



April 27, 2018

**Open Letter To Andrei Iancu, Director,  
US Patent and Trademark Office, and  
Sharon Prost, Chief Judge,  
United States Court Of Appeals For The Federal Circuit (CAFC)  
Regarding US Application 12/426, 034 and CAFC case #16-2525**

Dear Sir/Madam,

Both USPTO and CAFC have done great injustice to us, 1000s of inventors and companies claiming "composition of matter", and millions of Americans who suffer from chronic diseases associated with lipid imbalance.

117 million Americans suffer from chronic diseases associated with lipid imbalance, ~3 trillion annually is spent in US on treating those diseases, 99% of public cannot name lipids, nature is unpredictable in lipid content, and there is mass confusion and noise in the art. Lipids are in all foods, but added oils are a particular problem because they are concentrated extract absorbed differently than other foods. It is a perpetual problem continuing for centuries and expected to continue for centuries, unless solved as invented. Piecemeal patents will not solve the problem.

Our company Asha Nutrition Sciences, deeply understanding the flawed teachings in the art, invented lipid dosages contrary to prior art teachings, and filed for patents in 2009 because without patents economics do not work to turn the tide. USPTO mutilated our claims and disclosure, and **promoted falsities**, and misapplied the law across the board to deny patents, which falsities were copied by some other patent offices. We appealed to CAFC. CAFC **rubber-stamped USPTO falsities**, contrary to a large body of its own and Supreme Court precedents, and issued a disjointed evasive non-opinion, uncharacteristic and unexpected from the panel of judges and the 2nd highest seat of justice in the United States of America, the "most advanced country" in the world.

Main Issues:

Claims recite, "dosage of omega-6/omega-3" and "casings providing controlled delivery of the formulations", which nature cannot provide. The line of attack from USPTO and CAFC: mutilate the terms! Specification provides six tables and ~20 examples, where it emphasizes importance of dosages and that there is a rather sensitive dose-effect of omega-6 and omega-3 (changing by level of administrations and body stores). There is one statement in the Specification "any orally acceptable form" (meaning any food form), but the Specification does NOT say, "dosage means any amount." The falsity promoted by USPTO and upheld by CAFC is that "any orally acceptable form" means dosage is not limiting, **despite the six tables and ~20 examples teaching specific dosages, and that inventor and skilled persons provided testimony during prosecution that "dosage" means "specified amount for**

**administration," and despite that claims recite "dosage" and "casings providing controlled delivery of the formulations" not "any orally acceptable form."** As per CAFC and Supreme Court precedents, inventor's interpretation during prosecution and skilled person's testimony cannot be disregarded, and claims are examined by plain words of the claims.

By mutilating the terms "dosage of omega-6/omega-3" and "casings providing controlled delivery of the formulations" USPTO and CAFC alleged that claims are drawn to "products of nature" although claims also recite "intermixture of lipids from different sources," which by law is a structural limitation and a "composition of matter", patent eligible as per 35 USC § 101. Further, § 102-type analysis was applied under § 101, contrary to controlling law from Supreme Court in *Mayo* and *Alice*.

USPTO and CAFC also applied "anticipation" 35 USC § 102 rejections by mutilating and disregarding "dosage of omega-6/omega-3", "casings providing controlled delivery of the formulations", "intermixture of lipids from different sources," and prosecution disclaimers to "single source", even though anticipating reference must necessarily function as claimed, different from obviousness rejection under 35 USC § 103. They could not apply § 103 rejections because claimed subject matter is not obvious due to opposite teachings in the art.

There is a reason why § 103 has been legislated separately from § 102—to solve problems that are not well understood or critical but not solved. USPTO and CAFC wiped out the separation between §§ 101, 102, and 103, and the very purpose of the separations.

After the CAFC Opinion was published, several lawyers in the field unaffiliated with us also opined that the USPTO and Court had wronged us.

We have filed the enclosed Petition for Rehearing En Banc. The Petition includes annotated copies of the Opinion and the opinions issued by other lawyers. We hope it will provide us the long overdue justice. If we are unsuccessful at CAFC, we will appeal to Supreme Court.

During the nine years the application has been pending, 13.6 million (1.5 million in ~2 years the application has been pending at CAFC) Americans have died of associated diseases (<http://www.cdc.gov/nchs/fastats/deaths.htm>).

We request your attention so that further injustice can be avoided, and public can be provided with the solutions.

Sincerely,



Urvashi Bhagat

Chief Executive Officer

2016-2525  
(Serial No. 12/426,034)

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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**IN RE BHAGAT**

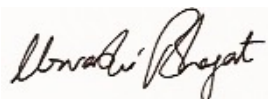
**APPEAL FROM THE UNITED STATES PATENT AND  
TRADEMARK OFFICE  
PATENT TRIAL AND APPEAL BOARD**

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**APPELLANT'S COMBINED PETITION FOR  
PANEL REHEARING AND REHEARING *EN BANC***

Pursuant to Federal Rule of Appellate Procedure 2, 35(a)(1) and (2), and 40 and Federal Circuit Rule 35 and 40, Appellant hereby petitions this Court to order a panel rehearing and rehearing *en banc* of this appeal.

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*Dated: April 25, 2018*

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## TABLE OF CONTENTS

TABLE OF CONTENTS.....	i
TABLE OF AUTHORITIES.....	iii
TABLE OF ABBREVIATIONS.....	vi
STATEMENT PURSUANT TO FEDERAL CIRCUIT RULE 35(b).....	1
POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL.....	3
ARGUMENTS IN SUPPORT OF A REHEARING.....	13
ARGUMENTS IN SUPPORT OF REHEARING EN BANC.....	16
I. Opinion Conflicts With Binding Precedents from SCOTUS and this Court.....	16
II. This Appeal Requires Answers To Precedent-Setting Questions Of Exceptional Importance.....	17
A. Is it proper to disregard structural limitation “intermixture” under § 101?.....	17
B. Is it proper to require applicants to distinguish claimed products from products proven not to be products of nature under §101?.....	17
C. Is it proper to hold functional printed matter or instructions combined with alleged product of nature as natural product under §101?.....	17
D. Is it proper to compromise innovation in nutrition and public health massively in favor of narrow patents, creating unfavorable economics for significant advancement in nutrition, preserving perpetual status quo?.....	18
CONCLUSION .....	23
ADDENDUM	
– Annotated Copy Of The Court’s Opinion Sought To Be Reheard	
– “Federal Circuit Finds Composition of Matter Ineligible For Patenting,” March 27, 2018. Opinion by Courtenay Brinckerhoff, BS chemistry; IP Partner at Foley & Lardner Chemical Practice; Admitted at CAFC.	

- “In Re Urvashi Bhagat: One More Decision Denying Patent Eligibility of Nature-Based Product Claims,” March 29, 2018. Opinion by Marina Miller, PhD. molecular biology/biochemistry; IP Partner at Oblon Chemical Patent Prosecution group; Admitted at CAFC.
- “In re Urvashi Bhagat – The Slippery Slope of Natural Product Claims,” March 22, 2018. Opinion by Warren Woessner, PhD organic chemistry; Patent Attorney; founding shareholder of Schwegman Lundberg & Woessner; Admitted at CAFC.
- “Omega-6 fatty acid” Wikipedia, accessed March 5, 2018
- Patents for Humanity Application (Repeated from Joint Appendix, Appx7908-7915, for emphasis)

## PROOF OF SERVICE

## TABLE OF AUTHORITIES

	Page(s)
<u>CASES</u>	
<i>Abbott Labs v. Sandoz</i> , 566 F.3d 1282, (Fed. Cir. 2009) (en banc).....	2, 11, 15
<i>Alice Corp. v. CLS Bank International</i> , 134 S. Ct. 2347 (2014).....	passim
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> 133 S. Ct. 2107 (2013).....	passim
<i>Baldwin County Welcome Center v. Brown</i> , 466 U.S. 147 (1984).....	15
<i>Classen Immunotherapies, Inc. v. Biogen Idec</i> , 659 F.3d 1057 (Fed. Cir. 2011) .....	2, 9
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980).....	passim
<i>Diamond v. Diehr</i> , 450 US 175 (1981) .....	2, 9
<i>Funk Bros. Seed Co. v. Kalo Inoculant Co.</i> , 333 U.S. 127 (1948).....	17
<i>Haines v. Kerner</i> , 404 U.S. 519 (1972) .....	15
<i>In re Alton</i> , 76 F.3d 1168 (Fed. Cir. 1996) .....	passim
<i>In re Bilski</i> , 545 F.3d 943 (Fed. Cir. 2008) (en banc).....	1, 8
<i>In re Cortright</i> , 165 F.3d 1353 (Fed. Cir. 1999).....	4, 5
<i>In re Elsner</i> ,	

381 F.3d 1125 (Fed. Cir. 2004) .....	1, 6
<i>In re Fine</i> ,	
837 F.2d 1071 (Fed. Cir. 1988).....	1, 6, 7
<i>In re Garnero</i> ,	
412 F.2d 276 (CCPA 1969).....	2, 11
<i>In re Gulack</i> ,	
703 F.2d 1381 (Fed. Cir. 1983) .....	passim
<i>In Re Hans Oetiker</i> ,	
977 F.2d 1443 (Fed. Cir. 1992) .....	2, 7, 10
<i>In re Herrmann</i> ,	
261 F.2d 598 (CCPA 1958) .....	13
<i>In re Imes</i> ,	
778 F.3d 1250 (Fed. Cir. 2015) .....	1, 3, 4
<i>In re Miller</i> ,	
418 F.2d 1392 (C.C.P.A. 1969) .....	2, 11, 17
<i>In re Rijckaert</i> ,	
9 F.3d 1531 (Fed. Cir. 1993) .....	1, 6, 7
<i>In re Robertson</i> ,	
69 F.3d 743 (Fed. Cir. 1999) .....	1, 6, 7
<i>In re Soni</i> ,	
54 F.3d 746 (Fed. Cir. 1995) .....	13
<i>In re Zletz</i> ,	
893 F.2d 319 (Fed. Cir. 1989) .....	passim
<i>Lindemann Maschinenfabrik GMBH v. Am. Hoist &amp; Derrick Co.</i> ,	
730 F.2d 1452 (Fed. Cir. 1984) .....	1, 6, 7
<i>Markman v. Westview Instruments, Inc.</i> ,	
52 F.3d 967 (Fed. Cir. 1995) (en banc) .....	1, 5

<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012) .....	passim
<i>Net MoneyIN, Inc. v. VeriSign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008) .....	1, 6, 7
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.</i> , 851 F.3d 1270 (Fed. Cir. 2017) .....	passim
<i>Perricone v. Medicis Pharm. Corp.</i> 432 F.3d 1368 (Fed. Cir. 2005) .....	1, 6, 13
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc) .....	1, 5
<i>Rapid Litigation Management Ltd. v. Cellzdirect</i> , 827 F. 3d 1042 (Fed. Cir. 2016) .....	passim
<i>Teva Pharms. USA Inc. v. Sandoz Inc.</i> , 135 S.Ct. 831(U.S., Jan. 20, 2015) .....	1, 5
<i>TriVascular, Inc. V. Samuels</i> , 812 F.3d 1056 (Fed. Cir. 2016) .....	passim

### STATUTES

35 U.S.C. § 101.....	passim
35 U.S.C. § 102(b) and 103.....	9, 17

### RULES

Fed. R. App. P. 2 .....	cover
Fed. R. App. P. 35/ Federal Circuit Rule 35.....	cover
Fed. R. App. P. 40/ Federal Circuit Rule 40 .....	cover



## TABLE OF ABBREVIATIONS

In addition to the abbreviations set forth in Appellant’s Opening Brief (at vii-viii) and Reply Brief (at vi), following abbreviations are used in this petition.

BRI	Broadest Reasonable Interpretation
UBRBr ____	Appellant’s Reply Brief at page ____
UBRBr ____,... ____	Appellant’s Reply Brief at page ____, and page ____
Opinion	Opinion, In re Bhagat, 2016-2525 (Fed. Cir. Mar. 16, 2018)
Op ____	Opinion, In re Bhagat, 2016-2525 (Fed. Cir. Mar. 16, 2018) at page ____
Op ____,... ____	Opinion, In re Bhagat, 2016-2525 (Fed. Cir. Mar. 16, 2018) at page ____, and page ____
WikipediaOils	<a href="https://en.wikipedia.org/wiki/Vegetable_oil#Production">https://en.wikipedia.org/wiki/Vegetable_oil#Production</a>
WikipediaNormann	<a href="https://en.wikipedia.org/wiki/Wilhelm_Normann">https://en.wikipedia.org/wiki/Wilhelm_Normann</a>
CBOp ____	“Federal Circuit Finds Composition of Matter Ineligible For Patenting,” March 27, 2018, at page ____ . Opinion by Courtenay Brinckerhoff.
MMOp ____	“In Re Urvashi Bhagat: One More Decision Denying Patent Eligibility of Nature-Based Product Claims,” March 29, 2018, at page ____ . Opinion by Marina Miller, PhD.
WWOp ____	“In re Urvashi Bhagat – The Slippery Slope of Natural Product Claims,” March 22, 2018, at page ____ . Opinion by Warren Woessner, PhD

All emphasis in this petition is added unless otherwise indicated.

**STATEMENT PURSUANT TO FEDERAL CIRCUIT RULE 35(b)(2)**

**I. Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States and the precedents of this court:** *In re Imes*, 778 F.3d 1250, 1251, 1254 (Fed. Cir. 2015); *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989); *TriVascular, Inc. V. Samuels*, 812 F.3d 1056, 1061-62 (Fed. Cir. 2016); *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999); *In re Alton*, 76 F.3d 1168, 1175-77 (Fed. Cir. 1996); *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995)(en banc); *Phillips v. AWH Corp.* 415 F.3d 1303, 1313-1314 (Fed. Cir. 2005)(en banc); *Teva Pharms. USA Inc. v. Sandoz Inc.*, 135 S.Ct. 831, 837 (2015); *Perricone v. Medicis Pharmaceutical Corp*, 432 F.3d 1368, 1375-79 (Fed. Cir. 2005); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988); *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1458-59 (Fed. Cir. 1984); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008); *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008) (en banc); *Rapid Litigation Management Ltd. v. Cellzdirect*, 827 F. 3d 1042, 1047-50 (Fed. Cir. 2016); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.

