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

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE BHAGAT

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

APPELLANT'S MOTION PURSUANT TO FEDERAL RULE 32.1(e) TO REISSUE PANEL DECISION AS PRECEDENTIAL

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Pro Se Appellant

Dated: May 14, 2018

Introduction

Appellant requests this Court to reissue its March 16, 2018, opinion on case #16-2525 ("Opinion") as precedential, subject to revision, pursuant to Federal Circuit Rule 32.1(e). Appellant hopes the Court will be honorable and grant the Petition for Panel Rehearing and Rehearing *En Banc* submitted on April 25, 2018 (hereinafter "Petition") and vacate the Opinion, because the Opinion as stands is extremely unjust as contrary to a large body of law established by this Court and the Supreme Court, including *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) and *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983), because it disregards claim terms; *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989), because it disregards Applicant's interpretation of terms provided during prosecution; *In re Cortright,* 165 F.3d 1353, 1358 (Fed. Cir. 1999), because it disregards PHOSITA (person having ordinary skill in the art) interpretation of claim terms; and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296-97 (2012), and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347, 2355 (2014), *Diamond v. Diehr*, 450 US 175, 188-9 (1981), and *Parker v. Flook* 437 U.S. 584, 594 (1978), because it fails to consider the claims as a whole.

However, if the Petition is denied then it is only fair that the new rule of law established by the Opinion be made precedential and applied uniformly to all cases. Appellant believes the panel is aware the Opinion is so wrong that it could not be

made precedential, that is why the panel issued the Opinion as "non-precedential." **However, it is improper for the panel to circumvent the law by issuing the Opinion as "non-precedential" to avoid impact on other patents and applications (protecting drug formulations, for example), while singling out and adversely treating the subject patent application (pertaining to nutrition). This compromises the credibility of the Court and the patent system. The same law must apply consistently to all patentees and applicants.**

Therefore, this request is filed to meet the deadline of Rule 32.1(e), and need only be considered if the Petition is denied. The Appellee has been notified of this request.

Appellant knows of no case pending before this Court that would be affected by reissuance of the Opinion as precedential. However, 1000s of granted patents and pending applications are drawn to "composition of matter" claimed in the Appellant's "formulation(s)", "dosage(s)", and "casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources," and many of them are non-anticipatory precisely because their claims contain elements not disclosed and enabled by the prior art, as do instant claims. Therefore, the reissuance of the Opinion as precedential would potentially invalidate 1000s of issued patents and adversely impact numerous pending applications.

The Opinion Conflicts With
Numerous Binding Precedents Of This Court and The Supreme Court

Federal Circuit Rule 32.1(b) states "An opinion or order which is designated as nonprecedential is one determined by the panel issuing it as not adding significantly to the body of law." However, the Opinion implicitly overturns a large body of patent law establishing a new rule of law creating conflict with past holdings cited supra and in the Petition and Appellant's briefs, and sets forth a new interpretation of Supreme Court decision *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) and of 35 USC § 101 because the Opinion **holds as irrelevant**, the improved utility of claimed "composition of matter" that nature cannot serve the ends recited in the claims ("dosages" and "controlled lipid delivery"), and the extremely important inventive concept present in the claims. Therefore, the Opinion does add significantly to the body of law and in accordance with Court's Internal Operating Procedure (IOP) #10.4(c)-(f), and (i), the Opinion should be made precedential. It is not possible to list the large number of precedents this opinion overturns; however, some of those are discussed below.

1. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) and *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983), because Opinion disregards and excises terms from the claims, specifically "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-

containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources".

2. *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989) and *TriVascular, Inc. V. Samuels,* 812 F.3d 1056, 1061-62 (Fed. Cir. 2016), because Opinion fails to read the full context of surrounding words in claims (subordinate clause with main clause together), for example, "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)" in Claim 65, and Applicant's interpretation of "dosage" and "casings…subject" provided during prosecution in Claims 65, 91, 129, and 130, and several dependent claims. For example, Applicant asserted the following interpretations during prosecution:

> Dosage means "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).
>
> "[o]ne or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject" means "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.

3. *In re Cortright,* 165 F.3d 1353, 1358 (Fed. Cir. 1999) and *In re Alton*, 76 F.3d 1168, 1175-77 (Fed. Cir. 1996), because the Opinion disregards PHOSITA interpretation and testimony regarding claim terms e.g. "'dosage' in the subject

patent application is clearly directed to determination of amount to be administered and/or administration in prescribed amounts" (Appx6485 ¶12, Appx6502 ¶12, Appx6519 ¶12), "omega-6 fatty acids are not more than 40 grams" in context of claims means "Omega-6 dosage less than 40 grams" (Appx6488 ¶17.c, Appx6505 ¶17.c, Appx6522 ¶17.c), and "'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)" (Appx7230 ¶5, Appx7239 ¶5, Appx7320 ¶5).

