of Appeal on September 23, 2015.

3. Appellant filed an Appeal Brief on October 27, 2015.

4. The Office issued an Examiner's Answer on February 3, 2016.

5. Appellant filed a Reply Brief on March 16,

2016.

6. The Board issued an Appeal Docketing Notice on March 23, 2016.

7. The Board issued a Decision on Appeal affirming the Examiner's rejections of the claims on April 15, 2016.

8. Appellant filed a Request for Rehearing of the Decision on Appeal on June 14, 2016.

9. The Board issued a Decision on Reconsideration denying the Request for Rehearing on June 21, 2016.

10. Appellant filed the present Petition for supervisory review under 37 CFR §§ 41.3 and 1.181 on July 5, 2016.

11. Appellant filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit ("CAFC") on August 16, 2016, seeking review of the Board's decision in the present appeal.

RELEVANT AUTHORITY

The Consolidated Patent Rules in the Code of Federal Regulations provides:

37 C.F.R. § 1.181(a)(3)

(a) Petition may be taken to the Director:

(3) To invoke the supervisory authority of the Director in appropriate circumstances. For petitions involving action of the Patent Trial and Appeal Board, see § 41.3 of this title.

37 C.F.R. § 41.3

(a) Deciding official. Petitions must be addressed to the Chief Administrative Patent Judge. A panel or an administrative patent judge may certify a question of policy to the Chief Administrative Patent Judge for decision. The Chief Administrative Patent Judge may delegate authority to decide petitions.

(b) Scope. This section covers petitions on matters pending before the Board (§§ 41.35, 41.64, 41.103, and 41.205); otherwise, see §§ 1.181 to 1.183 of this title. The following matters are not subject to petition:

(1) Issues committed by statute to a panel, and

(2) In pending contested cases, procedural issues. See § 41.121(a)(3) and § 4l.125(c).

(c) Petition fee. The fee set in § 41.20(a) must accompany any petition under this section except no fee is required for a petition under this section seeking supervisory review.

(d) Effect on proceeding. The filing of a petition does not stay the time for any other action in a Board proceeding.

(e) Time for action.

(1) Except as otherwise provided in this part or as the Board may authorize in writing, a party may:

(i) File the petition within 14 days from the date of the action from which the party is requesting relief, and

(ii) File any request for reconsideration of a

petition decision within 14 days of the decision on petition or such other time as the Board may set.

(2) A party may not file an opposition or a reply to a petition without Board authorization.

37 C.F.R. § 41.35(b)(2)

(b) End of jurisdiction. The jurisdiction of the Board ends when:

(2) The Board enters a final decision and judicial review is sought or the time for seeking judicial review has expired.

DELEGATION OF AUTHORITY

Pursuant to 37 C.F.R. §§ l.l8l(a)(3) and 41.3, a petition may be taken to the Director to invoke supervisory authority in appropriate circumstances and the Chief Administrative Patent Judge is the deciding official in petitions involving action of the Patent Trial and Appeal Board.

DISCUSSION

On April 15, 2016, the Board issued a Decision on Appeal affirming the Examiner's rejections of the claims of the application (FF 7), and the Board issued a Decision on Reconsideration denying the Request for Rehearing on June 21, 2016 (FF 9). On July 5, 2016, Appellant filed the present Petition requesting that the Chief Administrative Patent Judge review the proceedings of the present application and that the Chief Judge reverse the Board's ruling. Pet. 2, 20; FFs 7, 9, and 10. On August 16, 2016, Appellant filed a Notice of Appeal

to the CAFC seeking review of the Board's decision. FF 11.

The scope of the Board's authority includes petitions in matters pending before the Board, and the present Petition originally fell within the Board's jurisdiction. *See* 37 C.F.R. § 41.3(b). The jurisdiction of the Board ended, however, when the Board entered a final decision and judicial review was sought. *See id.* § 41.35(b)(2). Therefore, jurisdiction now lies with the CAFC, and any stay by the CAFC would not effectively return jurisdiction to the Board. As such, rendering a decision on this Petition is no longer within the scope of authority of the Board.

Had Appellant requested an extension of time to seek judicial review at the CAFC and waited for a response to Appellant's Petition, Appellant's Petition would likely have been denied given the limited scope of supervisory review and the nature of the arguments presented in Appellant's Petition. If Appellant is unsatisfied with the decisions rendered at the Board, Appellant should proceed with Appellant's Appeal filed to the CAFC as the CAFC is the proper venue to provide the relief Appellant is requesting, namely a reversal of the Board's ruling (see Petition 20).

CONCLUSION

On this record it is determined that the Board's jurisdiction has ended and rendering a decision on this Petition is no longer within the scope of authority of the Board. Therefore, the Petition is dismissed.

DECISION

For the reasons discussed above, the petition is DISMISSED.

/s/David P. Ruschke
David P. Ruschke
Chief Administrative Patent Judge

Appellant:
ASHA NUTRITION SCIENCES, INC.
P.O. BOX 1000
PALO ALTO, CA 94302

Filed: August 16, 2016

APPENDIX C

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte URVASHI BHAGAT

Appeal 2016-004154
Application 12/426,034
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and JOHN G. NEW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING[1]

Appellant requests rehearing of the decision entered April 15, 2016 ("Decision") affirming the rejection claims under 35 U.S.C. § 101 and 35 U.S.C. § 102(b).

We deny the requested relief.

ANALYSIS

An Appellant dissatisfied with the outcome of a Board decision is entitled to appeal the decision, *see* 35 U.S.C. §§ 141 and 145, but is not entitled to have the same issue decided multiple times on the same record.

We have carefully reviewed the original opinion

[1] Appellant identifies the Real Party in Interest as Asha Nutrition Sciences, Inc. (*see* App. Br. 3).

in light of Appellant's detailed request, but we find no fact or point of law which we overlooked or misapprehended in arriving at our decision. Therefore, Appellant's request is denied with respect to making any modifications to the decision affirming the Examiner's rejections.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REHEARING DENIED

Filed: June 21, 2016

APPENDIX D

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte URVASHI BHAGAT

Appeal 2016-004154
Application 12/426,034
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and JOHN G. NEW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to lipid- containing formulations. The Examiner rejected the claims as directed to a product of nature and as anticipated. We have jurisdiction under 35 U.S.C.

§ 6(b). We affirm.

Statement of the Case

Background

"Linoleic acid (LA) and Alpha-linolenic Acid (ALA) are the precursors for all omega-6 and omega-

[1] Appellant identifies the Real Party in Interest as Asha Nutrition Sciences, Inc. (*see* App. Br. 3).

3 fatty acids. It is well established that LA and ALA are 'essential' fatty acids" (Spec. ¶ 4). "Dietary deficiency or excess of the two essential fatty acids may cause many illnesses" (Spec. ¶ 4).

The Claims

Claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90–102, 107, 116–122, 124, and 128–145 are on appeal. Independent claim 65 is representative and reads as follows:

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4: 1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

(1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

The Issues

A. The Examiner rejected claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90–102, 107, 116–122, 124, and 128–145 under 35 U.S.C. § 101 as directed to non-statutory subject matter (Ans. 6–22).

B. The Examiner rejected claims 52, 61, 64, 65, 67–69, 73, 75, 77, 78, 80, 83, 90, 92–96, 98, 100, 129–131, 133–137, 142, and 144 under 35 U.S.C. § 102(b)

as anticipated by Mark[2] (Ans. 47–53).

C. The Examiner rejected claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90, 92–94, 96–98, 100, 129–131, 133, 136, 137, 142, and 144 under 35 U.S.C. § 102(b) as anticipated by Olives[3] as evidenced by "Olives Nutrient Analysis"[4] (Ans. 65–72).

D. The Examiner rejected claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 83, 90–101, 116–118, 120–122, 124, 128–140, and 141–145 under 35 U.S.C. § 102(b) as anticipated by Walnuts[5] as evidenced by "Walnut Nutrient Analysis"[6] (Ans. 73–83).

A. 35 U.S.C. § 101

The Examiner finds that

> a one ounce serving of walnut oil (28 grams, i.e. a 'dosage') is a lipid-containing formulation that contains 28 gm of fatty acids (lipids) and ~ 50 mg of "other" lipids . . . . The ratio of omega-6 to omega-3 fatty acids is 5.09: 1 (i.e.

---

[2] Mark et al., US 5,549,905, issued Aug. 27, 1996 ("Mark").
[3] Olives, web.archive.org/web/20060314112112/http://www.whfoods.com/genpage.php?pfriendly=1&tname=foodspice&dbid=46 (Mar. 14, 2006). We refer to pages by number in sequential order.
[4] Olives Nutrient Analysis, web.archive.org/web/20060314112106/http://www.whfoods.com/genpage.php?tname=nutrientprofile&dbid=111 (Mar. 14, 2006).
[5] Walnuts, http://www.whfoods.com/genpage.php?tname=foodspice&dbid=99 (Nov. 9, 2006).
[6] Walnut Nutrient Analysis, http://web.archive.org/web/20061109221127/http://www.whfoods.com/genpage.php?tname=nutrientprofile&dbid=132 (Nov. 9, 2006).

> 4:1 or greater). Walnut oil contains 14.81 grams (52.8% by weight; i.e. between 4 and 75% by weight of total lipids, or, greater than 20% by weight of total lipids) of omega-6 fatty acids. Walnut oil contains 2.91 grams (10% by weight of total lipids) of omega-3 fatty acids.

(Ans. 12). The Examiner finds that "walnut oil is a judicial exception (i.e. a product of nature)" (Ans. 18) and that "the claimed composition does not have markedly different characteristics from what occurs in nature" (Ans. 16).

Appellant contends that

> The claims include several elements that add significantly more than what occurs in nature, such as "intermixtures of lipids from different sources", "a dosage of omega-6 /omega-3 fatty acids", "a ratio of omega-6 to omega-3 fatty acids of 4: 1 or greater" or "omega-6 fatty acids greater than 20% by weight of total lipids", "contained in one or more complementing casings providing controlled delivery of the formulation to a subject," with defined "dosages" and defined concentrations.