Ct. 1289, 1296-97 (2012); *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347, 2355 (2014); *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1063-68 (Fed. Cir. 2011); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* 133 S. Ct. 2107, 2119 (2013); *In Re Hans Oetiker*, 977 F.2d 1443, 1449 (Fed. Cir. 1992); *In re Garnero*, 412 F.2d 276, 278-79 (C.C.P.A. 1969); *Abbott Labs v. Sandoz*, 566 F.3d 1282, 1294 (Fed. Cir. 2009)(en banc); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131, 135 (1948); *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980); *In re Miller*, 418 F.2d 1392, 1396 (C.C.P.A. 1969); *Diamond v. Diehr*, 450 US 175, 188-9 (1981). Full court needs to reconsider why panel has issued an Opinion contrary to SCOTUS and this Court's numerous controlling precedents.

**II. Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance.**

- A. Is it proper to disregard structural limitation “intermixture” under § 101?
- B. Is it proper to require applicants to distinguish claimed products from products proven not to be products of nature under § 101?
- C. Is it proper to hold functional printed matter or instructions combined with alleged product of nature as product of nature under § 101?
- D. Is it proper to compromise innovation in nutrition and public health massively in favor of narrow patents, creating unfavorable economics for significant advancement in nutrition, preserving perpetual status quo?

**POINTS OF LAW OR FACT OVERLOOKED OR  
MISAPPREHENDED BY THE PANEL**

1. Contrary to *Imes* 1251, panel failed to review all claim construction *de novo*.

“Nothing in this case implicates the deference to fact findings.” *Imes*. UBBR39-40.

2. Contrary to *Zletz* 321-22, panel failed to construct “dosage” in plain words of the claims (Op5), and per Applicant’s interpretation of the term in prosecution.

“determination of amount to be administered and/or administration in prescribed amounts,” “controlled/specified amount to ingest at one time or regularly during a period of time.” (Appx5822-5823, Appx7050, Appx7858)

“Dosage” is limiting in Specification is an **INDISPUTABLE FACT**: Four tables (9-12) titled, “Lipid Dosages...” recite specific doses; ¶34, ¶36, ¶39, ¶47-49, ¶57, ¶59, ¶67, ¶89, ¶97, ¶103 refer to “dose/dosage” as specified amount for ingestion; ¶39 and examples 11-27 teach importance of dosage and dose effect in detail; ¶39 recites, “steady **dosage** within the optimal range”; ¶67 recites, “In addition to **amount**... relatively steady **dosages**”; and ¶103 recites, “omega-6 and omega-3 are anti-inflammatory in small **doses** and inflammatory in large **doses**.” PTOBr25-26, 34 concede “any orally acceptable form” refers to foods e.g., “a nutritional bar”, **not** amount. Specification, e.g., at ¶36, ¶68, and Appx2966 teach to combine foods to achieve specific “dosage” of fatty acids. UBBR41-44; UBRBR2-3, 28-29. To allege “dosage” is not limiting in view of above is simply **NOT** reasonable.

3. Contrary to *Imes* 1254 and *TriVascular* 1061-1062, panel overlooked (Op5) the plain meaning of the claims in context of surrounding words. E.g., independent

claims recite, “casings providing controlled delivery of the formulation to a subject,” not just “casing” (Op5); and Claim 65 recites, “A lipid-containing formulation, comprising a dosage of omega-6 (main clause)...wherein ...omega-6 fatty acids are not more than 40 grams (subordinate clause).” The panel improperly divorced main clause from the subordinate clause (Op8). Contrary to *Zletz* 321-22, panel overlooked Applicant’s prosecution interpretation. UBBr28-30, 41, 44-45.

“Casings...designed to contain one or more dosages of the formulation in order to control the delivery (e.g., substantially avoid inadequate or excess delivery and/or substantially control release.)” Appx7048, Appx7301-7302.

4. Contrary to *Cortright* 1358, panel overlooked BRI must be consistent with PHOSITA interpretation; panel’s interpretation of “dosage” and “casings providing controlled delivery of the formulation to a subject” (Op5) conflicts with PHOSITA testimony and meaning given to “dosage” in analogous patents. UBBr41-42, 44-45.

“The use of the word ‘dosage’ in the subject patent application is clearly directed to determination of amount to be administered and/or administration in prescribed amounts (see para 34, 39, 47, 48, 49, 57, 59, 89, 97, 101, and 103).” (Appx6485 ¶12, Appx6502 ¶12, Appx6519 ¶12)

“As part of the correct fatty acid delivery teaching the following is clearly evident from the specifications...c. Omega-6 dosage less than 40 grams (Tables 9, 10, 11, 12, 13).” (Appx6488 ¶17c, Appx6505 ¶17c, Appx6522 ¶17c.)

“In light of the specification of the subject patent application, ‘casing’ or ‘one or more complementing casings providing controlled delivery of the formulation’ in amended claims 65, 91, 129 and 130 means one or more casings that are designed to contain one or more dosages of the formulation in order to control the delivery (e.g., substantially avoid inadequate or excess delivery and/or substantially control the release). This is clear from, for

example, paragraphs 10, 34, 37, 60, 61, and Tables 16-19 of the specification.” (Appx7230 ¶5, Appx7239 ¶, Appx7320 ¶5)

5. Contrary to *Garnero* 278-79, *Abbott* 1294, panel disregarded “intermixture of lipids from different sources” as a structural limitation, and disregarded that the structure of claimed products is not fully known, too complex to analyze, and expected to have unnatural properties (#23-24 *infra*). UBBr52-53; UBRBr4-7.
6. Contrary to *Alton* 1177, panel inexplicably overlooked eleven PHOSITA testimonies. Appx3849-3869; Appx5702-5705; Appx6479-6529; Appx7228-7245; Appx7318-7327; Appx7356. UBBr43-45, 62, 65-66, 70, 75; UBRBr15, 21-22, 24.
7. Contrary to *Gulack* 1385, panel excised “providing controlled delivery of the formulation to a subject” (Op5-8) and “intermixture of lipids from different sources” (Op6-8), and mutilated “a dosage of omega-6...wherein ...omega-6 fatty acids are not more than 40 grams” from claims (Op5, Op8); “dosage” and “casings providing...subject” are acknowledged at Op10, but excised in analysis at Op10-12.
8. Contrary to *Gulack*, *TriVascular*, and *Cortright*, panel overlooked in-context interpretation of all claims consistent with PHOSITA interpretation. UBBr41-49.
9. Contrary to *Markman* 978, *Phillips* 1313-1314, and *Teva* 837, panel failed to determine “ordinary meaning” and “scope” of Mark *de novo* as a matter of law in **temporal context**. There is no implication of deference to fact finding here. Panel failed to read Mark’s “lipid” means lipid source that include non-lipids (col.5.11.59-62) and “source” means source of nutrients (col.4.11.19-20). Mark discloses

“omega-3 to omega-6 fatty acid ratio of approximately 4:1 to 6:1” in col.2.ll.37-38, **not** “omega-6 to omega-3 fatty acid ratio of approximately 4:1 to 6:1” (Op3); and “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” (col.4.ll.27-31), **not** “omega-6 [omega-3] fatty acid is present in a range of...” Op3-4. UBBR30-33, 60, 62-65. Contrary to *Perricone* 1376-79, panel assumed something Mark did **NOT** disclose and overlooked Mark does not necessarily function as claimed.

**10.** Contrary to *Perricone* 1376-79 and *Elsner* 1127, panel overlooked Mark **does not enable** “dosage **of** omega-6 and omega-3” with any example, which is different among children 1-10 years old (O6 1-10g for infants; Appx71-72) as PHOSITA testified (Appx7324-7325). Op4 admits “Mark’s daily dosage **may** include 1,000 mL, as the table in column 4 refers to g/1,000 mL,” but to anticipate Mark must **necessarily, not may**, function as “dosage”, which it doesn’t, stating no toxicity even at 2500 kcal/day (O6 16.7g for infants) (col.5.ll.10-12). UBBR60-62. Contrary to *Alton* 1177, panel overlooked PHOSITA testimony. UBBR21-22.

**11.** Contrary to *Nidec* 1274, *Robertson* 745, *Lindemann* 1458-59, and *Net Money* 1369-71, panel overlooked Mark does not disclose the part-to-part relationship “arranged as in the claim”. UBBR17-18, 23-26, 66-67. In *Nidec* 1274, Judge Taranto of this panel ruled “*Kennametal* does not permit the Board [or this

panel] to fill in missing limitations simply because a skilled artisan would immediately envision them.” Mark recites conflicting ratios scattered over the disclosure, incomplete lipid profiles in inoperable tables in columns 4 and 6, does not necessarily function as “dosage” or “intermixture.” Contrary to *Gulack* 1385, panel mutilated claims, contrary to *Rijckaert* 1534 and *Fine* 1075 panel optimized Mark, and contrary to *Oetiker* 1445 panel overlooked preponderance of evidence *Mark* discloses incomplete data to rule anticipation. UBBR62-66; UBRBR17-26.

**12.** The panel overlooked to review several claims under Mark, e.g., independent Claims 129 and 130, and dependent claims 68, 69, 73, 96, 98, 100, 142, and 144. Op4 misapprehends, Claim 82 (dependent on 65) and independent Claim 91 are not rejected under Mark by PTO. Decision38. UBBR67-68; UBRBR26.

**13.** Contrary to *Zletz* 321-322, despite acknowledging “prosecution disclaimer of...olives and walnuts” (Op7), panel overlooked this **UNDISPUTED FACT** in ruling anticipation by WebOlives/WebWalnuts (Op7-9). UBBR69-71.

**14.** Contrary to *Nidec* 1274, *Robertson* 745, *Lindemann* 1458-59, and *Net Money* 1369-71, panel overlooked WebOlives/WebWalnuts do not disclose the part-to-part relationship “arranged as in the claim.” WebOlives/WebWalnuts are **INDISPUTABLY** not anticipatory; neither discloses “an intermixture of lipids from different sources,” let alone “dosage”/“casings...subject.” Contrary to *Alton* 1175-1177, panel overlooked PHOSITA testimony holds the references do



not teach “dosage” of omega-6/omega-3, stating, “The concentration of nutrients per cup of olives in the reference fails to disclose such predetermined/ prescribed amount to quantify the olives for a person to eat.” Anticipation law “does not permit the Board [or this panel] to fill in missing limitations,” *Nidec* 1274, which PHOSITA do not even envision. Appx6484-6485; Appx6501-6502; Appx6518-6519; Appx7234-7235; Appx7243-7244; Appx7325-7327. The references do not necessarily function as dosage at omega-6 to omega-3 >4:1; they teach random consumption of food mixtures (Appx6966-6967, Appx6981), wherein overall ratio of omega-6 to omega-3 is around 2:1 (Appx6142). UBBR68-76; UBRBR27-31.

**15.** Panel overlooked rebuttal to alleged anticipation of dependent claims (Op9) by WebOlives/WebWalnuts; Appx7716-7718; Appx7721-7724; Appx7901-7906; Appx8017-8021; Appx8031-8037; UBBR76-78; though not needed (#14 supra).

**16.** Contrary to *Bilski* 951 and *Rapid* 1047, the panel overlooked to review § 101 patent eligibility *de novo*, as a question of law **without deference**. UBBR40.

**17.** Contrary to controlling SCOTUS rulings *Mayo* 1296-97 and *Alice* 2355, and *Rapid* 1047, the panel overlooked **§ 101 inquiry is over at “step one”**; despite acknowledging (Op10) the features “dosage” and “casings providing controlled delivery” change functionality of omega-6 and omega-3, as they occur in nature, panel overlooked the features in eligibility analysis at Op10-12 and that they do add “significantly more” to natural products. UBBR51-53; UBRBR3-4, 12-14.

**18.** Contrary to controlling SCOTUS rulings *Mayo* 1296-97 and *Alice* 2355, and *Rapid* 1050, “**step two**” of § 101 inquiry (though not needed; #17 supra), the panel overlooked **extremely important inventive concept** is present in the claims as a whole and vast immediate and downstream public health benefit is expected from the solutions because the claimed subject matter is critical for health yet poorly understood. Prior art overwhelmingly teaches omega-6 to omega-3 ratio <4:1, omega-6 <10% of total fat and <6.67g/day, and teaches suppression of omega-6, which is deleterious; lipids are unpredictable in natural sources; 99% of public does not know the ABCs of lipids; due to all this public health suffers at large scale; 117 million people live with associated diseases; ~million die/year; and ~\$3 trillion/year is spent on the related diseases. UBBR3-10, 54, 79-81; UBRBR1-4.

**19.** Contrary to *Diehr* 188-9, *Rapid* 1048, and *Classen* 1068, panel has failed to consider **claims on the whole are patent eligible**. Claimed combination of “formulations”, “dosage of omega-6 and omega-3”, “casings providing controlled delivery of the formulation to a subject”, “intermixture of lipids from different sources”, and the extremely important inventive concept is sufficient to confer eligibility. No further analysis/evidence is needed. UBBR3-9, 36, 54; UBRBR12-16.

**20.** Contrary to controlling SCOTUS ruling *Mayo* 1295-97, and this Court in *Classen* 1063-68 and *Rapid* 1047-50, each holding **§101 separate from §§102 and 103** that if plain language of the claims is not directed to patent ineligible concept,

§101 inquiry is over and the claims pass §101 threshold, the panel affirmed §102-type analysis in §101 eligibility (Op10-12) though Claims 65, 91, 129, and 130 do not recite the cited oils. Dependent claims 142-143 (Appx7743-7744) illuminate claimed “intermixture” can be free fatty acids or other forms pointing to distinctions over a single source. UBBr36, 45-46. Thus, claimed products can simply be “dosage” of omega-6 and omega-3 in “casings providing controlled delivery of the formulation to a subject,” whereas oils contain 100s of components.

**Overwhelming evidence is on record minor lipid manipulations confer marked changes on starting product and changes in omega-6/omega-3 ratios affect their properties.** UBBr53; #23-24 *infra*. The panel improperly held the claims indistinct from oils, not recited in claims. UBBr54-56; UBRBr7-10.

**21.** Contrary to *Zletz* 321-22, despite acknowledging prosecution disclaimer to “single source” at Op9, panel overlooked it in eligibility analysis. Op10-12.

**22.** Contrary to controlling SCOTUS ruling *Myriad* 2119, panel overlooked a variety of oil “by process” was also disclaimed. Thus, by definition claimed product is necessarily distinct from “single source”. UBBr36, 45-46. UBRBr8.