(App. Br. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the claims are drawn to products of nature, a class of non-statutory subject matter?

Findings of Fact

1. The Specification teaches that "the lipid formulation disclosed herein may be administered to an individual in any orally accepted form" (Spec. ¶

34).

2. The Specification teaches that the "fatty acid components of the composition's lipid contents are achieved at least in part by using one or more of the following concentrated lipid sources: oils, butters, nuts, and seeds" (Spec. ¶ 9).

3. The Specification teaches that "synergy among complementing nutrients from different sources may be incorporated. Furthermore, using different sources avoids concentrated delivery of specific phytochemicals that may be harmful in excess" (Spec. ¶ 30).

4. The Erickson Declaration 3/31/15[7] states "'[d]ifferent sources' refers to different oils, butters, nuts, seeds, herbs, sweeteners, and/or other foods and/or their different varieties (containing different lipid profiles)" (Erickson Decl. 3/31/15 ¶ 6; *cf.* Rucker Decl. 4/30/15[8] ¶ 6); and Das Decl. 4/30/15[9] ¶ 6).

5. The Erickson Declaration 3/31/15 states that "each walnut (or olive) would not be considered to be a different source of lipids from one another by skilled artisans, unless one specific variety of walnut (or olive) is added to another, different, specific variety of walnuts (or olives) to enhance usefulness of the walnut (or olive) formulation" (Erickson Decl. 3/31/15 ¶ 7; *cf.* Rucker Decl. 4/30/15 ¶ 9; and Das Decl. 4/30/15 ¶ 9).

---

[7] Declaration of Dr. Kent L. Erickson, dated May 31, 2015.
[8] Declaration of Dr. Robert B. Rucker, dated Apr. 30, 2015.
[9] Declaration of Dr. Undurti N. Das, dated Apr. 30, 2015.

6. The Erickson Declaration 1/31/14[10] states that "[l]ipid content, including omega-6 and omega-3, of products of nature is extremely variable. This variability depends on the source, background genetics, cultivating conditions, including soils, fertilizer used, and other variable factors, such as hours of sunlight and water composition" (Erickson Decl. 1/31/14 ¶ 3).

7. Walnut Oil Nutrition Facts[11] teaches that walnut oil contains 14810 mg omega-6 fatty acids and 2912 mg omega-3 fatty acids resulting in a ratio of approximately 5: 1 omega 6 to omega 3 fatty acids with less than 40 grams of omega-6 fatty acids (Walnut Oil Nutrition Facts 2).

8. Olive Oil Nutrition Facts[12] teaches that olive oil contains 2734 mg omega-6 fatty acids and 213 mg omega-3 fatty acids resulting in a ration of ~ 12.8:1 omega 6 to omega 3 fatty acids with less than 40 grams of omega-6 fatty acids (Olive Oil Nutrition Facts 2).

Principles of Law

In *Funk Bros.*, "bacteria produced by the laboratory methods of culture are placed in a powder or liquid base and packaged for sale to and use by agriculturists in the inoculation of the seeds of leguminous plants." *Funk Bros. Seed Co. v. Kalo*

---

[10] Declaration of Dr. Kent L. Erickson, dated Jan. 31, 2014.
[11] Oil, vegetable, walnut, http://nutritiondata.self.com/facts/fats-and-oils/589/2 (accessed Feb. 11, 2015).
[12] Oil, olive, salad or cooking, http://nutritiondata.self.com/facts/fats-and-oils/509/2 (accessed Feb. 11, 2015).

Inoculant Co., 333 U.S. 127, 129 (1948). "The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id.* at 130.

"[E]xtensive effort alone is insufficient to satisfy the demands of § 101. Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2118 (2013). "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id.*

Analysis

i. Claim Interpretation

We begin with claim interpretation of the disputed claim phrase "intermixture of lipids from different sources " in claim 65 regarding the meaning of "different sources" and whether "intermixture of lipids" represents a product-by-process limitation.

"intermixture of lipids"

Claim 65 is drawn to a "lipid-containing formulation," not a process for making the composition. The weight of authority holds that the patentability of product-by-process claims is not dependent on process limitations. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("even though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself"; "[t]he patentability of a product does not depend on its method of production"; and "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.")

We agree with the Examiner that "any prior art lipid-containing formulation from a single source that occurs in nature but appears to be structurally the same, i.e. contains the same lipid components ... is considered to read on these claims" (Ans. 4; emphasis omitted). Appellant does not identify any necessary structural differences in the final "lipid-containing formulation" that results based upon the use of an "intermixture of lipids from different sources." For example, Appellant does not explain or provide evidence that a container of olive oil pressed from a single tree of Kalamata olives necessarily differs in lipid content from a container of blended olive oil pressed from an intermixture of different varieties of olives such as Kalamata, Nicoise, Picholine, and Manzanilla olives (*see* Olives 3).

We recognize, but find unpersuasive, Appellant's reliance upon the Erickson Declaration 3/31/15 teaching that "when lipids from different sources are intermixed, the resulting mixture will necessarily have different physical and chemical properties from a 'single' source" (Erickson Decl. 3/31/15 ¶ 8; *cf.* App. Br. 16–17). It is the composition which is being claimed. Appellant 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, nor that a different source would necessarily impart characteristics to the formulation which were absent when a single source was used.

If the term "different sources" is read so narrowly as to require any differences, distinguish single component or "intermixture" sources, then the Examiner's broad interpretation discussed above demonstrates natural products with "different sources." Alternatively, if the "intermixture" refers to the final product, which may be obtained in different ways by adding different amounts of components to obtain the desired composition, then the Examiner's product-by-process reasoning applies.

"casing" and "dosage"

The Specification does not provide a definition of the term "casing," expressly stating that any "orally accepted form" falls within the scope of the invention (FF 1). Additionally, claim 65 does not require any particular dosage of the formulation, so long as there are not more than 40 grams of omega-6 fatty acids.

Considering claim 65 as a whole, we agree with the Examiner that whether the lipid-containing formulation with a "dosage" of omega-6 and omega-3 fatty acids in a "casing" and derived from an "intermixture of lipids from different sources" is interpreted as a product-by-process claim (see Ans. 4).

ii. Product of Nature

We are constrained by the Supreme Court

decisions in *Funk Bros.* and *Myriad* to agree with the Examiner that walnut oil is a "product of nature" falling within the judicial exception to patentable subject matter.

In *Funk Bros.*, "products of nature" included bacteria that were "produced by the laboratory methods of culture" and "placed in a powder or liquid base and packaged for sale to and use by agriculturists in the inoculation of the seeds of leguminous plants." *Funk Bros. Seed Co.*, 333 U.S. at 129. Thus, the Supreme Court did not find routine production and extraction steps resulted in a product that was "markedly different" from the product of nature.

In *Myriad*, "products of nature" included isolated DNA that was extracted from cells and required "sever[ing] chemical bonds and thereby creat[ing] a nonnaturally occurring molecule." *Myriad*, 133 S. Ct. at 2118. Again, the Supreme Court did not find that routine production and extract steps resulted in a product, finding that the "processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents." *Id.* at 2119.

Appellant contends that walnut "oil extraction is a complex multi-step process during which physical and chemical properties of the plant seeds, such as walnuts and olives, transform dramatically producing oils and byproducts" (App. Br. 9). Appellant contends that "[t]hus, extracted oils, including Walnut Oil and Olive Oil are man-made products not products of nature and they have markedly different characteristics than products of nature, such as some walnuts/olives" (App. Br. 11).

We are not persuaded. The Examiner notes that "there are no limitations in the claims requiring any alleged sources of lipids to be prepared by the oil extraction processes described" (Ans. 23) and the ordinary artisan would recognize that some oils, like extra virgin olive oil, are "the initial unrefined oil from the first pressing" (Olives 3).

We recognize, but find unpersuasive, Appellant's contention that "isolated individual omega-6, omega-3, other fatty acids, or other lipids, or naturally occurring plant/animal parts are judicial exceptions, but composites of such matters are not judicial exceptions" (App. Br. 12). Consistent with Supreme Court precedent, some processing such as the walnut oil refining, may not result in a "markedly different" product as evidenced by the laboratory culture, powder, and packaging of bacteria in *Funk Bros.* or the chemical isolation and cleavage of DNA in *Myriad*. We see no principled reasoning that supports finding walnut or olive oil "markedly different" while finding the packaged and powdered bacteria of *Funk Bros.* or the isolated DNA of *Myriad* not "markedly different."

We recognize, but find unpersuasive, Appellant's contention that "even within the same species lipid content, including omega-6 and omega-3, of natural plant seeds and their oils cannot be predicted" (App. Br. 20). In this case, the Examiner relies upon evidence of particular compositions of walnut oil or olive oil that satisfy the requirements of claim 65 (FF 7-8). That other natural compositions may not fall within the scope of the claim is irrelevant because the exception is to any product of nature, not all products of nature.

We recognize, but find unpersuasive, Appellant's contention that the "products of instant claims serve the function of solving a long-felt critical unmet need" (App. Br. 21; *cf.* App. Br. 32-33). Long-felt need and secondary considerations are doctrines related to obviousness that do not apply to either utility or anticipation. *See Cohesive Techs., Inc. v. Waters Corp.* 543 F.3d 1351, 1364 (Fed. Cir. 2008) ("[O]bviousness requires analysis of secondary considerations of nonobviousness, while secondary considerations are not an element of a claim of anticipation.")

We recognize, but find unpersuasive, Appellant's contention that the "Examiner has rebuffed overwhelming evidence and testimony of skilled persons regarding the presence of not well-understood, non-routine, and non-conventional features in the claimed formulations, which confers patent eligibility based on case law" (App. Br. 22; emphasis omitted). Rather, the Examiner, constrained by *Funk Bros.* and *Myriad*, carefully considered the Declarations of Dr. Erickson, Rucker, and Das (*see* Ans. 26, 30, 31, 38) but found the evidence supported the§ 101 "product of nature" rejection. We have also carefully reviewed these expert Declarations, and find them unpersuasive for the reasons given above.