**23.** Contrary to *Alton* 1177, panel overlooked PHOSITA testimonies that claimed mixtures have properties not found in nature. UBBr45-46. UBRBr15-16.

“The only way to obtain [claimed mixtures] comprising omega-6 and/or omega-3 fatty acids is to either mix plant/animal tissue itself or extract omega-6 and/or omega-3 fatty acids in free fatty acid form and then mix them. Either way the physical and chemical properties of the resulting

mixture will be significantly and markedly different from what occurs in nature because composition of triacylglycerols versus free fatty acids will change, and composition of prooxidants versus antioxidants will change [citing *Chaiyasit* et al. Appx6650-6668, and *Chen* et al. Appx6669-6685].”

“Lipid sources, such as oils, butters, nuts, seeds, and herbs have 100s of compounds. Therefore, when lipids from different sources are intermixed, the resulting mixture will necessarily have different physical and chemical properties, as discussed above. A hypothetical mixture of lipids from Source A and lipids from Source B, where the resulting mixture has exactly the same properties as Source A or B is first practically impossible, and second, if possible, it would be an extremely complex scientific endeavor. There would be no motivation for a skilled artisan to intermix lipids from Source A and Source B to achieve exactly the same properties as Source A or Source B in the resulting formulation.”

Appx6493-6494¶24; Appx7230-7231¶7-8; Appx7239-7241¶7-8; Appx7320-7321¶6-8.

**24.** Contrary to *Oetiker* 1449, panel overlooked **preponderance of evidence** including five scientific publications (Appx6650-6707) and four PHOSITA testimonies (#23 supra) that in nature omega-6/omega-3 always occur with certain phytochemicals in configurations necessarily altered by manipulations, e.g. storing, extracting, mixing, encasing... E.g., *Gotoh* (Appx6696) evidences even changing ratios of omega-3 and omega-6 affect each other in oxidative stability. UBBR12, 16, 53, 59; UBRBR15-16. Op11-12 “Applicant has not shown [evidence]...” is false.

**25.** Contrary to SCOTUS ruling *Myriad* 2119 and *Chakrabarty* 309-10, despite accepting at Op10 walnut/olive oil are not “natural products” panel overlooked it in analysis at Op10-12, still comparing claims to WebOOil/WebWOil, which are A) disclaimed, B) not natural products as oils, and C) patented with unnatural cited

instructions present in the claims. *Gulack* 1385; *Miller* 1396. Op12 “limitations do not distinguish the claimed products and compositions from those shown in the cited references,” overlooks references are NOT natural. UBBr54-57.

26. Contrary to *Myriad* 2119, panel overlooked Claims 102, 107, and 109 composition is structurally distinct from products of nature **on the face**.

“Examiner has admitted ‘*Relative to the compositions of Claims 102, 107, and 119, there does not appear to be a naturally occurring counterpart to all of these elements present together in the claimed combination*’ (Appx7776)...Claim 102 recites, “ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1” [] neither WebWOil (mono:poly 1:2.8) (Appx6985) nor WebOOil (mono:poly 7:1) (Appx6970) meet the limitation, and similarly tables 7-20 in Claim 107 and 119 [mono:poly 1:1.7-5:1] are outside the scope of WebWOil/WebOOil (Appx7961-7962). UBBr34; 58-59.

27. Contrary to *Myriad* 2119, panel overlooked Claim 128(1) composition is structurally distinct from natural products **on the face**, and mixing almonds/peanuts/coconut with claimed omega-6/omega-3 ranges alters use. Appx60-64.

The Examiner has not met his burden of proof to provide evidence that almonds, peanuts, and/or coconut meat meet the limitations “...wherein... omega-3 fatty acids are present at 0.1% to 30% by weight.” Table 2 of Appellant’s specification and Scientific Psychic [Appx6054-6055] evidence 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%...“Walnut Oil” evidences that its concentration of omega-3 is over 13% and omega-6 is over 58%...“Olive Oil” evidences that its concentration of omega-3 is over 0.7%. Appx7694; Appx7879-7880. UBBr16-17, 49, 59.

28. Panel failed to review many dependent claims under § 101. UBBr53, 58-59.

29. Additional oversights are annotated on the copy of Opinion in Addendum.

## ARGUMENTS IN SUPPORT OF REHEARING

The Opinion is contrary to large body of law and overlooks most of Appellant's arguments (UBBr 81 pages and UBRBr 41 pages) and evidence (1421 pages of appendix showing opposite teachings including in alleged anticipatory references and 10 written (Appx3849-3869; Appx5702-5705; Appx6479-6529; Appx7228-7245; Appx7318-7327) and one oral (Appx7356-7357) PHOSITA testimony) that combination of claimed elements "dosage of omega-6 and omega-3", "casings providing controlled delivery", and "intermixtures" in defined "ratios" are not natural, are not disclosed in prior art, are not obvious, and represent an extremely important invention. The panel overlooked at least the 28 points cited supra. For example, Op4 admits Mark may, but not necessarily, functions as "dosage," but contrary to *Perricone* 1376 disregards this in ruling anticipation. Op7 admits Appellant disclaimed compositions "from single source", but then fails to explain at Op8-9 why undisputed "intermixtures of lipids from different sources" are anticipated by WebOlives/WebWalnuts. Further, Op10 admits, "the claimed limitations of 'dosage' and 'casings providing controlled delivery' 'do not exist as natural products'" but then fails to explain why claimed products including the features are unpatentable at Op10-12. The Opinion renders a decision without explanation, violating Court's Operating Procedure #10(3). *Herrmann* 600 and *Soni* 751, hold failure to answer an argument is tantamount to conceding there is

no answer. Several esteemed patent attorneys and PHOSITA, unaffiliated with Appellant, also find the Opinion to be deficient, see below and addendum for detail.

“For the most part, the court states that each PTAB finding was “correct” without explanation... The Federal Circuit acknowledged the Applicant’s arguments that ‘casings providing controlled delivery’ ‘do not exist as natural products,’ but did not address those arguments in its § 101 analysis.” CBOp2.

“The Applicant offered a number of arguments for patent eligibility but the court agreed with the Board...the analysis under section 102 was [] applied to the analysis under Section 101. However, as explained by the Supreme Court in Mayo, the analysis under section 101 is separate from the patentability analysis under sections 102 or 103. Here, the main claim appears to include limitations that are not nature-based or that add “significantly more” to the nature-based product, e.g., the limitations ‘dosage’ and ‘casings providing controlled delivery’ are not found in nature and natural counterpart products and the claimed mixture ‘avoids concentrated delivery of specific phytochemicals that may be harmful in excess.’ MMOp1-2.

“In fact, the main claim used as representative do contain limitations that are not nature-based products, and impart at least functional structure to the claims. The claims require that the composition comprised a dosage of the fatty acids, contained in ‘one or more complementing casings providing controlled delivery of the formulation to a subject...’ Applicant’s controlled release dosage form does not exist in nature and changes the characteristics of the acids as they occur in their natural state, in walnuts or olives...the need to distinguish the products from the prior art is not even a requirement... Applicant deserved better than the courts use of the ‘naked’ anticipation rejection to meet the standards for a judicial exception under s.101.” WWOp2-3.

Thus, patent attorneys and PHOSITA, unassociated with Appellant, agree,

A. the panel regurgitated and rubber-stamped PTO improprieties;

B. the panel’s holdings are contrary to SCOTUS and this Court’s precedents;

C. “dosage” and “casings providing controlled delivery” are limiting and that they “impart at least functional structure to the claims”; and

D. the panel disregarded Appellant’s submissions and Appellant deserved better than the panel’s treatment.

**Appellant submitted an intense appeal, with evidence of mass confusion, opposite teachings including from cited art, and large-scale public suffering (~117 million people) and national cost (~\$2.6 trillion/year). UBBr3-10, 54, 79-81; UBRBr1-4. In reply, the panel issued an opinion overturning a large body of binding law, even SCOTUS, labeled “non-precedential!” It is illogical.** Appellant pleaded PTO abused the Appellant and millions of Americans who might have benefited from the solutions (UBBr8-9, 38, 77, 80-81; UBRBr1-4); now the panel has abused the Appellant (and the millions of Americans), **applying more stringent—contrary to law and disregarding arguments and evidence—rather than less stringent standards applied to *pro se*. *Haines* 520; *Baldwin* 164.**

The disjointed evasive Opinion is uncharacteristic and unexpected of this esteemed panel (known to take positions as taken by Appellant, Judge Newman authoring *Zletz*, dissenting *Abbott*; Judge Taranto ruling *Nidec*; Judge O’Malley authoring *TriVaschuar*), and the 2nd highest seat of justice in United States of America the “most advanced country.” If such opinions can be issued at this level then inventors can have no confidence in justice. The case should be reheard.



## ARGUMENTS IN SUPPORT OF REHEARING EN BANC

### I. Opinion Conflicts With Binding Precedents from SCOTUS and this Court

The Opinion conflicts with binding precedents from SCOTUS and this Court cited supra and in UBBR and UBRBR. The opinion in principle invalidates 1000s of patents drawn to “new and useful...composition of matter” as per 35 USC §101, for example, US7759507B2, US8282977B2, and US9034389B2. The panel circumvents this by being evasive and issuing “non-precedential” opinion, but A) the Appellant will petition the Opinion be made precedential because it attempts to alter the existing rules of law, establishing new rule of law, creating conflict within this Court’s and with SCOTUS precedents (IOP#10(4)), and B) the non-precedential Opinion will be cited by parties in litigation. Indeed several attorneys practicing at this Court find the Opinion to be improper (CBOp, MMOp, WWOp). Court’s docket will soon be burdened with more appeals on same issues, as litigants will be less likely to settle before an appeal when both can cite cases in their favor. Opinion evades adjudication and is confusing. For example, OP9-10 without adjudicating independent claims 65, 91, 129, and 130, drawn to “dosages” and “casings providing controlled delivery of the formulation” that do not occur in nature, moves on to claims 128, 102, 107, and 119, which were also not adjudicated (#26-27 supra). Parties are more likely to engage in lawsuits when law is unclear. The Opinion compromises judicial efficiency and fairness of the process.

## II. This Appeal Requires Answers To Precedent-Setting Questions Of Exceptional Importance

### A. Is it proper to disregard structural limitation “intermixture” under § 101?

The term “intermixture” is capable of construction as a structural limitation.

*Garnero* 279. Further, product claims comprising such terms are patentable when structure of claimed products is not fully known, too complex to analyze, and expected to have distinct properties (#23-24 *supra*). *Abbott* 1294. Mutatis mutandis this law applies under § 101.

### B. Is it proper to require applicants to distinguish claimed products from products proven not to be products of nature under §101?

Appellant has submitted indisputable evidence that walnut/olive oils cited under §101 are not products of nature per SCOTUS rulings. UBBr54-56; UBRBr12.

“Oil[s] are man-made from products of nature, like walnuts or olives, through **non-natural manufacture, transforming** walnuts/olives into oils and pulp/nut flours, after which the products acquire **different names** (oil/pulp/nut flour), **character** (physical and chemical properties), and **use** (cannot germinate and nutritive worth is different), therefore are patent-eligible. *Funk*; *Chakrabarty*; *Myriad*.” UBBr55. “Even the amount/concentrations of omega-6 and omega-3 are not the same in walnut/olive oil as compared to walnuts/olives.” UBRBr12.

Then, is it proper to hold, “limitations do not distinguish the claimed products and compositions from those shown in the cited references [oils]” under 101? Op12.

### C. Is it proper to hold functional printed matter or instructions combined with alleged product of nature as natural product under §101?

This Court has repeatedly ruled a claim directed to a combination of printed matter having a functional relationship to the subject is patentable subject matter

and is properly evaluated under §§102 and 103. *Miller* 1396, *Gulack* 1385. Mutatis mutandis, cited reference providing printed instructions—“serving” of WebOOil/WebWOil—teaches “serving” having a functional relationship to the oil, which in combination with the oil (even if oils were held to be a product of nature) is patentable subject matter. Therefore, the combination cited from WebOOil/WebWOil is not product of nature (which in fact are patented products, U.S. Patent 7,620,531). UBBr56. Then, is it proper to hold “claim limitations do not distinguish the claimed products and compositions from those shown in the cited references [citing combination of oils with instructions] under 101?” Op12.

**D. Is it proper to compromise innovation in nutrition and public health massively in favor of narrow patents, creating unfavorable economics for significant advancement in nutrition, preserving perpetual status quo?**

This dispute arose because PTO compromised instant innovation holding narrow mixtures of certain oils/nuts/seeds (Claim 128(2)-(7); Appx7790) allowable but not “dosages of omega-6 and omega-3,” “casings providing controlled delivery” and “intermixture of lipids from different sources” in defined ratios. Appellant declined because such practice, A) has already caused great harm to public health; B) is stalling meaningful advancement in nutrition; and C) is unlikely to generate investor interest in backing this innovation, which requires extensive public teaching therefore is a risky investment. The panel improperly affirmed PTAB using the same tactics, excising terms and context from claims and mutilating

claims, mutilating the disclosure, and disregarding prosecution avowals/disavowals, PHOSITA testimony, scientific publications on record, the extremely important inventive concept, Appellant's briefs, and this Court's and SCOTUS precedents.

Claimed inventions solve a critical long-felt unsolved problem of correct lipid delivery benefitting vast number of Americans, particularly the impoverished (Appx7911-7913). Most chronic diseases are associated with mismanaged lipid intake; and lipid intake affects immunity and daily well-being. Dosages of omega-6, omega-3, other fatty acids, lipid vitamins, and lipid phytochemicals are critical for health, where too much or too little both have serious health consequences, and lipid intake has to be relative to other lipids because lipids can materially affect the activity of each other. Yet, there continues to be mass confusion in the art and teachings opposite of instant claims. In particular, prior art, including the cited art, overwhelmingly disparages omega-6, which is a critical nutrient, and teaches low intake of omega-6 relative to other lipids and suppression of omega-6 activity—teaching omega-6 to omega-3 ratio less than 4:1 or omega-6 is less than 10% of total lipids—which '034 Application teaches can be harmful. **There has never been a nutrient more poorly understood, more vehemently, publically, and widely disparaged and debated as omega-6.** UBBr3-9. Public is still misinformed, e.g., “Omega-6 fatty acid” Wikipedia, the most widely accessed publication, still fails to teach dosage of omega-6 and role of minor lipids.

The confusion is partly because the patent practice disfavors nutrition, forces narrow nutrition patents, and favors structurally altered molecules (Appx7777).

Narrow patents are less desirable in nutrition because they create confusion, e.g., by touting of nutrients out of context (marketing spins emphasizing protected compositions of oils, nuts and seeds by one party, and opposite spins on alternate compositions or isolated fatty acids from competition), and by compromising clear public education. This has already led to dangerous imbalances in nutrition (Appx7910), e.g., hype of omega-3 and olive oil. Then public views all solutions suspiciously and “snake oils” are coined. The problem precisely is that dosages of important lipids have been out of focus, but types of oils or fatty acids have been the focus. **Consequently, confusion perpetuates and nutritional problems affecting fundamental bodily structure and function are never solved.**

No meaningful advancement in nutrition and prevention can ever be expected under such patent practice. Purpose of patent is advancement, not ineffective token patents. SCOTUS and this Court have repeatedly held advancement in the art to be paramount. *Chakrabarty* 307, *Mayo* 1294, *Myriad* 2114, *Alice* 2355, *Rapid* 1050.

“The authority of Congress is exercised in the hope that ‘[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.’” *Chakrabarty* 307.

Lipid delivery fundamental to health has not materially advanced since the

invention of food oils ~6000 years ago (WikipediaOils). Periodically, certain fatty acids or oils or low-fat teachings have been hailed, only to reverse a few years later (Appx2771-2774; Appx4733-4739). To date random oils are randomly added to foods, evidenced by WebOOil/WebWOil listing ~12 of 100s of potent components in **batch** of oils (Appx6650-6707; #23 supra) **without** guidance on potent minor lipids components, **without** guidance that nutrient concentrations may be significantly **different** in other batches of the oils (UBBr51-52), and **without** guidance on daily dosage of omega-6 and omega-3. Oil making has advanced but delivery of oil for ingestion by subjects is still archaic because incentives are misaligned. Without proper patent protection, economics are unfavorable for significant innovation in the art. It is extremely expensive to teach public and implement the solutions because of confusion and noise. Therefore, investors shy away from risking capital in the absence of significant patent protection and term.

Patent system is asking for too much from public. Public has been paying for lipid patents for at least 100 years since hydrogenated fats patent of 1902 (WikipediaNormann), but the problem of healthy lipids for public is still not solved. Rather structurally altered molecules (hydrogenated fats) favored by patent practice (Appx7777) caused public suffering for ~100 years (Appx7913). Such molecules are likely to cause more public health havoc, because no matter what new molecules are designed, public still has to depend on food for nutrition, which

create the foundation of health or disease.

Therefore, in nutrition neither piecemeal patents nor structurally altered molecules should be favored. UBBR79-80.

Appellant's claims significantly improve over the prior art/products of nature [even oils] by limiting excess/inadequate lipids, by providing specified amounts and ratios of omega-6 and omega-3 for ingestion that were not known in the prior art, by controlling omega-6/omega-3 ratio relative to total lipids, and by controlling delivery of the formulation to a subject using casings. UBBR50-54, 79-80. As a whole, Appellant's claims correct an 80-plus year old misapplication of lipid consumption for animal/human health. UBRBR13.

It is too complex for public to formulate lipids due to the confusing teachings, unpredictability of lipids in natural sources, and that 99% Americans cannot even name lipids (Appx7910). Further, lipid requirements differ for members of the family (by body size, hormones...) adding to the complexity. 117 million Americans live with chronic diseases costing ~\$2.6 trillion in annual health care. During the **nine** years the '034 Application has been pending, **13.6 million (1.5 million in ~2 years the application has been pending at this Court) Americans have died of associated diseases** (<http://www.cdc.gov/nchs/fastats/deaths.htm>). Some of those lives could have been saved by the inventive solutions. UBBR8-9.

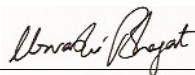
The panel has disregarded evidence in Specification, Joint Appendix, and PHOSITA testimony that the patent practice is subjecting public to unwarranted treatments causing suffering (UBBR8-9). Specification provides ~20 examples (Appx82-97), where medical system subjected (or would subject) the individual to

drugs, devices, expensive treatments, and pain and suffering, even though a large part of the suffering could have been abated by correcting the lipid delivery. If treatments are favored and made more financially rewarding by the patent practice, **then such patent practice is organized crime against humanity, then we should expect continuation in escalating healthcare costs and public suffering.**

Claimed inventions solve an 80-year old known long-felt critical unsolved problem (UBBr9), albeit the issues involve fundamental biochemistry so the problem has existed for 1000s of years. The innovation would also set humanity on a course for long-term solution to several downstream problems (Appx7914). Not granting appealed claims is tantamount to taking the position public should be kept confused, ill, and on drugs, and this 1000s of years old problem should continue into perpetuity. Ultimate purpose of research is to enhance human condition. If the solutions devised cannot be fully applied for public benefit then the patent policy is obstructing the very purpose of research. The Opinion is contrary to Congress' choice of expansive terms "composition of matter" in § 101 to "be given wide scope" and "ingenuity should receive a liberal encouragement." *Chakrabarty* 308.

### CONCLUSION

Therefore, this Court sitting *en banc* should rehear this case.



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**Urvashi Bhagat, Pro se Appellant**



# **ADDENDUM**

Note: Emphasis in the body and annotations in side columns are added by the Appellant. The #signs refer to points of law or fact overlooked or misapprehended by the panel and discussed in the petition.

NOTE: This disposition is nonprecedential.

## United States Court of Appeals for the Federal Circuit

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IN RE: URVASHI BHAGAT,  
*Appellant*

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2016-2525

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

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Decided: March 16, 2018

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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.

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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”) affirm-  
ing 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”).<sup>1</sup> We affirm the Board’s decision.<sup>2</sup>

#### 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.

Other claims add specificity of amounts or ratios, additional ingredients, sources of the lipids, and delivery methods. The examiner held all of the claims unpatenta-

Panels has failed to consider full background--the opposite teachings, mass confusion, public suffering--and advancement potential in the art and extremely important inventive concept in the claimed inventions. Prior art overwhelmingly teaches omega-6 to omega-3 ratio <4:1 and omega-6 <10% of total fat and <6.67g/day and and teaches suppression of omega-6, which is deleterious. Appellant submitted 14 pages of BACKGROUND because of mass confusion in the art UBBR3-9, 54, 79-80, and UBRBr1-4, calling attention to numerous scientific publications, PHOSITA testimony, and the cited art as evidence of opposite teachings in the art and public suffering in 1421-page Joint Appendix, which the panel has overlooked. See #18 and pages 18-23 in the Petition for Rehearing.

<sup>1</sup> *In re Bhagat*, Appeal No. 2016–004154 (P.T.A.B. Apr. 15, 2016) (“Board Op.”).

<sup>2</sup> Applicant’s motions to expedite are denied as moot.

ble 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.

Nothing in this case implicates deference to fact finding. It is simply a matter of reading the publications. Claims and prior art construction, and eligibility determinations is a matter of law that the panel has a duty to review DE NOVO without deference. Excising limitations from claims is simply not reasonable. See #1-9, 16, and 19.

## 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 intra-

There is no implication of deference to PTAB’s findings here, this is a question of interpretation of prior art, which is a legal question that panel has to review DE NOVO as per law, and it simply requires reading Mark. Panel failed to interpret Mark’s “lipids” de novo as per law, which in Mark means oils, which contain non-lipids. Mark discloses “omega-3 to omega-6 fatty acid ratio of approximately 4:1 to 6:1” in col.2.ll.37-38, i.e., “omega-6 to omega-3 fatty acid ratio of approximately 1:4 to 1:6” and SOURCE of omega-6 (e.g. an oil) is present at 4-6% of calories NOT omega-6 is present at 4-6% of calories in col.4.ll.27-31. See #9.

PANEL HAS FAILED TO CONSTRUCT CLAIMS DE NOVO AS PER LAW, AND OVERLOOKED UBBR40-49 WHERE CLAIM CONSTRUCTION ASSISTANCE WAS PROVIDED PROACTIVELY.

venously 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

PHOSITA have testified that Mark does not enable dosage of omega-6 and omega-3. See #10.

This is hindsight optimization. Mark did not disclose min/max amounts of n6/n3. See #9. Mark does not necessarily function as “intermixture of lipids from different sources.” PHOSITA have testified on record that Mark’s Table in col. 6 is NOT operable. See #11. Panel has misapprehended, PTO did not reject claims 82, 91 and dependent claims under Mark by PTO. See #12.

Under anticipation law Mark has to necessarily function and enable dosage of omega-6 and omega-3, “MAY” is not sufficient, specially in light of the fact that temporal art does not understand correct “dosage of omega-6.” Panel disregarded PHOSITA testimony. See #10

Panel failed to address claims 129 and 130 and several others claims under Mark. See #12.

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.

Panel has overlooked that Mark has NOT taught and enabled dosage, which is different among children 1-10. See #10.

Board's Op at 11 pertains to eligibility under § 101 not to Mark, panel is confusing § 101 with § 102.

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.

NO. In Nidec Judge Taranto ruled, "[anticipation law] does not permit [] to fill in missing limitations simply because a skilled artisan would immediately envision them." Here PHOSITA do not even envision the claimed limitations. See #9-12. "Dosage" IS A NEW USE.

PANEL FAILS TO CITE ANY LAW WHY INDEPENDENT CLAIMS ARE ANICIPATED BY MARK.

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.

A. Specification does NOT state "these claim elements" are not limiting. Specification provides five tables with "dosages" by age and gender and 17 examples where it repeatedly emphasizes dosage of omega-6 is critical and prior art has failed to understand dosage and dose effect (changing effect by dose level) of omega-6. Under such disclosure there is NO JUSTIFICATION for alleging "dosage" or "casings providing controlled delivery" are not limiting in Specification.

"ANY ORALLY ACCEPTED FORM" IN SPECEFICATION REFERS TO TYPE OF FOOD NOT AMOUNT OR "DOSAGE." #2.

Panel has overlooked that Claim 78 recites “omega-3 withdrawal ... increase is gradual” the limitations are missing from Mark. Appx7707, Appx7893. "[anticipation law] does not permit [] to fill in missing limitations simply because a skilled artisan would immediately envision them." Nidec.

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

B. In prosecution the inventor and PHOSITA gave testimony to the interpretation of "dosage" and "casings providing controlled delivery".

See #2-4. Frankly, the allegations are so improper that they are unfitting for 2nd highest seat of justice in USA, the "most advanced country" in the world.

Mark's typical feeding regimen, and does not overcome the Board's finding of prima facie anticipation of claim 78 by Mark.

PANEL HAS  
OVERLOOKED TO  
REVIEW AT LEAST  
CLAIMS 129, 130, 68, 69,  
73, 96, 98, 100, 142, 144  
UNDER MARK. SEE #12  
AND UBBR67-68.

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

It is improper to even discuss olives and walnuts. OPINION SHOULD JUST SAY:

A. olives and walnuts were disclaimed in prosecution; see #13; and

B. neither is "formulation" let alone "intermixture of lipids from different sources" in "casings providing controlled delivery of the formulation to a subject;" see #14; and

C. PHOSITA have testified that the references do not teach “dosage” of omega-6/omega-3; see #14. THEN FURTHER DISCUSSION IS NOT NEEDED.

Discussion of Claim 136 is insincere and deflects the point above.

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.

See points made above under #13-14. Bottom line is that olives/ walnuts were disclaimed and olives/walnuts do not disclose "intermixture of lipids from different sources" and do not necessarily function in accordance with the claims. They teach random consumption of olives and walnuts and mixing them with foods to lower omega-6 to omega-3 ratio below 2:1. UBB74.

PANEL ACKNOWLEDGES THAT APPLICANT DISCLAIMED SINGLE SOURCE SUCH AS OLIVES AND WALNUTS, THEN DISREGARDS THE UNDISPUTED FACT IN FURTHER ANALYSIS. #13.

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

PHOSITA testimony disagrees that serving size in olives is a dosage. See #14.

Claim 65 recites, "A lipid-containing formulation, comprising a dosage of omega-6 (main clause)... wherein ...omega-6 fatty acids are not more than 40 grams (subordinate clause)." The panel divorced main clause from the subordinate clause. Disregarding context of surrounding words is simply NOT reasonable. Even without the subordinate clause, "dosage" in MAIN CLAUSE cannot be excized. #2-4, 7-8.

References provide catalog of LARGE number of parts. Considering that relevance of total lipids in temporal art is not understood, part-to-part teaching is critical, which the references fail to provide. UBB76; UBRBr30. #14.

Panel has disregarded Appellant's rebuttal to Decision on claims 68, 73, 74, 77, 78, 96-98, 102, 107, 118, 119, 121, 122, 124, 128(1), 137, 140, 141. UBB76-77. Panel insincerely regurgitated PTAB Decision.

PANEL FAILS TO CITE ANY LAW WHY INDEPENDENT CLAIMS 65, 91, 129, AND 130 ARE ANTICIPATED BY WEBOLIVES/WEBWALNUTS.

EXAMINER AND PTAB  
MUTILATED CLAIMS AND  
SPECIFICATION, AND  
DISREGARDED  
APPELLANT'S ASSERTED  
INTERPRETATION OF  
TERMS ON RECORD,  
PHOSITA TESTIMONY, AND  
RECONSTRUCTED CITED  
ART TO RULE  
ANTICIPATION. PANEL HAS  
AFFIRMED THE SAME. THE  
COURT HAS NOT  
FUNCTIONED AS APPEAL  
COURT. IT HAS RUBBER  
STAMPED PTAB.

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).

Panel overlooked the rebuttals  
Appx7716-7718;  
Appx7721-7724;  
Appx7901-7906;  
Appx8017-8021;  
Appx8031-8037;  
UBBr76-78;  
though not necessary because  
independent claims are  
INDISPUTABLY  
not anticipated by the references.  
See #14-15.

II

SECTION 101

PANEL HAS FAILED TO  
REVIEW §101 DE NOVO  
AS PER LAW. #16.

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

PANEL ACKNOWLEDGES  
APPLICANT  
DISCLAIMED SINGLE  
SOURCE PRODUCT OF  
NATURE, THEN  
DISREGARDS THE FACT  
IN FURTHER ANALYSIS.  
#21-22.