We recognize, but find unpersuasive, Appellant's contention that the prior art "specifically teaches against high omega-6 to omega-3 ratios, and places emphasis on low ratios of the fatty acids not amounts/dosages" (App. Br. 23; emphasis omitted). Just as "[t]eaching away is irrelevant to anticipation." *Seachange Int'l, Inc., v. C-COR, Inc.*,

413 F.3d 1361, 1380 (Fed. Cir. 2005), teaching away is also irrelevant to the issue of patentable subject matter. Either the claims read on products of nature or they do not.

We recognize, but find unpersuasive, Appellant's contention that "the prior art neither understood the importance of omega-6, nor its relationship with other lipids; and the prior art routinely recommended use of other lipids that suppress omega-6 activity" (App. Br. 28). This argument is irrelevant to the issue of statutory subject matter and utility, because significant or not, the issue is whether the claimed formulation reads on a "product of nature" not whether that formulation has unexpected properties.

Appellant separately argue the limitations of dependent claims 67 and 68 (App. Br. 35), but do not rebut the Examiner's finding that "there is no evidence in the specification that combining walnut oil with any source of naturally occurring proteins and carbohydrates, in any amounts, results in a marked change in function" (Ans. 19). The Examiner's reasoning is consistent with *Funk Bros.*, where the combination of natural occurring bacteria did not overcome the lack of statutory subject matter. See *Funk Bros.*, 333 U.S. at 131 ("The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.")

Appellant argues that claim 77 differs as "one-part or [comprises] multi-part" components (App. Br.

35). We are not persuaded because the walnut or olive oils teach one ounce serving sizes that are reasonably interpreted as one-part dosages (*see* Walnut Oil 1).

Appellant contends that claims 78 and 124 "cannot be said to provide steady delivery of the claimed formulation" (App. Br. 35). Appellant provides no evidence that the natural compositions fail to satisfy this claim limitation. *See In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (Arguments and conclusions unsupported by factual evidence carry no evidentiary weight.)

Appellant points to limitations in claims 102, 107, and 119, but does not identify any evidence that these limitations distinguish from the disclosed walnut or olive oils.

Appellant contends, regarding claim 128, that "at least some varieties of almonds, peanuts, and coconuts, and their oils, have no omega-3 content at all, and that their omega-6 concentration is at most 32%" (App. Br. 36). We find this argument unpersuasive because the claim 128 is drawn to a formulation that may include olive oil and walnut oil expressly, and Appellant has provided no evidence of necessary structural difference based on the product-by-process language. *In re Thorpe*, 777 F.2d at 697.

Appellant contends regarding claims 136 and 139 that regarding starches and sugars, "[t]here is no evidence that any product of nature meets this requirement" (App. Br. 36). We agree with the Examiner that "[t]here is no evidence of record that including, for example, ANY naturally occurring sugar or starch, in ANY amount, with the lipid-

containing formulations of Claims 65 and 91 would result in a marked change in the characteristics of walnut oil (or olive oil)" (Ans. 45). The Examiner's reasoning remains consistent with *Funk Bros.*, where the combination of natural occurring bacteria did not overcome the lack of statutory subject matter. *See Funk Bros.*, 333 U.S. at 131.

We remain unpersuaded by Appellant's reiteration of their argument on the scope of "intermixed" for claims 142 and 144 for the reasons already given above (see App. Br. 36).

Conclusion of Law

The evidence of record supports the Examiner's conclusion that the claims are drawn to products of nature, a class of non-statutory subject matter.

B. 35 U.S.C. § 102(b) over Mark

The Examiner finds that:

> Mark teaches the detailed lipid profile of the 38.5 g lipid component in the one liter (1000 ml) oral pediatric composition (column 4, lines 40 – 60) as containing 12.2% omega-6 fatty acids and 2.4% omega-3 fatty acids based on total lipids, thus meeting limitation (1) recited in instant Claims 65 and limitation (i) and (ii) of instant Claim 83. Further, it is noted that the amount by weight of omega-6 fatty acids is 4.70g (12.2% of 38.5 g) and the amount by weight omega-3 fatty acids is 0.924 g (38.5 g x 2.4%) which meets limitation (2) recited in instant Claim 65.

(Ans. 48).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Mark anticipates the claims?

Findings of Fact

9. Mark teaches "a nutritional composition designed for pediatric patients" (Mark, col. 1, 11. 65–66).

10. Mark teaches "a lipid source comprising a mixture of medium and long chain triglycerides. The lipid source includes an omega-3 to omega-6 fatty acid ratio of approximately 4:1 to 6:1" (Mark, col. 2, 11. 35–38).

11. Mark teaches that a "lipid profile containing such long chain triglycerides is designed to have a polyunsaturated fatty acid omega-6 (n-6) to omega-3 (n-3) ratio of approximately 4:1 to 6:1" (Mark, col. 4, 11. 21–23).

12. Mark teaches that in "an embodiment, the n-6 to n-3 fatty acid ratio is approximately 5: 1. Both the omega-6 and omega-3 fatty acids are provided in sufficient quantity to meet tissue growth maintenance needs" (Mark, col. 4, 11. 23–27).

13. Mark teaches that "the source of omega-6 fatty acids is present in a range of approximately 4–6% of the total calories. The omega-3 fatty acid source is preferably present in the range of approximately 0.8–1.2% of the total calories" (Mark, col. 4, 11. 27–31).

14. Mark teaches "an example of a fatty acid lipid profile that may be used in the composition of the

present invention will now be given.

LIPID PROFILE (38.5 g/L)			
LIPID	% of Total Fatty Acids	g/1000 ml	% OF KCAL
C6:0	0.8	0.3	
C8:0	29.1	11.2	
C10:0	20.6	7.9	
C12:0	1.2	0.5	
C14:0	0.6	0.2	
C16:0	3.8	1.5	
C18:0	1.7	0.7	
TOTAL SAT	57.8	22.3	21.6%
C16:1	0.1	0.0	
C18:1	13.4	5.2	
TOTAL MONO	13.5	5.2	5.6%
C18:2 n6	12.2	4.7	4.9%
C18:3 n3	2.4	0.9	0.9%
TOTAL POLY	14.6	5.6	5.8%
TOTAL	86.0	33.1	33.0%

(Mark, col. 4, ll. 35–60).

15. Mark teaches "typical feeding regimens (e.g. 50mL/hour for 20 hours/day)" (Mark, col. 5, 11. 8–9).

16. Mark teaches a composition that "has the following nutrient composition (per 1000 calories)

NUTRIENT COMPOSITION	AMOUNT/l
CAL. DENSITY	1.0 (kcal/ml)
PROTEIN	30.0(12%) g(%)
WHEY	100%
CARBOHYDRATE	137.5(55%) g(%)
LIPID	38.5(33%) g(%)
SAFFLOWER OIL	—
CANOLA OIL	13%
SOY OIL	16%
COCONUT OIL MCT	60%
RESIDUAL MILK FAT	6%
SOY LECITHIN	5%
N6:N3 RATIO	5:1
WATER	850 ml
VITAMIN A (RETINOL)	2400 IU
BETA-CAROTENE	1.0 mg
VITAMIN D	560 IU
VITAMIN E	28 IU
VITAMIN K	30 mcg
VITAMIN C	100 mg
THIAMINE B_1	2.4 mg
RIBOFLAVIN B_2	2.0 mg
NIACIN	20 mg
VITAMIN B_6	2.4 mg
FOLIC ACID	400 mcg
PANTOTH. ACID	10 mg
VITAMIN B_{12}	6 mcg
BIOTIN	300 mcg
CHOLINE	300 mg
TAURINE	80 mg
L-CARNITINE	40 mg
INOSITOL	80 mg
CALCIUM	1000 mg
PHOSPHORUS	800 mg
Ca:P	1.25:1 weight
MAGNESIUM	200 mg
ZINC	15 mg
IRON	14 mg
COPPER	1.0 mg
MANGANESE	1.5 mg
IODINE	120 mcg
SODIUM	460 mg
POTASSIUM	1320 mg
CHLORIDE	1080 mg
Na:K	0.59:1 molar
(Na + K)/Cl	1.71 molar
CHROMIUM	30 mcg
MOLYBDENUM	30 mcg
SELENIUM	30 mcg

"

(Mark, col. 4, ll. 35–60).

Principles of Law

"A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of Mark (Ans. 47–53; FF 9–16) and agree that the claims are anticipated by Mark. We address Appellant's arguments below.

Dosage

Appellant contends that "[t]here is no 'dosage of omega-6 and omega-3 fatty acids' disclosed anywhere by Mark et al. The table in column 4 of Mark et al. discloses concentration of C 18:2 n6, i.e. linoleic acid (not total omega-6), and C18:3 n3, i.e. linolenic acid (not total omega-3) in 86% (not 100%) of the fatty acids (see line 60)" (App. Br. 40).

We are not persuaded. Mark teaches "typical feeding regimens (e.g. 50mL/hour for 20 hours/day)" (FF 15), thereby teaching a typical daily dose of 1,000 ml (50 ml/hour x 20 hours/day). The claims do not require the dosage to be ingested at one time. The table in column 4 of Mark refers to amounts in g/1000 ml, thereby teaching daily amounts typically fed to a child in need of the supplement (FF 14–15). This reasoning is consistent with the Erickson

Declaration 3/31/15, which states that "feeding regimen of Mark et al. compositions may be few milliliters for a 1-year old child and few liters for a 10-year old child" (Erickson Decl. 3/31/15 ¶ 15). That is, even the Erickson Declaration 3/31/15 concedes that the ordinary artisan would recognize Mark's dosages may include 1,000 ml (1 liter).