A. “dosage” and “casings  
providing controlled delivery”  
CHANGE FUNCTIONALITY of  
omega-6 and omega-3, as they  
occur in nature, and DO add  
significantly more to nature. §101  
INQUIRY IS OVER AT THIS  
POINT. "Step one" Mayo. #17.  
B. Claims are drawn to an  
extremely important inventive  
concept which confers eligibility.  
"Step two" Mayo. #18.  
C. Claims on the whole are patent  
eligible. #19.  
D. Claims do not recite any oil.  
No requirement under §101 to  
show distinction over product not  
recited in claims. #20.  
E. Single source oil including by-  
process was disclaimed. #21-22.  
F. Oils are not products of nature.  
G. Instructions cited from  
references are not products of  
nature. #25.

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.

Preponderance of evidence as scientific publications and four PHOSITA testimonies have been submitted that claimed mixtures have properties that do not occur in nature. #23-24.

PANEL ACKNOWLEDGES "DOSAGE" AND "CASINGS PROVIDING CONTROLLED DELIVERY" DO NOT EXIST IN NATURAL PRODUCTS AND THEN DISREGARDS THE FACT IN FURTHER ANALYSIS #17.

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.

Panel moves on to Claims 128, and others without concluding patentability of independent claims 65, 91, 129, and 130.

### *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.”).

A. Decision 37 did not make the statements panel has made here. Decision alleged claim 128(1) is a product-by process claim drawn to olive/walnut oil. Appellant asserted almonds, peanuts, and/or coconut meat are compositionally different from olive/walnut oil.

B. Mixing almonds/peanuts/coconut with omega-3/omega-6 as claimed changes the compositions. Nature did not intend almonds/peanuts/coconut to have omega-3 amounts claimed. Each have certain antioxidants which mixed with claimed omega-6/omega-3 changes their properties and use. Panel has overlooked this from Specification. Appx60-64. #27.

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 antici-

pation, 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

Appellant rebutted Decision 37 to be safe. If Appellant had not, it could have been used against the Appellant.

Panel overlooked the briefs that Claim 102 recites, “ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1” and that neither olive nor walnut oil meet the limitation, and similarly elements combined in tables 7-20 in Claim 107 and 119 are outside the scope of the cited oils. Examiner failed to cite a single product, even an oil, that meets the limitations in Claim 102, 107, and 119. See #26.

- A. As per law, "servings" are instructions, not product of nature. #25.
- B. As per law, "intermixture" is capable of structural limitation. #5.
- C. Under §101 there is no requirement to distinguish claims from products (oils) not recited in claims. #20.
- D. Oils are not natural. #25.
- E. Single source oil including by-process is disclaimed, i.e. the intermixture is NECESSARILY distinct v single source #21-22.
- F. OVERWHELMING EVIDENCE including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been submitted that oils are not products of nature and claimed mixtures necessarily have properties not found in nature. #23-24.

Panel has conflated analysis of independent claims with dependent Claims 102, 107, and 119. Panel starts to discuss dependent claims 102, 107, and 119 then drops the analysis...

...here and shifts to independent claims 65, 91, 129, and 130.

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.

Preponderance of evidence including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been submitted that in nature omega-6/omega-3 always occur with certain phytochemicals in configurations necessarily altered by manipulations, e.g. storing, extracting, mixing, encasing... E.g., Gotoh (Appx6696) evidences even changing ratios of omega-3 and omega-6 affect each other in oxidative stability. UBBR12, 16, 53, 59; UBRBR15-16. "Applicant has not shown [evidence]..." is false. #23-24.

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.

A. Claims are drawn to "dosage" and "casings providing controlled delivery" which CHANGE FUNCTIONALITY of omega-6 and omega-3, as they occur in nature, and DO add significantly more to nature. §101 INQUIRY IS OVER AT THIS POINT. "Step one" Mayo. #17. Claims do not recite any oil. No requirement under §101 to show distinction over product not recited in claims. #20.

**AFFIRMED**

No costs.

B. Claims are drawn to an extremely important inventive concept which confers eligibility. "Step two" Mayo. #18. p18-23 of the petition.

C. Claims on the whole are patent eligible. #19.

PANEL ACKNOWLEDGES OILS ARE TRANSFORMED FROM PRODUCTS OF NATURE THEN DISREGARDS THE FACT IN FURTHER ANALYSIS AND STILL REQUIRES APPLICANT TO DISTINGUISH CLAIMS FROM CITED OILS. #25.

PANEL FAILS ITS DUTY TO DETERMINE §101 ELGIBILITY DE NOVO WITHOUT DEFERENCE AS PER LAW. #16.

PANEL FAILS TO CITE ANY LAW WHY INDEPENDENT CLAIMS ARE NOT PATENATBLE.

PANEL HAS OVERLOOKED TO REVIEW CLAIMS 68, 73, 74, 77, 78, 98, 118, 121-122, AND 124 UNDER §101. UBBR53, 58-59. #28.

NOTE: The highlights and the text in side bar have been added by the Applicant.



# Federal Circuit Finds Composition of Matter Ineligible For Patenting

By Courtenay C. Brinckerhoff and Oyvind Dahle  
27 March 2018

*PharmaPatents*

In a non-precedential decision issued in *In re Bhagat*, the Federal Circuit affirmed the decision of the USPTO Patent Trial and Appeal Board (PTAB) that claims directed to certain lipid compositions were ineligible for patenting under 35 USC § 101. Did the court do more or less harm by rendering its decision without much explanation?

## The Claims At Issue

The claims at issue were pending in U.S. Patent Application No. 12/426,034. Claim 65 was the broadest claim considered by the court:

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 examiner found that walnut oil and olive oil contain omega-6 and omega-3 oils in amounts within the claimed ranges, and rejected the claims under the “product of nature” paradigm based on the conclusion that the claimed formulations are not markedly different from naturally occurring walnut oil or olive oil.

The examiner also rejected the claims as being anticipated by U.S. Patent No. 5,549,905 (directed to a nutritional composition that includes omega-6 and omega-3 fatty acids) and publications of nutritional analyses of olives and walnuts showing that those natural products include omega-6 and omega-3 fatty acids in the ratios and amounts claimed.

The PTAB upheld all rejections.

## The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Newman and joined by Judge O’Malley

The reference is not operable due a number of reasons, and considering temporal context, it cannot anticipate. Petition #9-12.

and Taranto.

The decision summarizes the basis of the examiner’s rejections, the reasoning behind the PTAB’s affirmance, and the Applicant’s arguments on appeal. For the most part, the court states that each PTAB finding was “correct” without explanation.

The Applicant argued that the claim language reciting an “intermixture of lipids from different sources” made the formulation markedly different from naturally occurring products, and that the formulation provided synergistic benefits and avoided “concentrated delivery of specific phytochemicals that may be harmful in excess.” The Board had held that there was no evidence of record that could support that a mixture of oils from different sources is different from oil from one source. The Federal Circuit agreed, stating:

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 Federal Circuit acknowledged the Applicant’s arguments that “casings providing controlled delivery” “do not exist as natural products,” but did not address those arguments in its § 101 analysis. It did address similar arguments in its anticipation analysis, agreeing with the PTAB that the terms “casing” and “dosage” do not impart patentability, finding:

[T]he specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations.

Thus, the court affirmed all rejections.

Overwhelming evidence including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been submitted that in nature omega-6/omega-3 always occur with certain phytochemicals in configurations necessarily altered by manipulations, e.g. storing, extracting, mixing, encasing... E.g., Gotoh (Appx6696) evidences even changing ratios of omega-3 and omega-6 affect each other in oxidative stability. UBBR12, 16, 53, 59; UBRBr15-16. Op11-12 “Applicant has not shown [evidence]...” is false. Petition #23-24.

Specification does NOT say these elements are not limiting. Petition #2-4. This is a falsity, promoted by PTO upheld by Federal Circuit. It is extremely distressing that Federal Circuit would do that.

## The USPTO Subject Matter Eligibility Examples

Could Bhagat have invoked Example 28 of the USPTO’s [Subject Matter Eligibility Examples?](#) That example relates to a vaccine based on a naturally occurring peptide. According to the example, a claim reciting “A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier” does not satisfy § 101 because the carrier could be water, another natural product. On the other hand, a claim reciting “A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier selected from the group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment” does satisfy § 101 because the recited carriers change the physical characteristics of the mixture.

The ‘034 application does not appear to use the term “casing,” but does disclose the use of a “controlled release capsule.” However, since such a capsule may not “change the physical characteristics of the mixture” contained therein, it may not fall under the patent-eligible claim of this USPTO example.

Claims DO NOT recite "casing", claims recite "contained in one or more complementing casings providing controlled delivery of the formulation to a subject". Claims have to be examined by the plain words of the claims in context of surrounding words. In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983). Trivascular, Inc. V. Samuels, 812 F.3d 1056, 1061 (Fed. Cir. 2016).

NOTE: The highlights and the text in side bar have been added by the Applicant.

## Publications

# In Re Urvashi Bhagat: One More Decision Denying Patent Eligibility of Nature-Based Product Claims

March 29, 2018

Urvashi Bhagat appealed the decision of the PTAB (“the Board”) affirming the examiner’s anticipation rejections and the rejection under Section 101 of multiple claims in application 12/426,034. The Federal Circuit affirmed the Board’s decision in the recent *In re Urvashi Bhagat* nonprecedential opinion. The claims of this application were directed to lipid-containing formulations comprising omega-6 and omega-3 fatty acids. The ’034 application stated that dietary deficiency or imbalance of these fatty acids might 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 claimed ranges and ratios of the fatty acids and other limitations.

Claim 65 recited:

*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.*

Other claims included specific amounts and/or ratios, additional components, sources of the lipids, and delivery methods.

Under Section 101, the examiner rejected the claims (and the Board agreed) as being directed to non-statutory subject matter, because the claimed fatty acid mixtures occur naturally in walnut oil and olive oil. The Patent Office did not provide a clear step-by-step analysis under Section 101, as required by its own guidelines, and merely offered a mixed and brief statement 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 found that the claims were directed to natural products of walnut oil and olive oil, and that the additional limitations in the claims did not change the characteristics of the products, or add “significantly more” to the claims. The Applicant offered a number of arguments for patent eligibility but the court agreed with the Board.

The Applicant’s arguments for patent eligibility included statements 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 natural products from a single source. The Applicant pointed to the specification describing that the claimed mixtures provide benefits of “synergy” and “avoid concentrated delivery of specific phytochemicals that may be harmful in excess.” The Applicant further argued that the claimed mixtures of fatty acids from different sources were “structurally different” from the single-source walnut oil and olive oil. However, the Applicant apparently did not offer evidence to bolster this argument. The Applicant explained that while naturally occurring plants or their isolated lipids might be natural products, extracts and composites or mixtures are not natural products because the extraction processes required for obtaining edible oils from olives and walnuts transform the claimed lipids from natural products. However, the Board held that the arguments did 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 included this lipid content. The Board stated that the specification did 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 did not provide evidence of such

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Overwhelming evidence including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been submitted that in nature omega-6/omega-3 always occur with certain phytochemicals in configurations necessarily altered by manipulations, e.g. storing, extracting, mixing, encasing... E.g., Gotoh (Appx6696) evidences even changing ratios of omega-3 and omega-6 affect each other in oxidative stability. UBBR12, 16, 53, 59; UBRBr15-16. Op11-12 “Applicant has not shown [evidence] ...” is false. Petition #23-24.



distinction. The court agreed that the Board properly found that Bhagat failed to show that the claimed mixtures were a "transformation" of the natural products, or that the claimed mixtures had properties not possessed by these products in nature.

The Applicant further argued that the claimed limitations of "dosage" and "casings providing controlled delivery" do not exist as natural products, that natural products cannot provide a controlled delivery or dosage because lipid profiles in nature are unpredictable and that walnut oil and olive oil are not "natural products," as they can be obtained only by treatment of natural products. Here, the court seems to rely on the anticipation section of the opinion for the analysis under Section 101. In the anticipation analysis, the court agreed with the Board that the terms "casing" and "dosage" do not provide patentability to the compositions because "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 court also agreed that the claims were directed to 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." Thus, the analysis under section 102 was apparently applied to the analysis under Section 101. However, as explained by the Supreme Court in *Mayo*, the analysis under section 101 is separate from the patentability analysis under sections 102 or 103. Here, the main claim appears to include limitations that are not nature-based or that add "significantly more" to the nature-based product, e.g., the limitations "dosage" and "casings providing controlled delivery" are not found in nature and natural counterpart products and the claimed mixture "avoids concentrated delivery of specific phytochemicals that may be harmful in excess."

Another rejected claim 102 recited specific ratios of polyunsaturated, monounsaturated, and saturated fatty acids. The Board observed that the servings of olive oil and walnut oil shown in the references cited by the PTO in the anticipation rejections contained omega-6 and omega-3 fatty acids in the amounts within the claimed ranges. 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."

The Applicant also argued that claim 128 was distinguished from natural products, and was not anticipated based on the limitation that the compositions contain "nuts or their oils" obtained from "almonds, peanuts, and/or coconut meat." However, the Board held that admixture with other natural products of known compositions 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 court simply agreed that the Board correctly held that "claim 128 does not avoid the rejection on the ground that the claims are directed to known natural products."

Thus, the court concluded that substantial evidence supported the Board's findings and the rulings of unpatentability.

*In re Urvashi Bhagat*, Appeal No. 2016-2525 (Fed. Cir., March 16, 2018)

*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)

Specification does NOT say these elements are not limiting. Petition #2-4. This is a falsity, promoted by PTO upheld by Federal Circuit. It is extremely distressing that Federal Circuit would do that.

Rejection of Claim 102 is extremely improper. Claim 102 recites combination of ratios of fatty acids that are NOT known in nature. Examiner failed to cite a single product, even oil, that meets the ratios in Claim 102. Petition #26.

In nature "almonds, peanuts, and/or coconut meat" do not contain omega-6 and omega-3 in the claimed ratios and concentrations, and mixing almonds/peanuts/coconut with claimed omega-6/omega-3 ranges alters use because of antioxidants in them. Petition #27.

**NOTE: The highlights and the text in side bar have been added by the Applicant.**

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## In re Urvashi Bhagat – The Slippery Slope of Natural Product Claims

Monday, March 19, 2018

I will start out by recommending that you read all of [MPEP 2106 – Patent Subject Matter Eligibility](#). I rarely admire PTO policy rules and guidelines, but this section reflects a lot of work, particularly in the standards for evaluating whether or not a claim is directed to a natural product. Please turn to Table at 2016(3). As I have written previously, the key sections – especially for natural products – are sections 2A and 2B.

Section 2A requires the Examiner to analyze whether or not the claim is directed to a natural product. If there is more than one claim element that could be a natural product, they are to be evaluated to see if they occur together in nature. If they do not, the components are each compared to its closest naturally occurring counterpart to see if any of the components is clearly not a product of nature. If none is, the nature-based combination is examined to see if the combination of components has “markedly different” characteristics due to the interactions in the combination.

This requires evidence of some change in physical or chemical properties if there is just one nature-based product in the claim or, alternatively some interaction between the natural products (if there is more than one). If this analysis leads to the conclusion that the nature-based component or components is significantly different from its/their natural state, it/they are not a product of nature and the inquiry stops. Also, carriers for a natural product that is the active ingredient, which are not themselves natural products, e.g., nanoparticles, will often have structural and physical characteristics that distinguish them from their closest natural counterparts (if there are any). Therefore a carrier can render a natural product patent-eligible. (These comments are based on Examples 3 and 4 in the [Interim Examination Guidelines, May 4, 2016 Life Sciences Update](#)).

If, however, the claim encompasses no more than a natural product or a simple combination thereof, and the marked difference is absent, the Examiner will subject the claim to the

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dreaded Step 2B analysis, in which to reach patent-eligibility, the claim must possess a further “inventive concept” that renders it “significantly more” and which cannot be satisfied by the product(s) of nature per se. While the PTO Guidelines state that the “inventive concept” question should not be decided on the basis of a ss. 102 or 103 analysis, the Board and the courts almost always do just that.

Now, at last, let’s take a look at the Fed. Cir.’s affirmance of the Board’s rejections **In re Bhagat**. Facially the claim is directed to a formulation comprising a dosage of specified amounts of omega-6 (o-6) and omega-3 fatty acids. One wrinkle in the claiming is the further limitation that the formulation is contained “in one or more complemented casings providing controlled delivery of the formulation to a subject.”

Well, there is no doubt that these fatty acids are natural products, especially since the inventor could not point to any marked difference between the individual acids and the mixture thereof and their naturally occurring counterparts. The Examiner had rejected the claims over a “nutritional composition for pediatric patients” as containing all the limitations present in the main claim. Other claims were rejected over the fatty acid profile of a serving of walnuts or olives. With respect to one claim, the inventor argued that the Examiner had not established that olives contained a group of carriers recited in the claim. Unfortunately, one of the carriers was sugar, and walnuts contain sugar.

In the 101 analysis, the Examiner abbreviated, if not conflated, the 2A and 2b; apart from the finding that o-6 and o4 fatty acids are directed to natural products, the Examiner found that

“the additional limitations in the claims do not change the characteristics of the products [2A] or add ‘significantly more’ to the claims.’ [2B]. That’s a lot of law for about half a sentence, and made the court’s s.101 arguments difficult to follow. In fact, the main claim used as representative do contain limitations that are not nature-based products, and impart at least functional structure to the claims. The claims require that the composition comprised a dosage of the fatty acids, contained in “one or more complementing casings providing controlled delivery of the formulation to a subject....”

While the court simply dismissed the claim element “casing” as meaning “any orally accepted form”, in the anticipation section of the decision, court’s reasoning was simply the term does not provide patentability to the compositions because the specification states that the term is not claim-limiting and, that it does not describe any novel characteristics of the components or their formulations. While this analysis may be appropriate in a patentability analysis under ss. 102/103, it should not be carried over into a s. 101 analysis.

In the 101 analysis, the Applicant again argues that the claimed limitation “casings providing controlled delivery” are not natural products. So we are not in inventive concept territory yet, but are still evaluating whether or not the formulations are markedly different than the fatty acids as they occur in nature, e.g., in walnuts or olives. The court simply did not comment on this argument but certainly, Applicant’s controlled release dosage form does not exist in nature and changes the characteristics of the acids as they occur in their natural state, in walnuts or olives. Unfortunately, applicant did not make this argument as clearly as I have with the benefit of hindsight, probably because the court was using facts largely derived from its anticipation ruling.

One of Applicant’s better “markedly changed” arguments is that the claimed mixtures “avoid concentrated delivery of specific phytochemicals [also present in the olives or walnuts, I presume] that may be harmful in excess. The Board had argued that the entirety of the natural products finding should rest on the identity of the [recited] oils, to the naturally occurring lipid profiles in walnut or olive oil. The court agreed with the Board, simply stating that evidence supporting this argument was lacking.

Overwhelming evidence including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been submitted that in nature omega-6/omega-3 always occur with certain phytochemicals in configurations necessarily altered by manipulations, e.g. storing, extracting, mixing, encasing... E.g., Gotoh (Appx6696) evidences even changing ratios of omega-3 and omega-6 affect each other in oxidative stability. UBBR12, 16, 53, 59; UBBR15-16. Op11-12 “Applicant has not shown [evidence]... is false. Petition #23-24.

Anticipation by olives and walnuts is wrong on the face because anticipation law requires same part to part relationship, the references do not disclose “intermixtures” and there are other issues with them. Petition #13-15.

Specification does NOT say these elements are not limiting. Petition #2-4. This is a falsity, promoted by PTO upheld by Federal Circuit. It is extremely distressing that Federal Circuit would do that.

Also, claims DO NOT recite “casing”, claims recite “contained in one or more complementing casings providing controlled delivery of the formulation to a subject”. Claims have to be examined by the plain words of the claims in context of surrounding words. Petition #3.

The arguments were made VERY clearly and REAPEATEDLY with evidence, Federal Circuit disregarded them. “Preponderance of evidence is that nature cannot provide dosage (specified amount for once/regular ingestion) or controlled delivery, because nature is random and unpredictable in lipid ratios and amount. (Appx5472-5474, Appx5480, Appx5703, Appx6054-6055, Appx7673, Appx7677-7678, Appx7875-7878). PTO has acknowledged “lipid components (e.g., amounts and ratios of omega-6/omega-3 fatty acids) present in any specific product of nature are not always the same.” (Appx7783). Thus, there will be no specified amount for ingestion of omega-6/omega-3 in any given product of nature and there will be no controlled delivery. The very purpose of the inventions comprising process and composition of matter (dosages, casings, controlling delivery, intermixtures) is to solve the problem of deficiency, excess, or unpredictability in products of nature. (Appx7670-7673, Appx7677-7679).” UBBR50-52.

In the final paragraph, the court simply agrees with the Board that the fatty acids occur in nature and the “asserted claim limitations do not distinguish the claimed products and compositions from those shown in the cited references.” Whether or not the oils occur in nature is part of the step 2A analysis, but the need to distinguish the products from the prior art is not even a requirement of the 2B analysis. Applicant deserved better than the courts use of the “naked” anticipation rejection to meet the standards for a judicial exception under s. 101.

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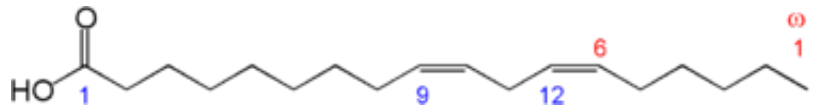
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# Omega-6 fatty acid

**Omega-6 fatty acids** (also referred to as **ω-6 fatty acids** or ***n*-6 fatty acids**) are a family of pro-inflammatory and anti-inflammatory polyunsaturated fatty acids<sup>[1]</sup> that have in common a final carbon-carbon double bond in the *n*-6 position, that is, the sixth bond, counting from the methyl end.<sup>[2]</sup>



The chemical structure of linoleic acid, a common omega-6 fatty acid found in many nuts, seeds and vegetable oils.

The biological effects of the omega-6 fatty acids are largely produced during and after physical activity for the purpose of promoting growth and during the inflammatory cascade to halt cell damage and promote cell repair by their conversion to omega-6 eicosanoids that bind to diverse receptors found in every tissue of the body.

## Contents

**Biochemistry**

**Pharmacology**

**Suggested negative health effects**

**Omega-6 consumption**

**List of omega-6 fatty acids**

**Dietary linoleic acid requirement**

**Dietary sources**

**See also**

**Notes and references**

Additional sources

## Biochemistry

Linoleic acid (18:2, *n*-6), the shortest-chained omega-6 fatty acid, is one of many essential fatty acids and is categorized as an essential fatty acid because the human body cannot synthesize it. Mammalian cells lack the enzyme omega-3 desaturase and therefore cannot convert omega-6 fatty acids to omega-3 fatty acids. Closely related omega-3 and omega-6 fatty acids act as competing substrates for the same enzymes.<sup>[3]</sup> This outlines the importance of the proportion of omega-3 to omega-6 fatty acids in a diet.<sup>[3]</sup>

Omega-6 fatty acids are precursors to endocannabinoids, lipoxins, and specific eicosanoids.

Medical research on humans found a correlation (though correlation does not imply causation) between the high intake of omega-6 fatty acids from vegetable oils and disease in humans. However, biochemistry research has concluded that air pollution, heavy metals, smoking, passive smoking, lipopolysaccharides, lipid peroxidation products (found mainly in vegetable oils, roasted nuts and roasted oily seeds) and other exogenous toxins initiate the inflammatory response in the cells which leads to the expression of the COX-2 enzyme and subsequently to the temporary production of inflammatory *promoting* prostaglandins from arachidonic acid for the purpose of alerting the immune system of the cell damage and eventually to the production of anti-inflammatory molecules (e.g. lipoxins & prostacyclin) during the resolution phase of inflammation, after the cell damage has been repaired.<sup>[4][5][6][7][8][9][10][11][12][13][14][15]</sup>

## Pharmacology

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The conversion of cell membrane arachidonic acid (20:4n-6) to omega-6 prostaglandin and omega-6 leukotriene eicosanoids during the inflammatory cascade provides many targets for pharmaceutical drugs to impede the inflammatory process in atherosclerosis,<sup>[16]</sup> asthma, arthritis, vascular disease, thrombosis, immune-inflammatory processes, and tumor proliferation. Competitive interactions with the omega-3 fatty acids affect the relative storage, mobilization, conversion and action of the omega-3 and omega-6 eicosanoid precursors (see Essential fatty acid interactions).

## Suggested negative health effects

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Some medical research suggests that excessive levels of omega-6 fatty acids from seed oils relative to certain omega-3 fatty acids may increase the probability of a number of diseases.<sup>[17][18][19]</sup>

Modern Western diets typically have ratios of omega-6 to omega-3 in excess of 10 to 1, some as high as 30 to 1; the average ratio of omega-6 to omega-3 in the Western diet is 15:1–16.7:1.<sup>[16]</sup> Humans are thought to have evolved with a diet of a 1-to-1 ratio of omega-6 to omega-3 and the optimal ratio is thought to be 4 to 1 or lower,<sup>[16]</sup> although some sources suggest ratios as low as 1:1.<sup>[20]</sup> A ratio of 2–3:1 omega 6 to omega 3 helped reduce inflammation in patients with rheumatoid arthritis.<sup>[16]</sup> A ratio of 5:1 had a beneficial effect on patients with asthma but a 10:1 ratio had a negative effect.<sup>[16]</sup> A ratio of 2.5:1 reduced rectal cell proliferation in patients with colorectal cancer, whereas a ratio of 4:1 had no effect.<sup>[16]</sup>

Excess omega-6 fatty acids from vegetable oils interfere with the health benefits of omega-3 fats, in part because they compete for the same rate-limiting enzymes. A high proportion of omega-6 to omega-3 fat in the diet shifts the physiological state in the tissues toward the pathogenesis of many diseases: prothrombotic, proinflammatory and proconstrictive.<sup>[21]</sup>

Chronic excessive production of omega-6 eicosanoids is correlated with arthritis, inflammation, and cancer. Many of the medications used to treat and manage these conditions work by blocking the effects of the COX-2 enzyme.<sup>[22]</sup> Many steps in formation and action of omega-6 prostaglandins from omega-6 arachidonic acid proceed more vigorously than the corresponding competitive steps in formation and action of omega-3 hormones from omega-3 eicosapentaenoic acid.<sup>[23]</sup> The COX-1 and COX-2 inhibitor medications, used to treat inflammation and pain, work by preventing the COX enzymes from turning arachidonic acid into inflammatory compounds.<sup>[24]</sup> (See Cyclooxygenase for more information.) The LOX

inhibitor medications often used to treat asthma work by preventing the LOX enzyme from converting arachidonic acid into the leukotrienes.<sup>[25][26]</sup> Many of the anti-mania medications used to treat bipolar disorder work by targeting the arachidonic acid cascade in the brain.<sup>[27]</sup>

A high consumption of oxidized polyunsaturated fatty acids (PUFAs), which are found in most types of vegetable oil, may increase the likelihood that postmenopausal women will develop breast cancer.<sup>[28]</sup> Similar effect was observed on prostate cancer, but the study was performed on mice.<sup>[29]</sup> Another "analysis suggested an inverse association between total polyunsaturated fatty acids and breast cancer risk, but individual polyunsaturated fatty acids behaved differently [from each other]. [...] a 20:2 derivative of linoleic acid [...] was inversely associated with the risk of breast cancer".<sup>[30]</sup>

## **Omega-6 consumption**

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Industry-sponsored studies have suggested that omega-6 fatty acids should be consumed in a 1:1 ratio to omega-3,<sup>[31]</sup> though it has been observed that the diet of many individuals today is at a ratio of about 16:1, mainly from vegetable oils.<sup>[31]</sup> Omega-6 and omega-3 are essential fatty acids that are metabolized by some of the same enzymes, and therefore an imbalanced ratio can affect how the other is metabolized.<sup>[32]</sup> In a study performed by Ponnampalam,<sup>[33]</sup> it was noticed that feeding systems had a great effect on nutrient content on the meat sold to consumers. Cynthia Doyle conducted an experiment to observe the fatty acid content of beef raised through grass feeding versus grain feeding; she concluded that grass fed animals contain an overall omega-6:omega-3 ratio that is preferred by nutritionists.<sup>[32]</sup> In today's modern agriculture, the main focus is on production quantity, which has decreased the omega-3 content, and increased the omega-6 content, due to simple changes such as grain-feeding cattle.<sup>[16]</sup> In grain-feeding cattle, this is a way to increase their weight and prepare them for slaughter much quicker compared to grass-feeding. This modern way of feeding animals may be one of many indications as to why the omega-6:omega-3 ratio has increased.