4:1 ratio of Omega-6 to Omega-3

Appellant contends that "the table [in column 4 of Mark] does not expressly state that it discloses the composition of triglycerides, only. It can be concluded that the data in the table in column 4 of Mark et al. is corrupted and not operable due to many errors, such as erroneous use of the term 'TOTAL' in lines 50, 54, and 59, and the missing fatty acids in line 60" (App. Br. 42). Appellant cites the Erickson Declaration 1/31/14 for variability in lipid content (*see* App. Br. 42, Erickson Decl. 1/31/14 ¶ 3). Appellant contends that "[i]t is impossible to guess the composition of the missing 14% of fatty acids in the table in column 4" (App. Br. 43). The Erickson 3/31/15, Rucker 4/30/15, and Das 4/30/15 Declarations each state that "[i]t is not possible to ascertain omega-6 to omega-3 ratio from the table in column 4 because *only* 86% of the fatty acids are disclosed, 14% of the fatty acids are missing" (Erickson Decl. 3/31/15 ¶ 10; *cf.* Rucker Decl. 4/30/15 ¶ 10; Das Decl. ¶ 10).

We are not persuaded for two reasons. First, the Examiner points to the example at column 6, which expressly states that there is a 5: 1 ratio of N6:N3, satisfying the ratio requirement of claim 65 (FF 16).

Second, even the table in column 4 of Mark is a

specific example of a fatty acid profile with 12.2% omega-6 fatty acids or 4.7 g/1000 ml and 2.4 % omega-3 fatty acids or 0.9 g/1000 ml resulting in a ratio exceeding 4:1 (FF 14). While only 86% of the total fatty acids are shown in table 4 (FF 14), Mark teaches the maximal amounts of total calories for omega-6 and omega-3 fatty acids (FF 13). In particular, Mark teaches a maximal calorie amount of 6% for omega-6 and 1.2% for omega-3 (FF 13). The table in column 4 of Mark discloses omega-6 fatty acids are 4.9% of total calories and omega-3 fatty acids are 0.9% of total calories.

Thus, Mark sets an upper limit on the amount of omega-3 fatty acids that can be present in the undisclosed 14% of fatty acids as 0.3% of total calories because the maximal amount permitted is 1.2% (FF 13–14). This fact and teaching of Mark was not addressed by any of the expert Declarations. Therefore, even if omega-3 fatty acids reach the maximal 1.2% of total calories permitted, the ratio of 4.9% omega-6 fatty acids to 1.2% omega-3 fatty acids exceeds 4:1, the ratio required by claim 65. Moreover, even if the omega-6 fatty acids reach the maximal 6% of total calories permitted (FF 13), the total grams of omega-6 fatty acids in a 1,000 91mL dose would not exceed 40 grams as required by claim 65 (FF 14).

Therefore, when the teachings of Mark are considered in their entirety, we agree with the Examiner that the preponderance of the evidence supports the Examiner's finding that Mark anticipates the claimed 4:1 ratio of omega-6 to omega-3 fatty acids (FF 13, 14, 16).

Intermixture from different sources

Appellant contends that Mark does not teach a "disclosure of 'an intermixture of lipids [fatty acids] from different sources' in light of the lexicography of Appellant's specification" (App. Br. 44).

We do not find this argument persuasive because "different sources" is a product-by-process limitation. As discussed above, the patentability of a product-by-process claim is not dependent on process limitations. *See In re Thorpe*, 777 F .2d at 697. Here, the sources represent process limitations that have not been shown to necessarily impose any structural limitations on the claimed composition. Indeed, even if this limitation were given structural weight, column 6 of Mark teaches a formulation comprising a mixture of oils including canola, soy, and coconut oils that all have both omega-6 and omega-3 fatty acids (FF 16; *cf.* Rucker Decl. 4/30/15 ¶ 10) with a omega-6 to omega-3 fatty acid ratio of 5:1 (FF 16).

Omega-6 and Omega-3 amounts

Appellant contends that "[c]oncentration of total omega-6 and omega-3 fatty acids cannot be calculated because 14 % of the fatty acids are missing. Thus, Mark et al. do not disclose omega-6 and omega-3 concentrations" (App. Br. 45).

We are not persuaded. As already discussed, the minimal and maximal amounts of omega-6 and omega-3 fatty acids were disclosed by Mark (FF 13) resulting in weight values of fatty acids that necessarily fall within the 4–75% range for omega-6 and 0.1-30% range for omega-3 fatty acids, because the undisclosed 14% of fatty acids in Mark cannot

cause the omega-6 or omega-3 fatty acid amounts to increase above the 75% or 30% maximums. Indeed, even if the entire 14% was omega-6 fatty acid, the total omega-6 fatty acid amount would be 26.2% (12.2% shown in table 4 plus 14% undisclosed) and if the entire 14% was omega-3 fatty acid, the total omega-3 fatty acid amount would be 16.4% (2.4% shown in table 4 plus 14% undisclosed). However, Mark's teaching that omega-6 cannot exceed 6% of KCAL and omega-3 cannot exceed 1.2% of KCAL (FF 13) further constrains these amounts to necessarily fall within the claimed range.

Mark Operability

Appellant cites the Erickson Declaration, which states that "Mark et al is not a credible reference. The reference uses terms such as 'Total' and 'lipids' negligently . . . . A practitioner using Mark et al. will not know what omega-6 to omega-3 ratios to use in total lipids and how much omega-6 and omega-3 to put into Mark et al formulations" (Erickson Decl. 3/31/15 ¶ 16; *cf.* Rucker Decl. 4/30/15 ¶ 10 and Das Decl. 4/30/15 ¶ 10).

We have considered the Erickson, Rucker, and Das Declarations, but do not find them persuasive of inoperability of the Mark reference. Mark specifically teaches a 5:1 omega-6 to omega-3 ratio in column 6 and provides a specific composition including amounts of a large number of formulation components (FF 16). The concerns the Declarants raise regarding lipid amounts do not apply to the composition of column 6 which teaches specific amounts of canola, soy and coconut oils as well as milk fat and soy lecithin to add to the composition

(FF 16). "Enablement of prior art requires that the reference teach a skilled artisan to make or carry out what it discloses in relation to the claimed invention." *In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012). Here, Mark teaches the skilled artisan the specific amounts of each component required by the formulation (FF 16).

Appellant and Declarants have not provided evidence that undue experimentation would have been required to follow the instructions of Mark and formulate the composition of column 6 using the specifically disclosed oils along with sources for carbohydrates, protein, vitamins, minerals, and any other listed components.

Claim 130

Appellant contends that "the descriptive 'vitamin E-alpha/ gamma less than 0.5% by weight of total lipids' is missing from Mark" (App. Br. 47).

The Examiner finds that "the 18 mg of generic 'vitamin E' in the Nutrient Composition of Mark existed is present at ~ 0.047 % by weight of total lipids, which meets the limitation (less than 0.5% by weight) [of] Claim 130" (Ans. 60).

The Examiner's position is supported by the weight of the evidence. In the table at column 6, Mark teaches 28 IU of vitamin E (FF 16). 28 IU of vitamin E is an amount that converts to some value less than 28 mg, depending upon the specific form of vitamin E. With a total lipid amount of 38.5 g, the amount by weight of vitamin E is less than 28 mg/38,500 mg or 0.07 %, a value less than the required 0.5% of total lipids.

Dependent Claims

We recognize, but find unpersuasive, Appellant's arguments regarding claim 68 (App. Br. 48) because Mark teaches 33% lipid, which reasonably supports the Examiner's position in the absence of evidence to the contrary (FF 16). Claim 68 requires less than 25% calories from either milk or cheese, so if whey is different than milk and cheese as argued by Appellant, then the amount of whey is irrelevant because it is not specifically excluded by claim 68.

We recognize, but find unpersuasive, Appellant's arguments regarding claim 69 (App. Br. 48) because claim 69 only requires that "one or more of the following apply," not that all of the following conditions apply. Thus, while Appellant is correct that the zinc level in Mark exceeds that permitted by claim 69(vi), the vitamin C level in Mark is 100 mg (FF 16), less than the 400 mg required by claim 69(vi) and thereby satisfying the claim requirement for "one or more of the following" (*see* Ans. 62).

We recognize, but find unpersuasive, Appellant's argument regarding claim 73 (App. Br. 49) because the claim imposes no specific structural requirement on the formulation, and the "when the formulation is provided" limitation represents an intended use. However, a "mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." *In re Zierden*, 411 F.2d 1325, 1328 (CCPA 1969).

We recognize, but find unpersuasive, Appellant's argument regarding claim 77 (App. Br. 49) because the composition of Mark may be administered in one-part as a feeding formula for any desired period

of time (FF 9, 15).

We recognize, but find unpersuasive, Appellant's argument regarding claim 78 (App. Br. 49) because Appellant provides no evidence demonstrating that the delivery of omega-3 or omega-6 fatty acids is not gradual or steady. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.").

We recognize, but find unpersuasive, Appellant's argument regarding claim 83 (App. Br. 49) because only one of the four recited conditions need apply and Mark teaches elements (i) and (ii) of claim 83 (FF 16).

We recognize, but find unpersuasive, Appellant's argument regarding claims 92, 93, and 95 (App. Br. 49) because Mark teaches 4.7 g of omega-6 fatty acids that represents 4.9% total calories and maximally 6% of total calories and therefore less than 6 g total (FF 13-14). These values fall within those required by claims 92 and 93, and the 0.9 g amount of omega-3 fatty acids falls within the range required by claim 95, even if the KCAL value is increased to the 1.2% maximum suggested by Mark (FF 13-14).

We recognize, but find unpersuasive, Appellant's argument regarding claim 96 (App. Br. 50) because Mark teaches the presence of additional nutrients (FF 16) and Appellant provides no evidence that the formulation in column 6 of Mark does not inherently

satisfy the requirement of claim 96. *Best*, 562 F.2d at 1255.

We recognize, but find unpersuasive, Appellant's argument regarding claim 98 (App. Br. 50) because it represents intended uses of the formulation. *Zierden*, 411 F.2d at 1328. No specific structural limitations are imposed by claim 98.