## **List of omega-6 fatty acids**

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Common name	Lipid name	Chemical name
<u>Linoleic acid</u> (LA)	18:2 ( <i>n</i> -6)	<i>all-cis</i> -9,12-octadecadienoic acid
<u>Gamma-linolenic acid</u> (GLA)	18:3 ( <i>n</i> -6)	<i>all-cis</i> -6,9,12-octadecatrienoic acid
<u>Calendic acid</u>	18:3 ( <i>n</i> -6)	8E,10E,12Z-octadecatrienoic acid
<u>Eicosadienoic acid</u>	20:2 ( <i>n</i> -6)	<i>all-cis</i> -11,14-eicosadienoic acid
<u>Dihomo-gamma-linolenic acid</u> (DGLA)	20:3 ( <i>n</i> -6)	<i>all-cis</i> -8,11,14-eicosatrienoic acid
<u>Arachidonic acid</u> (AA, ARA)	20:4 ( <i>n</i> -6)	<i>all-cis</i> -5,8,11,14-eicosatetraenoic acid
<u>Docosadienoic acid</u>	22:2 ( <i>n</i> -6)	<i>all-cis</i> -13,16-docosadienoic acid
<u>Adrenic acid</u>	22:4 ( <i>n</i> -6)	<i>all-cis</i> -7,10,13,16-docosatetraenoic acid
<u>Osbond acid</u>	22:5 ( <i>n</i> -6)	<i>all-cis</i> -4,7,10,13,16-docosapentaenoic acid
<u>Tetracosatetraenoic acid</u>	24:4 ( <i>n</i> -6)	<i>all-cis</i> -9,12,15,18-tetracosatetraenoic acid
<u>Tetracosapentaenoic acid</u>	24:5 ( <i>n</i> -6)	<i>all-cis</i> -6,9,12,15,18-tetracosapentaenoic acid

It is interesting to note that melting point of the fatty acids increase as the number of carbons in the chain increases.

## Dietary linoleic acid requirement

Adding more controversy to the omega-6 fat issue is that the dietary requirement for linoleic acid has been questioned, because of a significant methodology error proposed by University of Toronto scientist Stephen Cunnane.<sup>[34]</sup> Cunnane proposed that the seminal research used to determine the dietary requirement for linoleic acid was based on feeding animals linoleic acid-deficient diets, which were simultaneously deficient in omega-3 fats. The omega-3 deficiency was not taken into account. The omega-6 oils added back systematically to correct the deficiency also contained trace amounts of omega-3 fats. Therefore, the researchers were inadvertently correcting the omega-3 deficiency as well. Ultimately, it took more oil to correct both deficiencies. According to Cunnane, this error overestimates linoleic acid requirements by 5 to 15 times.

## Dietary sources

Four major food oils (palm, soybean, rapeseed, and sunflower) provide more than 100 million metric tons annually, providing more than 32 million metric tons of omega-6 linoleic acid and 4 million metric tons of omega-3 alpha-linolenic acid.<sup>[35]</sup>

Dietary sources of omega-6 fatty acids include:<sup>[36]</sup>

- poultry
- eggs
- nuts
- hulled sesame seeds
- cereals



- [durum wheat](#)
- [whole-grain breads](#)
- [most vegetable oils](#)
- [grape seed oil](#)
- [evening primrose oil](#)
- [borage oil](#)
- [blackcurrant seed oil](#)
- [flax/linseed oil](#)
- [rapeseed or canola oil](#)
- [hemp oil](#)
- [soybean oil](#)
- [cottonseed oil](#)
- [sunflower seed oil](#)
- [corn oil](#)
- [safflower oil](#)
- [pumpkin seeds](#)



The evening primrose flower (*O. biennis*) produces an oil containing a high content of  $\gamma$ -linolenic acid, a type of omega-6 fatty acid.

## See also




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- [Essential fatty acid interactions](#)
- [Essential nutrients](#)
- [Linolenic acid](#)
- [Omega-3 fatty acid](#)
- [Omega-7 fatty acid](#)
- [Omega-9 fatty acid](#)
- [Wheat germ oil](#)
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
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## Humanitarian Use Application

Application Title: **Pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients.**



Application Date: November 8, 2015

Category: Nutrition

Organization Applying:



Primary Location of the applicants:

City: Palo Alto State: CA Country: USA

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If you wish to provide private contact info to be notified about your application status, please email it to [patentsforhumanity@uspto.gov](mailto:patentsforhumanity@uspto.gov). Otherwise we will use any contact info associated with your submission.

It is estimated that the Humanitarian Award Application will take 4 hours to complete. Applying for the Award is voluntary; however, if you apply you must provide the information requested. Failure to provide this information may delay or prevent processing of your application. Please send any comments on the amount of time required to complete this form and/or suggestions for reducing the time burden to the Chief Information Officer, USPTO, PO Box 1450, Alexandria, VA 22313-1450. DO NOT SEND APPLICATIONS TO THIS ADDRESS

**Qualifying Patents**

1. List the relevant U.S. utility patents or patent applications you own or license that you wish to apply under. These patents must relate to the technology described in this submission. Add more rows if needed. Only one patent or patent application is required for eligibility. If any patents or applications are found ineligible, the remaining items will be considered. If no eligible items remain, the PTO may contact the applicants to determine if eligible material can be identified.

U.S. Patent Application Number (PCT Number) (PCT Publication number)	Title	Filing Date
12/426,034 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof	April 17, 2009
13/332,251 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof	December 20, 2011
13/877,847 (PCT/US2011/056463) (WO 2012/051591 A2)	Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof	April 4, 2013

2. Are any of these patents or patent applications licensed from an entity not listed as an applicant on this form?  
 NO

In no more than five pages, please address the following questions.

**Eligibility Questions**

3. What humanitarian issue(s) does this application cover? If not widely recognized, provide enough information to determine whether the issues significantly affect the health or quality of life of an impoverished population.

This application covers, pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients, a game-changing solution for protecting and advancing public health at foundational level, whereby millions of people worldwide can benefit particularly for the impoverished populations.

The foundation to health is nutrition. The most important and difficult to manage nutrients consumed are lipids, which include omega-6, omega-3, and several antioxidants and phytochemicals. Micronutrients include antioxidants, phytochemicals, and minerals, which affect metabolism of omega-6, omega-3, and other fatty acids. Most of the chronic diseases are associated with mismanaged lipid consumption, further immunity and daily well being is affected by lipid consumption, furthermore lipid requirements are different for different members of the family (by body size, hormones...)(See *Bhagat et al. 2015, Arch Med Sci 2015; 11, 4: 807–818*). In 2012, in the US chronic diseases affected 117 million people costing ~\$2 trillion (<http://www.cdc.gov/chronicdisease/overview/index.htm>); worldwide chronic and infectious diseases affected ~2 billion people ([http://www.who.int/healthinfo/global\\_burden\\_disease/estimates/en/index2.html](http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html)).

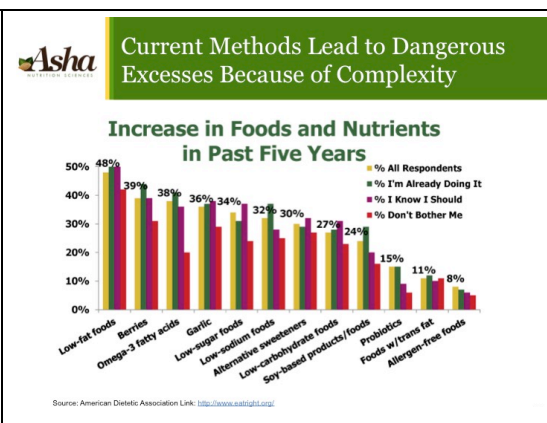
Natural lipid sources, oils, nuts and seeds etc, are variable and unreliable in lipid content and composition, and they contain many components that materially affect lipid metabolism. Important lipids such as polyphenols and several phytochemicals are poorly understood and absent from available dietary guidance, see Dietary Guidelines for Americans ([http://www.cnpp.usda.gov/sites/default/files/dietary\\_guidelines\\_for\\_americans/PolicyDoc.pdf](http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf)). Adding to the complexity is mass confusion in the field with many spins on what is desirable and what is not. For example, many bodies and publications have disparaged omega-6 or taught low amounts of omega-6 and low omega-6 to omega-3 ratios (*Lands, Nutrition Reviews 1986:44-6:189-95; Lands, Ann. N.Y. Acad. Sci. 1055: 179–192 (2005); Simopoulos, Ann Nutr Metab 1999;43:127–130; Hamazaki et al. World Rev Nutr Diet. Basel, Karger, 2003:92:109–132*), even though omega-6 is the most critical fatty acid for health. Further, too many supplements are sold without regard for interactions. For example, it is a misconception that omega-3, antioxidants, and phytochemicals are always good for health. Such issues have increased the risk of some diseases. It is extremely complex for public to solve this problem. For example, **less than 1%** of Americans can correctly name types of fats (see surveys at <http://www.foodinsight.org>), let alone lipids. Unless corrected, the chaotic out-of-context touting of nutrients will create further problems in the field of nutrition and consequently health.

**Fatty acid composition of some common edible fats and oils.**

Percent by weight of total fatty acids.

Oil or Fat	Unsat./Sat ratio	Saturated						Mono unsaturated	Poly unsaturated	
		Capric Acid C10:0	Lauric Acid C12:0	Myristic Acid C14:0	Palmitic Acid C16:0	Stearic Acid C18:0	Oleic Acid C18:1	Linoleic Acid (ω6) C18:2	Alpha Linolenic Acid (ω3) C18:3	
Almond Oil	9.7	-	-	-	7	2	69	17	-	
Beef Tallow	0.9	-	-	3	24	19	43	3	1	
Butterfat (cow)	0.5	3	3	11	27	12	29	2	1	
Butterfat (goat)	0.5	7	3	9	25	12	27	3	1	
Butterfat (human)	1.0	2	5	8	25	8	35	9	1	
Canola Oil	15.7	-	-	-	4	2	62	22	10	
Cocoa Butter	0.6	-	-	-	25	36	32	3	-	
Cod Liver Oil	2.9	-	-	8	17	-	22	5	-	
Coconut Oil	0.1	6	47	18	9	3	6	2	-	
Corn Oil (Maize Oil)	6.7	-	-	-	11	2	28	58	1	
Cottonseed Oil	2.8	-	-	1	22	3	19	54	1	
Flaxseed Oil	9.0	-	-	-	3	7	21	16	53	
Grape seed Oil	7.3	-	-	-	8	4	15	73	-	

Also see <http://www.ars-grin.gov/duke/> for other lipid content.



Pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient delivery to public, can prevent or at least reduce the suffering from many chronic diseases. Such pre-formulated lipids are particularly indispensable for impoverished populations who have inadequate access to medical care, are subjected to poor living conditions, and have poor knowledge to choose lipids making them disproportionately susceptible to infections and diseases. Thus, delivering pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient to public, especially to impoverished populations, can significantly reduce incidence and/or severity of disease.



4. What technologies does this application cover? Provide a brief description of each and indicate how they relate to the patents or patent applications in question 1.

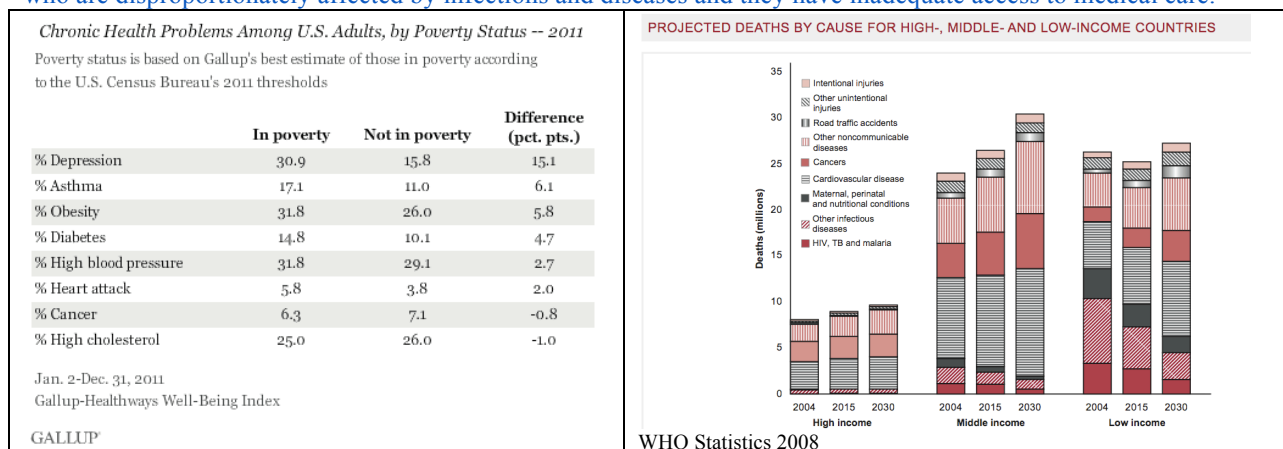
Technologies covered; product name: **LIPILIFE** (subject to change):

- US 12/426,034 and 13/332,251 cover **pre-formulated lipids** containing omega-6 and omega-3 with omega-6 to omega-3 ratios greater than 4:1 or omega-6 greater than 20% of total lipids, wherein their dosages are controlled and/or content of other lipids in controlled. These applications also cover **tailored lipids** delivery wherein ratios and/or amounts of omega-6 and omega-3 are controlled by age, gender, and diet type, and lipid-free or low-lipid foods are designed to complement the tailored lipids.
- US 13/877,847, covers **nutritional managements systems**, which include multi-component nutritional formulations and methods of providing nutrition by demographic cohorts, designed to control the delivery of lipids including omega-6 and micronutrients, including antioxidants and phytochemicals. It also covers computer systems by means of which public can be remotely guided to managing sensitive lipid and phytochemical consumption.
- It is important to manage the dosage of omega-6 and omega-3, and lipids that affect their metabolism, as discussed above. Many variables modulate the metabolism of various fatty acids. It is difficult for consumers to calibrate on a daily basis the demands of the body for various fatty acids, since the requirements of various biologically active unsaturated fatty acids change depending on age, gender, and various life style factors. It is possible that there could exist differences in the requirements of various fatty acids and their co-factors even among members of the same family. (*Bhagat et al. 2 015 Supra, page 808*)

5. What populations are your actions described in this application targeting? Please describe how these populations are impoverished, and how they are affected by the humanitarian issues described in question 4.