We recognize, but find unpersuasive, Appellant's argument regarding claim 100 (App. Br. 50) for two reasons. We agree with the Examiner that "Mark teaches TOTAL fatty acids, explicitly teaches TOTAL mono and polyunsaturated fatty acids and thus allows for calculation of the ratio that meets the claim limitation" (Ans. 63). In addition, we note that whether the entire 14% was added to total fatty acids or to mono unsaturated fatty acids, the resultant values would fall within the range of 1:1 to 15:1, the ratio required by claim 100.

We recognize, but find unpersuasive, Appellant's argument regarding claim 136 (App. Br. 50) because the "intended function of sucrose as recited in the claim is not accorded patentable weight" (Ans. 63). *Zierden*, 411 F.2d at 1328.

We recognize, but find unpersuasive, Appellant's argument regarding claim 137 (App. Br. 50) because Mark teaches pediatric patients (FF 9) which necessarily encompasses human infants and children.

We recognize, but find unpersuasive, Appellant's argument regarding claims 142 and 144 (App. Br. 50–51) because Mark clearly teaches lipids from canola, soy, and coconut oils, which clearly represent

different sources (FF 16).

Appellant also lists claims 61, 68, 69, 74, 82, 94, 97, 102, 107, 142, and 144 but provides no specific arguments. "A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." 37 C.F.R. § 41.37(c)(1)(iv). Here, Appellant does not even identify the claim recitations and provides no specific argument that Mark does not anticipate these claims.

Conclusion of Law

The preponderance of the evidence in the record supports the Examiner's conclusion that Mark anticipates the claims.

C. 35 U.S.C. § 102(b) over Olives and "Olives Nutrient Analysis"

The Examiner finds that the "lipid-formulation of 'Olives' is clearly edible and .... The intended use of the olive/brine formulation is to be eaten" (Ans. 66). The Examiner finds that "Olive Nutrient Analysis" ("ONA") teaches that:

> 1.00 cup serving of black olives contains: 1) 1.14 g omega-6 fatty acids (7.94% by weight of total lipids) and 0.09 g omega-3 fatty acids (0.63% by weight of total lipids); instant Claims 65, 83, 92, 93, 118 and 129), 2) olive oil (instant Claim 61; embodiment (iii)), 3) linoleic acid (18:2) (instant Claim 52), 4) carbohydrates and protein (instant Claim 67), 5) a source of fiber (instant Claim 69), 6) a ratio of total fatty acids:monounsaturated fatty acids= 1.35:1 (14.35/10.60) (instant Claim 100), 7) 154.56

> calories, of which 129.19 of the calories (83.5%) are from fat, (as such, the diet (1.00 cup of olives) supplies 83.5% of the diet's fat calories; instant Claim 74), 8) 14.35 g of fatty acids (expressed as "Total Fat"; instant Claim 94), and, 9) 2.9% calories from 1.13 g protein (i.e. "less than 75% are from legumes and "less than 15% ... from other sources"; instant Claim 68).

(Ans. 68–69).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that "Olives" as evidenced by "Olive Nutrient Analysis" anticipates the claims?

Findings of Fact

17. "Olives" teaches "[S]ome of the many available delicious varieties of olives include Moroccan oil-cured, Kalamata, Nicoise, Picholine and Manzanilla" ("Olives" 2-3).

18. "Olives Nutrient Analysis" teaches "Olives, black, canned" with a serving size of "1.00 cup (134.40 g)" that contains

Olives, black, canned (Note: "--" indicates data unavailable)		
1.00 cup (134.40 g)	GI: very low	
BASIC MACRONUTRIENTS AND CALORIES		
nutrient	amount	DRI/DV (%)
Protein	1.13 g	2.26
Carbohydrates	8.41 g	3.74
Fat - total	14.35 g	--
Dietary Fiber	4.30 g	17.20
Calories	154.56	8.59

INDIVIDUAL FATTY ACIDS		
nutrient	amount	DRI/DV (%)
Omega-3 Fatty Acids	0.09 g	3.75
Omega-6 Fatty Acids	1.14 g	

resulting in~ 12: 1 ratio of omega-6 to omega-3 ("Olives Nutrient Analysis" 1, 5).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of "Olives" and "Olive Nutrient Analysis" (Ans. 65–72; FF 17–18) and agree that the claims are anticipated. We address Appellant's arguments below.

Appellant contends that "[t]here is no suggestion in Olives or ONA regarding an intermixture of lipids [fatty acids] from different varieties or sources" (App. Br. 53).

We do not find this argument persuasive for the reasons extensively addressed above. To briefly recap, the limitation to "intermixture of lipids from different sources" is a product-by-process limitation that imposes no specific structure on the lipid-containing formulation. *Thorpe*, 777 F.2d at 697.

Appellant contends that "it is improper to

construe the feature 'intermixtures of lipids [fatty acids] from different sources' as product-byprocess" (App. Br. 55).

We do not find this argument persuasive because Appellant has not demonstrated a difference between a can of black olives composed of the Kalamata variety from a can of black olives of the Manzanilla variety. This is the essence of product-by-process because the final formulation differs only in the process by which it is made, but contains the same omega-3 to omega-6 fatty acid ratio in the same amounts as required by the claims.

Appellant contends that "the webpages that disclose 'Olives' and 'ONA' teach mixtures of foods, including lipids from different sources, wherein overall ratio of omega-6 to omega-3 is around 2:1" (App. Br. 55). Appellant contends that "[t]hree skilled persons have testified, 'This teaching is applicable to all food mixtures taught by the site.' See paragraph [0010] of the Rucker, Rustagi, and Das declarations submitted on October 1, 2014" (App. Br. 55).

We are not persuaded. The teaching of "WHFoods"[13] is that the "ideal ratio of omega-3 to omega-6 is not known, but is estimated to be around 1:2; whereas, the current ratio in the typical American diet is more like 1:25" ("WHFoods" 9). This is not relevant to the amounts of omega-3 and omega-6 fatty acids in a specific food such as a

---

[13] WHFoods: A New Way of Looking at Proteins, Fats and Carbohydrates, http://web.archive.org/web/20070104020351/http://whfoods.com/genpage.php?tname=faq&dbid=7 (accessed Apr. 12, 2014).

serving of olives.

Further, the Declarations simply contend that "authoritative guidelines do not recognize the significance of 'total lipids' as a category" (Rucker Decl. 4/30/15 ¶ 13; *cf.* Erickson Decl. 3/31/15 ¶ 20; Das Decl. 4/30/15 ¶13; Rustagi Decl. 9/29/14[14] ¶ 10), but provide no evidence that olives in cans for consumptions lack the required omega-3 and omega-6 fatty acids in the required ratio.

Appellant contends that "the practitioner is neither motivated nor taught to modify ONA ... in order to obtain total lipids or a ratio of omega-6 and/or omega-3 to total lipids.'" (App. Br. 56).

We are not persuaded because the rejection is for anticipation, not obviousness. The Examiner cites "Olive Nutrient Analysis" to evidence that olives contain 14.35 g total fat composed in part of 0.09 g omega-3 fatty acids and 1.14 g of omega-6 fatty acids, "resulting in ~ 12:1 ratio of omega- 6 to omega-3" (FF 18). Appellant provides no evidence in rebuttal, nor do the Declarants specifically contest the composition disclosed by "Olive Nutrient Analysis."

Claim 130

Appellant contends that "Claim 130 requires presence of additional features that add to the novelty over 'Olives' and 'ONA'" (App. Br. 57).

We are not persuaded because the Examiner finds that "it is noted that Olives contains 4.03 mg vitamin E (less than 0.5% total lipids)" (Ans. 89), a

---

[14] Declaration of Dr. Pradip K. Rustagi, dated Sept. 29, 2014.

finding that is not rebutted by Appellant.

Dependent Claims

We recognize, but find unpersuasive, Appellant's arguments regarding claim 67 (App. Br. 58) because "Olive Nutrient Analysis" teaches that olives contain protein and carbohydrates (FF 18).

We recognize, but find unpersuasive, Appellant's arguments regarding claim 68 (App. Br. 58) because "protein in olives and walnuts . . . is less than 75% are from legumes, and less than 15% are from other sources" (Ans. 89). That is, the protein in olives is not derived from the prohibited sources of claim 68.

We recognize, but find unpersuasive, Appellant's argument regarding claims 73 and 74 (App. Br. 58) because the claims impose no specific structural requirement on the formulation, and the "when the formulation is provided" or "supplies 60-90% of a diet's fat calories" limitations represent intended uses. However, a "mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." *Zierden*, 411 F.2d at 1328.

We recognize, but find unpersuasive, Appellant's argument regarding claim 77 (App. Br. 58) because the olive composition may be administered in one-part "serving size" for any desired period of time (FF 18).

We recognize, but find unpersuasive, Appellant's argument regarding claim 78 (App. Br. 59) because Appellant provides no evidence demonstrating that the delivery of omega-3 or omega-6 fatty acids is not gradual or steady. *See Best*, 562 F.2d at 1255

("Where, as here, the claimed and prior art products are identical or substantially identical ... the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.").

We recognize, but find unpersuasive, Appellant's argument regarding claims 96 and 97 (App. Br. 59) because "Olive Nutrient Analysis" teaches the presence of additional nutrients (FF 18) and "Olives" teaches that "olives contain a variety of beneficial active phytonutrient compounds including *polyphenols*" (Olives 1). Appellant provides no evidence that the formulation does not inherently satisfy the functional requirements of claims 96 and 97. *Best*, 562 F.2d at 1255.

We recognize, but find unpersuasive, Appellant's argument regarding claim 98 (App. Br. 59) because it represents intended uses of the formulation. *Zierden*, 411 F.2d at 1328. No specific structural limitations are imposed by claim 98.

We find Appellant's argument regarding claim 136 (App. Br. 59) persuasive because the Examiner has not established the presence of any of the listed carriers in olives.

We recognize, but find unpersuasive, Appellant's argument regarding claim 137 (App. Br. 59) because olives may be consumed by adults.

We recognize, but find unpersuasive, Appellant's argument regarding claim 142 (App. Br. 60) because the olives contain fatty acids that are necessarily either in the free or ester form.

We recognize, but find unpersuasive, Appellant's

argument regarding claim 144 (App. Br. 60) that olives are not an "intermixture" for the reasons already given above.

Appellant also lists claims 61, 68, 69, 95, 102, 107, 142, and 144 but provides no specific arguments. "A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." 37 C.F.R. § 41.37(c)(1)(iv). Here, Appellant does not identify the claim recitations and provides no specific arguments that "Olives" does not anticipate these claims.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that "Olives" as evidenced by "Olive Nutrient Analysis" anticipates the claims.

D. 35 U.S.C. § 102(b) over Walnuts and "Walnut Nutrient Analysis"

The Examiner finds that "'Walnuts' teaches . . . amounts and health ratings of certain nutrients present in a 0.25 cup serving of walnuts" (Ans. 73). The Examiner finds that "a 0.25 cup serving of walnuts contain: 1) 9.52 g omega-6 fatty acids (54% by weight of total lipids) and 2.27 g omega-3 fatty acids (13.9 % by weight of total lipids)" (Ans. 77).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that "Walnuts" as evidenced by "Walnut Nutrient Analysis" anticipates the claims?

Findings of Fact

19. Walnut teaches "[w]alnuts are a delicious way

to add extra nutrition, flavor and crunch to a meal" and that "several polyphenolic compounds [are] found in walnuts" (Walnut 1). Walnut teaches that "three of the main types of walnuts consumed are the English (or Persian) walnut, *Juglans regia*; the Black walnut, *Juglans nigra*; and the White (or butternut) walnut, *Juglans cinerea*" (Walnut 4).

20. "Walnut Nutrient Analysis" teaches 25 g serving size contains

Basic Components		
nutrient	**amount**	**%DV**
calories	163.50	
calories from fat	146.72	
calories from saturated fat	13.78	
protein	3.81 g	
carbohydrates	3.43 g	
dietary fiber	1.68 g	6.72
soluble fiber	0.40 g	
insoluble fiber	0.81 g	
sugar - total	0.65 g	
monosaccharides	0.00 g	
disaccharides	0.53 g	
other carbs	1.10 g	
fat - total	16.30 g	
saturated fat	1.53 g	
mono fat	2.23 g	
poly fat	11.79 g	
trans fatty acids	0.00 g	
cholesterol	0.00 mg	
water	1.02 g	
ash	0.45 g	

Other Fats		
nutrient	**amount**	**%DV**
omega 3 fatty acids	2.27 g	90.80
omega 6 fatty acids	9.52 g	

("Walnut Nutrient Analysis" 1, 3).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of "Walnuts" and "Walnut Nutrient Analysis" (Ans. 73–83; FF 19–20) and agree that the claims are anticipated. We address Appellant's arguments below.

Appellant contends that "there is no suggestion in 'Walnuts' or 'WNA' regarding an "intermixture of lipids [fatty acids] from different varieties or sources'" (App. Br. 62).

We do not find this argument persuasive for the reasons extensively addressed above. To briefly recap, the limitation to "intermixture of lipids from different sources" is a product-by-process limitation that imposes no specific structure on the lipid-containing formulation. *Thorpe*, 777 F .2d at 697.

Appellant contends that "the webpages that disclose 'Walnuts' and 'WNA' teach mixtures of foods, including lipids from different sources, wherein overall ratio of omega-6 to omega-3 is 'around 2: 1 '" (App. Br. 62).

We do not find this argument persuasive because "Walnut Nutritional Analysis" expressly teaches that a serving of walnuts contains 9 .52 g omega- 6 fatty acids and 2.27 g omega-3 fatty acids for a ratio of 4.2:1, satisfying the requirements of claim 65.

Claims 91 and 130

Appellant contends that "Claims 91 and 130 require presence of additional features that add to

the novelty over 'Walnuts' and 'WNA'" (App. Br. 63).

We are not persuaded because Walnuts teaches the presence of polyphenols (FF 19), one of the optional nutrients required by claims 91 and 130.

Dependent Claims

We recognize, but find unpersuasive, Appellant's arguments regarding claim 67 (App. Br. 64) because "Walnut Nutrient Analysis" teaches that olives contain protein and carbohydrates (FF 20).

We recognize, but find unpersuasive, Appellant's arguments regarding claim 68 (App. Br. 64) because "protein in olives and walnuts . . . is less than 75% are from legumes, and less than 15% are from other sources" (Ans. 89). That is, the protein in walnuts is not derived from the prohibited sources of claim 68.

We recognize, but find unpersuasive, Appellant's argument regarding claims 73 and 74 (App. Br. 64) because the claims impose no specific structural requirement on the formulation, and the "when the formulation is provided" or "supplies 60-90% of a diet's fat calories" limitations represent intended uses. However, a "mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." *Zierden*, 411 F.2d at 1328.

We recognize, but find unpersuasive, Appellant's argument regarding claim 77 (App. Br. 64) because the walnut composition may be administered in one-part "serving size" for any desired period of time (FF 20).

We recognize, but find unpersuasive, Appellant's argument regarding claims 78 and 124 (App. Br. 64)

because Appellant provides no evidence demonstrating that the delivery of omega-3 or omega-6 fatty acids is not gradual or steady. *See Best*, 562 F.2d at 1255 ("Where, as here, the claimed and prior art products are identical or substantially identical ... the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.").

We recognize, but find unpersuasive, Appellant's argument regarding claims 96 and 97 (App. Br. 64–65) because "Walnut Nutrient Analysis" teaches the presence of additional nutrients (FF 20) and "Walnuts" teaches that "several polyphenolic compounds [are] found in walnuts" (FF 19).

Appellant provides no evidence that the formulation does not inherently satisfy the functional requirements of claims 96 and 97. *Best*, 562 F.2d at 1255.

We recognize, but find unpersuasive, Appellant's argument regarding claims 98, 102, 118, and 122 (App. Br. 65) because the arguments rely upon intended uses of the formulation. *Zierden*, 411 F.2d at 1328. No specific structural limitations are imposed by these claims.

We recognize, but find unpersuasive, Appellant's argument regarding claim 128 (App. Br. 65) because the claim is a product-by-process claim and Appellant has not shown any structural differences resulting from the process. *Thorpe*, 777 F .2d at 697.

We recognize, but find unpersuasive, Appellant's argument regarding claims 136 and 139 (App. Br.

65) because "Walnut Nutrient Analysis" teaches that walnuts contain sugars including disaccharides as required by the claims (FF 20).

We recognize, but find unpersuasive, Appellant's argument regarding claims 137 and 140 (App. Br. 66) because walnuts may be consumed by adults.

We recognize, but find unpersuasive, Appellant's argument regarding claims 142 and 144 (App. Br. 66) that walnuts are not an "intermixture" for the reasons already given above.

Appellant also lists claims 61, 68, 69, 82, 107, 118, 120, 135, 138, and 141-145 but provides no specific arguments. "A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." 37 C.F.R. § 41.37(c)(1)(iv). Here, Appellant does not identify the claim recitations and provides no specific arguments that "Walnuts" does not anticipate these claims.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that "Walnuts" as evidenced by "Walnut Nutrient Analysis" anticipates the claims.

SUMMARY

In summary, we affirm the rejection of claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90–102, 107, 116–122, 124, and 128–145 under 35 U.S.C. § 101 as directed to non-statutory subject matter.

We affirm the rejection of claims 52, 61, 64, 65, 67–69, 73, 75, 77, 78, 80, 83, 90, 92–96, 98, 100, 129–131, 133–137, 142, and 144 under 35 U.S.C. § 102(b)

as anticipated by Mark.

We affirm the rejection of claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90, 92–94, 96–98, 100, 129–131, 133, 137, 142, and 144 under 35 U.S.C. § 102(b) as anticipated by Olives as evidenced by "Olives Nutrient Analysis."

We reverse the rejection of claim 136 under 35 U.S.C. § 102(b) as anticipated by Olives as evidenced by "Olives Nutrient Analysis."

We affirm the rejection of claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 83, 90–101, 116–118, 120–122, 128–140, and 141–145 under 35 U.S.C. § 102(b) as anticipated by Walnuts as evidenced by "Walnut Nutrient Analysis."

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Filed: April 15, 2016

APPENDIX E

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

IN RE: URVASHI BHAGAT,

Appellant

2016-2525

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 12/426,034

ON MOTION

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM

O R D E R

Appellant Urvashi Bhagat filed a combined petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on June 8, 2018.

FOR THE COURT

June 1, 2018
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX F

STATUTES

5 U.S.C. §706 (1994 ed. and suppl. III (Jan. 26, 1998). Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall-

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be-

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

35 U.S.C. § 31 (1946)

Inventions patentable.

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant, not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof, or more than one year prior to his application, and not in public use or on sale in this country for more than one year prior to his application, unless the same is proved to have been abandoned, may, upon payment of the fees required by law, and other due proceeding had, obtain a patent therefor. (R. S. § 4886; Mar. 3, 1897, ch. 391, § 1, 29 Stat. 692; May 23, 1930, ch. 312, § 1, 46 Stat. 376; Aug, 5, 1939, ch. 450, § 1, 53 Stat. 1212.)

APPENDIX G

Claims at Issue Below

52. The formulation of claim 65, comprising one or more fatty acids selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

61. The formulation of claim 65, wherein one or more of the following apply:

(i) comprising one or more of seeds, nuts, oils, legumes, dairy, cocoa, lentils, grains, culinary nuts and/or seeds in their whole form or their oils;

(ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, and other foods, as source of fatty acids, antioxidants, minerals, and/or phytochemicals;

(iii) comprising one or more of peanut oil, corn oil, avocado oil, olive oil, sunflower oil, safflower oil, coconut oil, mustard oil, palm oil, soybean lecithin, and anhydrous butter;

(iv) comprising one or more of peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter**,** and coconut meat, or their oils; or

(v) comprising omega-6 fatty acids at 4% to 75% by weight and omega-3 fatty acids at 0.1% to 30% by weight of total lipids, and wherein the nuts or their oils comprise almonds, peanuts, and/or coconut meat, and the formulation optionally comprises anhydrous butter.