The patent applications (see appendices) describe that technologies covered have prophylactic and therapeutic effect on almost all medical conditions, such as menopause, musculoskeletal disorders, mood, cognitive function, neural disorders, mental disorders, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, infectious diseases, inflammatory diseases, and cardiovascular disease. Further, the described technologies improve quality of life by stabilizing hormones, mood, and sleep for example.

The actions described in this application are beneficial to all populations, particularly to impoverished populations who are disproportionately affected by infections and diseases and they have inadequate access to medical care.






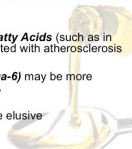
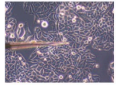




Thus, the disclosed solutions can especially reduce the burden of disease for impoverished populations. Applicant is targeting to provide the disclosed solutions in all economies with large share of impoverished populations.

## Scoring Questions

6. Effectiveness – How do the applicants' technologies effectively address the humanitarian issues in question 5? Are any products or services that employ these technologies being used to benefit the target population?

Applicant's technologies effectively address almost all chronic and infectious diseases, which lead to ill health in 117 million people (133 million by some estimates) in US, and in ~2 billion people worldwide ([http://www.who.int/healthinfo/global\\_burden\\_disease/estimates/en/index2.html](http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html)). In fact, suffering is more than accounted here. For example, ~80% of females above the age of 13 (not counted in 2 billion) suffer from hormonal fluctuations, which can be debilitating and can be abated with controlled lipid delivery (*Filho et al., Reproductive Health 2011, 8:2*).

 <p><b>Tailored Lipids are the Most Sensible, Effective, and Sustainable Solution to Chronic Diseases...</b></p>  <p><b>133M People in US!</b></p>	 <p><b>Tailored And Steady Lipid Consumption Can Optimize Hormones</b></p>  <p><b>Very large percentage of teenage girls and women, 80% according to some reports, suffer from hormonal fluctuations and associated symptoms, which can be debilitating with consequences on school, education, work, and family.</b></p> <p>The instability costs them further in access to education, jobs, and economic and social standing.</p> <p><b>Hormonal fluctuations and associated symptoms can be abated to a large extent with correct and steady lipid delivery.</b></p> <p>Lipids affect hormone levels therefore erratic lipid consumption can lead to erratic hormone levels.</p> <p><b>Lipid requirements for girls and women are different from boys and men. Thus tailored lipids can help prevent health issues associated with hormones.</b></p>	
 <p><b>Scientific Evidence – MUFA &amp; PUFA</b></p> <p><b>Conclusions from Fatty Acids Symposium by National Lipid Association:</b></p> <p><b>Monounsaturated Fatty Acids</b> (such as in olive oils) are associated with atherosclerosis</p> <p><b>Dietary PUFA (omega-6)</b> may be more protective than MUFA</p> <p><b>Omega-3</b> benefits are elusive</p>  <p><small>Burns et al. "Fatty Acids in cardiovascular health and disease: A comprehensive update." <i>Journal of Clinical Lipidology</i> (2012) 6: 216–234</small></p>	 <p><b>Scientific Evidence – PUFA &amp; Cancer</b></p> <p>An Omega-6 PUFA (LA) <b>inhibited</b> colorectal cancer cell growth</p> <p>Results suggested that this PUFA is <b>toxic to colorectal tumor cells</b> but not normal cells</p>  <p><small>Lu et al. "Linoleic acid suppressed colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction." <i>Lipids in Health and Disease</i> 2010, 9:156</small></p>	 <p><b>Scientific Evidence – PUFA &amp; Learning Disorders, e.g. ADHD</b></p> <p>Certain types of Omega-6 and Omega-3 PUFAs are <b>significantly below normal in people with learning disorders</b></p> <p>This was particularly true for children. Authors theorized, "Children in Westernized countries may be eating a diet containing suboptimal AA to satisfy their dietary requirements during growth." Antioxidants and phytochemicals can inhibit AA (long-chain omega-6) activity.</p>  <p><small>N.L. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid." <i>Prostaglandins, Leukotrienes and Essential Fatty Acids</i> 91 (2009) 375–389</small></p>

Most tissue contains ~10 times omega-6 as compared omega-3 and utilization of omega-6 is higher than omega-3. Omega-6 and other lipids are critical for optimal functioning of the cells and organisms (see *Bhagat et al, 2015* and *Morse 2009*). Further, immunity is materially enhanced by controlled lipid delivery. Therefore, health effects of the technology are at a broad level. Consumer feedback to LipiLife from preliminary market research has been positive (see table below). Several scientific publications published after the patent applications were filed, also report similar benefits from higher omega-6 consumption. See Appendices.


Thus, significant reduction in the cost of chronic diseases and human suffering can be achieved by implementation of the solutions disclosed in the patent applications. Some of the suffering and cost estimates are as follows:

<p><b>United States Estimates</b> (<a href="http://www.cdc.gov/chronicdisease/overview/">http://www.cdc.gov/chronicdisease/overview/</a>)</p> <ul style="list-style-type: none"> <li>• 86% percent of all health care spending, ~\$2 trillion annual healthcare spending (2010)</li> <li>• ~117 million people affected by chronic diseases (2012)</li> </ul>	<p><b>Worldwide 2012 Estimates</b> (<a href="http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html">http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html</a>)</p> <ul style="list-style-type: none"> <li>• ~2 billion people suffer from chronic and infectious diseases</li> <li>• Heart disease and stroke ~393 million people</li> <li>• Cancer ~223 million people</li> </ul>
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<ul style="list-style-type: none"> <li>• Costs of heart disease and stroke \$315.4 billion (2010)</li> <li>• Costs of cancer care \$157 billion (2010)</li> <li>• Costs of diagnosed diabetes \$245 billion (2012)</li> <li>• Costs of arthritis and related conditions \$128 billion (2003)</li> <li>• Costs linked to obesity \$147 billion (2008)</li> </ul>	<ul style="list-style-type: none"> <li>• Diabetes ~60 million people</li> <li>• Musculoskeletal disorders ~111 million people</li> <li>• Infectious diseases ~432 million people</li> <li>• Neurological conditions ~80 million people</li> </ul>
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Additionally, LipiLife solves 100-year old problem of spoilage of unsaturated fats. In the 1900s, hydrogenated fats were introduced to solve the problem that unsaturated fats form toxic compounds sitting on shelf. However, we now know that hydrogenated fats are deleterious. We also know that unsaturated fats are critical for health, but cannot be added to food meant sit on shelf. The most effective solution is to pre-formulate and tailor lipids and deliver separately from the rest of the food, such that they are not made to sit on shelf for long durations, as LipiLife does. LipiLife is prepared separately from rest of the food and delivered in containers that are meant to last 1-4 weeks, i.e. not designed to sit on shelf for months.


**Consumer Feedback to LipiLife\***

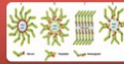


- **LipiLife is a Game Changer**
- It makes so easy to keep track of fat intake, specifically Omega-3 and Omega-6
- It makes eating healthy easy
- It reduces the probability of overeating
- It makes me think and concentrate better, and I feel more grounded
- I sleep better and wake up rested
- I haven't had a cold since I started this
- I reduced my cholesterol and improved diabetes symptoms


\* Preliminary Market Research

**LipiLife Solves 100-Year Old Problem  
Toxicity of Lipids and Correct Dosage**







Lipids form toxic compounds sitting on shelf over time




Hydrogenated fats were introduced in early 1900s to solve this problem



Hydrogenated fats cause diseases - stopped in early 2000s



Polyunsaturated fats good for health but most vulnerable to forming toxic compounds



LipiLife best solution - replacement bottle/box delivered to consumers every 7 days and used with foods prepared without fat

The product, LipiLife, is in limited supply at present due to limited capital. Significant capital is necessary to effectively solve this problem, which includes public education in addition to product implementation. It is important for the patents to be granted for the Applicant to raise sufficient capital. All of the three applications are currently pending. Faster advancement of these applications is necessary for the applicant to secure sufficient capital and implement the solutions with public education to benefit the target populations.

7. Contribution – What meaningful actions did the applicants take to make the technology more available for addressing humanitarian issues?

Applicant is a small entity with very limited resources. Proprietors of the company have invested their personal intellectual and material resources for 10 years with dedication, without remuneration, to advance and implement the technology. Applicant needs sufficient capital to effectively solve this problem and patents need be granted to raise sufficient capital and effectively implement the solutions.

Applicant has committed to providing subsidized/free products to impoverished populations from part of the income generated from for-profit segments. Applicant plans to direct 10-25% of profits generated for providing subsidized/free products to impoverished populations. Such plans will be opportunistically reevaluated based on Applicant's financial strength. Partnerships will be developed with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. For example, Applicant has had

discussions for establishing such relationships with the following organizations: The HSC Foundation, The California Endowment, and California Wellness Foundation.

Applicant has invested very significant resources in building worldwide intellectual property portfolio in order to successfully make technology available to impoverished populations in economies with a disproportionate share of impoverished populations, such as Nigeria, Mexico, South Africa, Ukraine, Indonesia, Sri Lanka, China, and India.

8. **Impact** – How has deployment of the technology to benefit the target populations been significantly advanced as a result of the applicants' contributions? Are the target populations using the technology or products and services based on it? Are they benefitting in other ways? Include downstream actions by third parties stemming from the applicants' contributions.

As stated above, Applicant is a small entity. The products are currently in limited supply due to scarce resources. Applicant has put all resources available to deployment of the technology to benefit the target populations. Applicant has committed to providing subsidized/free products to impoverished populations from part of the for-profit segments returns, and to developing partnerships with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. As evidenced throughout this application unprecedented humanitarian benefits can be realized through this technology.

In the enclosed declarations from Drs. Rustagi, Rucker, and Das, the scientists declared:

*“Thus, the art recognized in 1929 that the problem existed as noted in paragraph [0019]. However, the art has failed to solve the long-felt, critical and unmet need until the April 2008 priority date of the subject patent application, i.e. for ~80 years. There have been many persistent attempts as evidenced by the references cited above (e.g. Mark et al., whfoods.com, Lands 1986 and 2005; Simopoulos 1999; Hamazaki et al., 2003 supra), but the problem has not been solved. Lipid art has been struggling to find what are the right combinations of omega-6 and omega-3 and other lipids for consumption, how to keep the fatty acids stable on shelf (without formation of toxic compounds) but bio-available in-vivo (Chen and Chaiyasit supra). Inventions of instant claims 65, 91, 98, 122, 129, and 130 have devised the solutions. Thus, the invention of the subject patent application solves a long-felt critical persistent unmet need, and has great potential to protect and improve public health.” See para [0019]-[0023].*

*“[The technologies] ... are well-reasoned and directed at much needed lipid solutions, particularly in light of mass erroneous teachings and confusion in the lipid art.” See para [0026].”*

Thus, the technology has many immediate and long-term benefits.

- The immediate benefits are reduction in global disease burden and public suffering.
- Long-term benefits include solution to the problem of toxicity from spoilage of unsaturated fatty acids, which has plagued the society for over 100 years.
- Long-term benefits also include that tailored delivery of lipids and micronutrients can prevent diseases from acculturation because of tailoring to demographics.
- The disclosed approach will largely re-align the currently dysfunctional nutrition system.
- The technology has additional long-term benefits, such as when tailored lipids and micronutrients solve the large part of the disease burden, resources and research are focused on solving deeper causes of diseases in populations free of the confounding effects of mismanaged lipid consumption.

Thus, there are numerous immediate and downstream beneficial actions by third parties stemming from the applicants' contributions, which will advance humanitarian causes and make a lasting impact on humanity.

### **Additional Information**

If there's any additional information you would like the judges to consider, include it here. Judges are not required to read more than five pages of material, not counting the pages of this form.

#### Appendices:

1. Bhagat et al. 2015, "Potential role of dietary lipids in the prophylaxis of some clinical conditions" Arch Med Sci 2015; 11, 4: 807–818
2. Lands, "Renewed Questions about Polyunsaturated Fatty Acids" Nutrition Reviews 1986:44-6:189-95
3. Lands, "Dietary Fat and Health: The Evidence and the Politics of Prevention" Ann. N.Y. Acad. Sci. 1055: 179–192 (2005)
4. Simopoulos, "Essentiality of and Recommended Dietary Intakes for Omega-6 and Omega-3 Fatty Acids" Ann Nutr Metab 1999;43:127–130
5. Calder PC, "Polyunsaturated fatty acids and inflammatory processes: New twists in an old tale" Biochimie 91 (2009) 791–795
6. Johnson et al., "Effect of Dietary Linoleic Acid on Markers of Inflammation in Healthy Persons: A Systematic Review of Randomized Controlled Trials" J Acad Nutr Diet. 2012;112:1029-1041.
7. Baum et al., Journal of Clinical Lipidology 2012:6:216–234 "Fatty acids in cardiovascular health and disease: A comprehensive update"
8. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid" Prostaglandins, Leukotrienes and Essential Fatty Acids 2009:81:373–389
9. Lu et al. "Linoleic acid suppresses colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction" Lipids in Health and Disease 2010, 9:106.
10. Brasky et al., "Plasma Phospholipid Fatty Acids and Prostate Cancer Risk in the SELECT Trial" July 2010
11. Yip et al., "The Omega-3 Fatty Acid Eicosapentaenoic Acid Accelerates Disease Progression in a Model of Amyotrophic Lateral Sclerosis" PLoS ONE 8(4)
12. Declaration from Dr. Pradeep K. Rustagi dated September 29, 2014.
13. Declaration from Dr. Undurti N. Das dated September 30, 2014.
14. Declaration from Dr. Robert B. Rucker dated September 29, 2014.
15. Lipid-Containing Compositions And Methods Of Use Thereof
16. Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof
17. Filho et al. "Essential fatty acids for premenstrual syndrome and their effect on prolactin and total cholesterol levels: a randomized, double blind, placebo-controlled study" Reproductive Health 2011, 8:2

## PROOF OF SERVICE

I hereby certify that on April 25, 2018, I served a copy of the foregoing

**APPELLANT'S COMBINED PETITION FOR PANEL REHEARING AND  
REHEARING *EN BANC*** via email on:

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