64. The formulation of claim 65, wherein the formulation is an enteral or parenteral formulation.

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

(1) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

67. The formulation of claim 65, further comprising a source of carbohydrates, and a source of protein.

68. The formulation of claim 67, wherein one or more of the following apply:

(i) comprising 20-45% of a diet's calories from fat, 45-65% of a diet's calories from carbohydrates, and 10%-25% of a diet's calories from protein;

(ii) comprising carbohydrates calories of which 50-70% are from grains, 15-30% are from vegetables, and 10-30 % are from fruits, wherein optionally grains are selected from wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, and quinoa; or

(iii) comprising protein calories of which less than 75% are from legumes, less than 25% are from eggs, less than 25% are from cheese, less than 25% are from milk, less than 25% are from yogurt, less than 30% are from poultry, less than 30% are from seafood, less than 30% are from meat, and less than 15% are from other sources.

69. The formulation of claim 65, wherein one or more of the following apply:

(i) comprising one or more polyphenols selected from: a flavonoid, a flavonol, a flavanone, an isoflavone, an anthocyanidin, a phytoestrogen, a catechin, a quercetin, resveratrol, a lignan, gallic acid, ellagic acid, and curcumin;

(ii) comprising one or more phytochemicals selected from: phytosterols, campesterol, sitosterol, and stigmasterol, organosulfur, sulfide, melatonin, carotenoid, beta carotene, lycopene, lutein, zeaxanthin, and a phenol;

(iii) comprising dosage of phytosterols less than 150mg;

(iv) comprising one or more of: dosage of campesterol less than 1.5mg, dosage of sitosterol less than 30mg, and dosage of stigmasterol less than 1.5mg;

(v) comprising one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements;

(vi) comprising one or more of: dosage of vitamin A less than 30000IU, dosage of folic acid or folate less than 800mcg, dosage of vitamin C less than 400mg, dosage of vitamin D less than 400IU, dosage of vitamin E tocopherol beta less than 0.5mg, dosage of vitamin E tocopherol delta less than 0.5mg, dosage of vitamin E tocopherol gamma less than 4mg, dosage of vitamin E tocopherol alpha less than 15mg, dosage of copper less than 3mg, dosage of zinc less than 14mg, dosage of manganese less than 8mg, dosage of iron less than18mg, dosage of selenium less than 80mcg, and dosage of magnesium less than 700mg;

(vii) comprising one or more of: dosage of alpha carotene less than 4000mcg, dosage of beta carotene less than 14000mcg, dosage of beta cryptoxanthin less than 850mcg, dosage of betaine less than 50mg, dosage of choline less than 250mg, dosage of lycopene less than 1900 mcg, and dosage of lutein/zeaxanthin less than 14000mcg;

(viii) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids; or

(ix) comprising a dosage of fiber less than 45g.

73. The formulation of claim 65, whereby the lipid-containing formulation provides a substitution and/or supplementation of lipids that are typically added to food preparations so that when the formulation is provided in combination with a lipid-free or low-lipid food product, the combination of the formulation and the food preparation provides a balanced lipid intake to the subject ingesting the combination.

74. The formulation of claim 65, whereby the formulation supplies 60-90% of a diet's fat calories.

75. The formulation of claim 65, wherein the formulation is in the form of a liquid, semi-solid, solid, granule, powder, capsule, tablet, lozenge, pill, or combination thereof.

77. The formulation of claim 65, wherein the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.

78. The formulation of claim 65, whereby the formulation provides gradual and/or steady delivery so that any omega-3 withdrawal is gradual, and/or any omega-6 and/or other fatty acid increase is gradual.

80. The formulation of claim 65, further comprising a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat.

82. The formulation of claim 65, wherein

(i) the omega-6 to omega-3 ratio is greater than 6:1; or

(ii) the omega-6 to omega-3 ratio is at least 9:1.

83. The formulation of claim 65, wherein one or more of the following apply:

(i) the formulation of (2) wherein omega-6 fatty acids are present at 4% to 75% by weight of total lipids;

(ii) the formulation of (2) wherein omega-3 fatty acids are present at 0.1% to 30% by weight of total lipids;

(iii) the dosage of eicosapentaenoic acid (C20:5) is not more than 0.5 grams, and/or the dosage of docosahexaenoic acid (C22:6) is not more than 0.2 grams; or

(iv) omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

90. The formulation of claim 65, whereby one or more nutrients are effective to provide a therapeutic effect comprising prophylaxis or alleviation of one or more symptoms associated with a disease or condition selected from the group consisting of: menopause, aging, musculoskeletal disorders, hypercholesterolemia, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases,

cancer, autoimmune diseases, infectious diseases, inflammatory diseases, dyslipidemia and cardiovascular disease.

91. A lipid-containing formulation, comprising a dosage of omega-6 fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, the formulation comprising polyunsaturated, monounsaturated, and saturated fatty acids, and wherein the formulation includes at least

(i) one or more polyunsaturated fatty acids selected from linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6), and

(ii) nutrients including at least

(a) one or more polyphenols, or

(b) one or more phytochemicals,

the one or more phytochemicals being selected from: phytosterols, campesterol, sitosterol, stigmasterol, organosulfur, sulfide, melatonin, lycopene, lutein, zeaxanthin, and a phenol.

92. The formulation of claim 65, wherein the formulation provides 40 grams or less of omega-

6 dosage.

93. The formulation of claim 65, wherein the dosage of omega-6 fatty acids is from 1 to 10 grams, or from 2 to15 grams, or from 2 to 25 grams, or from 2 to 40 grams.

94. The formulation of claim 65, wherein the dosage of total fat in grams is from 10-100 grams, 10-75 grams, or 20-100 grams.

95. The formulation of claim 65, wherein the dosage of omega-3 fatty acids is from 0.1 to 1.0 grams, or from 0.2 to 1.0 grams, or from 1.0 to 2.0 grams, or from 2.0 to 3.0 grams, or from 2.0 to 4.0 grams or from 2.0 to 6.0 grams.

96. The formulation of claim 65, wherein the formulation comprises one or more nutrients effective to provide beneficial effects at omega-6 to omega-3 ratio of at least 4:1, and/or one or more nutrients at amounts effective to reduce omega-3 requirements and/or allow for higher omega-6 to omega-3 ratio than in the absence of the nutrient and/or increase effective levels of omega-3 in the subject.

97. The formulation of claim 65, wherein the formulation comprises one or more polyphenols, and is effective to increase omega-3 levels in the subject.

98. The formulation of claim 65, wherein the formulation comprises daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the

subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and climate of the subject's living area.

99. The formulation of claim 91, wherein omega-3 fatty acids are present at 0.1% to 30% by weight of total lipids; the dosage of eicosapentaenoic acid (C20:5) is not more than 0.5 grams, and/or the dosage of docosahexaenoic acid (C22:6) is not more than 0.2 grams; and/or omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

100. The formulation of claim 65, wherein the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; the ratio of total fatty acids to saturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1.

101. The formulation of claim 91, wherein the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; the ratio of total fatty acids to saturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1.

102. The formulation of claim 65, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams; the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids

to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1.

107. The formulation of claim 98, wherein the fatty acid content is as set forth in Tables 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20.

116. The formulation of claim 91, comprising one or more fatty acids selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

117. The formulation of claim 91, wherein one of the following apply:

(i) comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is 4:1 to 45:1; or

(ii) comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is at least

9:1.

118. The formulation of claim 91, wherein one or more of the following apply:

(i) the dosage of total lipids is from 10-100 grams;

(ii) the formulation comprises less than 40 grams of dosage of omega-6 fatty-acids;

(iii) the dosage of omega-6 fatty acids is from 1 to 40 grams;

(iv) the dosage of omega-3 fatty acids is from 0.1 to 6.0 grams;

(v) the dosage of total of lipids is 10-100 grams, dosage of omega-6 fatty acids is from 1 to 40 grams, dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1 to 3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1;

(vi) whereby the formulation supplies 60-90% of a diet's fat calories; or

(vii) the formulation is adapted for use in combination with or provided with a lipid-free or low-lipid food product.

119. The formulation of claim 91, wherein the fatty acid content is as set forth in Tables 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20.

120. The formulation of claim 91, wherein one or more of the following apply:

(i) comprising one or more polyphenols selected from: a flavonoid, a flavonol, a flavanone, an isoflavone, an anthocyanidin, a phytoestrogen, a catechin, a quercetin, resveratrol, a lignan, gallic acid, ellagic acid, and curcumin;

(ii) comprising dosage of phytosterols less than 150mg;

(iii) comprising one or more of: dosage of campesterol less than 1.5mg, dosage of sitosterol less than 30mg, and dosage of stigmasterol less than 1.5mg;

(iv) comprising one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements;

(v) comprising one or more of: dosage of vitamin A less than 30000IU, dosage of folic acid or folate less than 800mcg, dosage of vitamin C less than 400mg, dosage of vitamin D less than 400IU, dosage of vitamin E tocopherol beta less than 0.5mg, dosage of vitamin E tocopherol delta less than 0.5mg, dosage of vitamin E tocopherol gamma less than 4mg, dosage of vitamin E tocopherol alpha less than 15mg, dosage of copper less than 3mg, dosage of zinc less than 14mg, dosage of manganese less than 8mg, dosage of iron less than18mg, dosage of selenium less than 80mcg, and dosage of magnesium less than 700mg;

(vi) comprising one or more of: dosage of alpha carotene less than 4000mcg, dosage of beta

carotene less than 14000mcg, dosage of beta cryptoxanthin less than 850mcg, dosage of betaine less than 50mg, dosage of choline less than 250mg, dosage of lycopene less than 1900 mcg, and dosage of lutein/zeaxanthin less than 14000mcg;

(vii) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids; or

(viii) comprising a dosage of fiber less than 45g.

121. The formulation of claim 91, wherein one or more of the following apply:

(i) comprising a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat;

(ii) comprising 20-45% of a diet's calories from fat, 45-65% of a diet's calories from carbohydrates, and 10%-25% of a diet's calories from protein;

(iii) comprising carbohydrates calories of which 50-70% are from grains, 15-30% are from vegetables, and 10-30 % are from fruits, wherein optionally grains are selected from wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, and quinoa; or

(iv) comprising protein calories of which less than 75% are from legumes, less than 25% are from eggs, less than 25% are from cheese, less than 25% are from milk, less than 25% are from yogurt, less than 30% are from poultry, less than 30% are from seafood, less than 30% are from meat, and less than 15% are from other

sources.

122. The formulation of claim 91, wherein the formulation comprises daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and climate of the subject's living area.

124. The formulation of claim 91, wherein the formulation is configured for administration by gradual and/or steady delivery.

128. The formulation of claim 91, wherein the formulation is selected from:

(1) a formulation wherein omega-6 fatty acids are present at 4% to 75% by weight, and omega-3 fatty acids are present at 0.1% to 30% by weight, and wherein the formulation comprises nuts or their oils, wherein said nuts or their oils are obtained from almonds, peanuts, and/or coconut meat, and the formulation optionally comprises anhydrous butter;

(2) a formulation comprising:

a peanut oil present at 8 to 56 percent by weight in the formulation; and

at least two of: a vegetable oil present at 8 to 46 percent by weight in the formulation, wherein the vegetable oil is selected from one or more of acai oil, amaranth oil, apple seed oil, apricot kernel oil, argan oil, artichoke oil,

babassu oil, ben oil, blackcurrant seed oil, borage seed oil, borneo tallow nut oil, bottle gourd oil, buffalo gourd oil, 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*), grapeseed oil, 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, sheanut oil, soybean lecithin oil, tea oil, thistle oil, tomato seed oil, ucuhuba butter oil, wheat germ oil, acorn oil, almond oil, beech nut oil, brazilnut oil, breadnut oil, candlenut oil, chestnut oil, chilacayote nut oil, chilean hazelnut oil, coconut oil, cashew oil, colocynth nut oil, filbert oil, hazelnut oil, hickory oil, kola nut oil, macadamia oil, mamoncillo oil, mongongo oil, obongo nut oil, pecan oil, pili nut oil, pine nut oil, pistachio oil, soya oil, poppy seed oil, pumpkin seed oil, hemp seed oil, flax seed oil, sesame seed oil, walnut oil, and watermelon seed oil;

an avocado oil present at 3 to 16 percent by weight in the formulation;

an olive oil present at 5 to 32 percent by weight in the formulation;

a sunflower oil present at 6 to 34 percent by weight in the formulation;

and

a safflower oil present at 2 to 30 percent by weight in the formulation;

(3) a formulation comprising three or more of:

an almond oil present at 2 to 23 percent by weight in the formulation;

an avocado oil present at 1 to 7 percent by weight in the formulation;

a soybean oil present at 1 to 7 percent by weight in the formulation;

a cashew oil present at 2 to 15 percent by weight in the formulation;

a pistachio oil present at 1 to 7 percent by weight in the formulation;

a pumpkin seed oil present at 1 to 8 percent by weight in the formulation;

a walnut oil present at 3 to 25 percent by weight in the formulation;

a peanut oil present at 5 to 30 percent by weight in the formulation;

a corn oil present at 3 to 19 percent by weight in the formulation;

an olive oil present at 3 to 17 percent by weight in the formulation;

a safflower oil present at 1 to 14 percent by weight in the formulation; and

an anhydrous butter present at 5 to 29 percent by weight in the formulation; or

(4) a formulation comprising three or more of:

an almond oil present at 1 to 36 percent by weight in the formulation;

a pumpkin seed oil present at 1 to 24 percent by weight in the formulation;

an oil from walnuts present at 2 to 36 percent by weight in the formulation;

a peanut oil present at 4 to 72 percent by weight in the formulation;

a corn oil present at 1 to 24 percent by weight in the formulation;

an olive oil present at 2 to 36 percent by weight in the formulation;

a sunflower oil present at 4 to 72 percent by weight in the formulation;

a safflower oil present at 2 to 60 percent by weight in the formulation; and

an anhydrous butter present at 2 to 36 percent by weight in the formulation;

further comprising one or more of:

a mustard oil present at 8 percent or less by weight in said formulation,

a palm oil present at 2 percent or less by weight in said formulation,

a flaxseed oil at 8 percent or less by weight in said formulation,

a coconut oil present at 8 percent or less by weight in said formulation, and

a soybean lecithin present at 4 percent or less by weight in said formulation;

(5) a formulation comprising three or more of:

peanuts present at 2 to 11 percent by weight in the formulation;

almonds present at 5 to 32 percent by weight in the formulation;

olives present at 6 to 36 percent by weight in the formulation;

soybeans present at 4 to 25 percent by weight in the formulation;

cashews present at 4 to 21 percent by weight in the formulation;

pistachios present at 2 to 9 percent by weight in the formulation;

pumpkin seeds present at 2 to 15 percent by weight in the formulation;

sunflower seeds present at 1 to 4 percent by weight in the formulation;

walnuts present at 3 to 25 percent by weight in the formulation;

anhydrous butter present at 4 to 24 percent by weight in the formulation; and

coconut meat present at 1 to 6 percent by weight in the formulation;

(6) a formulation comprising at least three of safflower oil, sunflower oil, peanut oil, almond or almond oil, corn oil, and anhydrous butter; and

(7) a formulation comprising three or more of peanuts, almonds, olives, soybeans, cashews,

flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, and coconut meat, or their oils.

129. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of fatty acids from different sources; and wherein

omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids.

130. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of fatty acids from different sources; and wherein

omega-6 fatty acids are not more than 40 grams and the formulation further comprises one or more polyphenols, or one or more phytochemicals selected from: phytosterols, campesterol, sitosterol, stigmasterol, organosulfur, a sulfide, melatonin, lycopene, lutein, and zeaxanthin, or vitamin E-alpha/gamma less than 0.5% by weight of total lipids, or one or more specific protein types listed in Table 21 in a dosage not more than the upper limit disclosed in the table.

131. The formulation of claim 65, wherein the omega-6 to omega-3 ratio is 4:1 to 45:1.

132. The formulation of claim 91, wherein the nutrients include at least the one or more polyphenols and the one or more phytochemicals.

133. The formulation of claim 65, wherein the formulation is in the form of full meal or dietary component selected from an oil, a gel, sauce, spread, butter, dressing, side dish, snack, salad, nutritional bar, bread, dessert, chocolate, fudge, pastry, truffle, pudding, cake, bakery product, yogurt, drink, and combinations thereof.

134. The formulation of claim 91, wherein one or more of the following apply:

(i) the formulation is in the form of full meal or a dietary component selected from an oil, gel, sauce, dressing, spread, butter, drops, nutritional bar, snack, bread, bakery product, dairy product, side dish, salad, dessert, chocolate, fudge, pastry, truffle, pudding, cake, yogurt, drink, and combinations thereof; or

(ii) the formulation is in the form of enteral, parenteral, a liquid, a semi-solid, a solid, capsule, tablet, granule, powder, lozenge, pill, or a combination thereof; or

(iii) the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.

135. The formulation of claim 65, wherein one or more dosages are therapeutically effective.

136. The formulation of claim 65, wherein the formulation includes one or more carriers selected from starches, sugars, granulating agents, binders and disintegrating agents.

137. The formulation of claim 65, wherein the formulation is for a human infant, or adult.

138. The formulation of claim 91, wherein one or more dosages are therapeutically effective.

139. The formulation of claim 91, wherein the formulation includes one or more carriers selected from starches, sugars, diluents, granulating agents, binders and disintegrating agents.

140. The formulation of claim 91, wherein the formulation is for a human infant, adult, or child.

141. The formulation of claim 91, wherein one or more of the following apply:

(i) comprising one or more nutrients effective to reduce omega-3 requirement and/or allow for higher omega-6 to omega-3 ratio than in the absence of the nutrient and/or increase effective levels of omega-3 in the subject; or

(ii) comprising one or more polyphenols effective to increase omega-3 levels in the subject.

142. The formulation of claim 65, wherein one or more of the following apply:

(i) the lipids in the intermixture are fatty acids in their free form;

(ii) the lipids in the intermixture are fatty acids

in their ester form;

(iii) the lipids in the intermixture are in their isolated form;

(iv) the sources of lipids include butters, nuts, seeds, herbs, and/or sweeteners;

(v) the lipids from different sources are wherein lipid profile of two or more sources intermixed are different from each other;

(vi) the lipids from different sources are wherein different lipids from different sources are intermixed synergistically; or

(vii) excess delivery of lipids from a single source is avoided.

143. The formulation of claim 91, wherein one or more of the following apply:

(i) the lipids in the intermixture are fatty acids in their free form;

(ii) the lipids in the intermixture are fatty acids in their ester form;

(iii) the lipids in the intermixture are in their isolated form;

(iv) the sources of lipids include butters, nuts, seeds, herbs, and/or sweeteners;

(v) the lipids from different sources are wherein lipid profile of two or more sources intermixed are different from each other;

(vi)) the lipids from different sources are wherein different lipids from different sources are intermixed synergistically; or

(vii) excess delivery of lipids from a single source is avoided.

144. The formulation of claim 65, wherein one or more of the following apply:

(i) the intermixture is a gel;

(ii) the intermixture is a powder;

(iii) the intermixture is solid;

(iv) the intermixture is semi-solid; or

(v) the intermixture is a blend.

145. The formulation of claim 91, wherein one or more of the following apply:

(i) the intermixture is a gel;

(ii) the intermixture is a powder;

(iii) the intermixture is solid;

(iv) the intermixture is semi-solid; or

(v) the intermixture is a blend.