4. *In re Garnero*, 412 F.2d 276, 278-79 (C.C.P.A. 1969) and *Abbott Labs v. Sandoz,* 566 F.3d 1282, 1294 (Fed. Cir. 2009)(en banc), because Opinion fails to construct "intermixture of lipids from different sources" as a structural limitation and disregards that structure of the products is not fully known, too complex to analyze, and expected to have unnatural properties (Appx7051-7056, Appx7674-7677, Appx7859-7862, Appx7867-7874, Appx7230-7232, Appx7239-7241, Appx7320-7321).

5. *Perricone v. Medicis Pharmaceutical Corp*, 432 F.3d 1368, 1375-79 (Fed. Cir. 2005) and *In re Elsner,* 381 F.3d 1125, 1127 (Fed. Cir. 2004), because the Opinion disregards the alleged anticipatory references Mark and WebOlives/

WebWalnuts do not necessarily function as "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources" and are not enabled as PHOSITA testified. Opening Brief at 60-62, 64, 69-74; Reply Brief at 18-26, 27-31.

6. *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), and *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008), because contrary to anticipation law, the Opinion fills in missing limitations in Mark and WebOlives/ WebWalnuts. Opening Brief at 60-62, 64, 69-74; Reply Brief at 18-26, 27-31.

7. *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), and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948), because the Opinion fails to include the elements "dosage" and "casings providing controlled delivery" in eligibility analysis under 35 USC § 101 and that they change functionality of omega-6 and omega-3, as they occur in nature, therefore, do add "significantly more" to natural products, and that **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.

8. *Berkheimer v. HP Inc.,* 881 F.3d 1360, 1369 (Fed. Cir. 2018), because USPTO never found facts relating to whether after taking claims as a whole in account the subject matter of independent claims 65, 91, 129, and 130 is "well-understood, routine, and conventional."

9. *Diamond v. Diehr*, 450 US 175, 188-9 (1981), *Parker v. Flook* 437 U.S. 584, 594 (1978), *Mayo* 1298, and *Alice* 2355, because Opinion fails to consider claims as a whole. The features "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources" were disregarded in the Opinion.

10. 35 USC § 101 because Opinion **holds as irrelevant**, the improved utility of claimed "composition of matter", that nature cannot serve the ends recited in the claims, namely "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing

comprises an intermixture of lipids from different sources", and the extremely important inventive concept present in the claims.

Thus, as detailed above the Opinion contradicts binding precedents from Supreme Court and this Court cited supra and in Appellant's Opening and Reply Briefs, and it sets forth a new interpretation of 35 USC § 101. 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. Therefore, the Opinion does add significantly to the body of law, and as per IOP #10.4(c)-(f) and (h)-(i), the Opinion should be reissued as precedential.

The Opinion Sets Forth A New Legal and Factual Situation Of Interest To A Wide Spectrum of Persons

The Court's Internal Operating Procedure #10.4(h), states an opinion that sets forth a new legal and factual situation of interest to a wide spectrum of persons other than the parties to the case should be issued as precedential. Several patent attorneys and PHOSITA, unaffiliated with Appellant, find the Opinion to be setting forth new factual and legal situation. See citations below and addendum for detail.

I. "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, states,

> "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." Page 2.

II. "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, states,

> "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." Pages 1-2.

III. "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, states,

> "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." Pages 2-3.

Thus, a wide spectrum of persons, who are also PHOSITA and lawyers, find the Opinion sets forth a new legal and factual situation.

The panel's entire basis for disregarding "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources", is based on the **falsification of facts by USPTO and adoption of same by the Court creating a new factual situation**. Opinion states at page 5,

> "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."

However, the factual statement in Specification is, "[i]n some embodiments, the compositions comprising the lipid formulation disclosed herein may be administered to an individual in any orally accepted form." (emphasis added) Specification ¶ [0034] Appx65. In context of the statement and rest the disclosure "any orally acceptable form" refers to form of "composition", i.e. type of food e.g.,

"a nutritional bar", "powder" "granule", not "amount" relevant to "dosage". Note the statement "[i]n some embodiments, the compositions comprising the lipid formulation disclosed herein may be administered to an individual in any orally accepted form," does NOT contain the words "dosage" or "amount" or "casing." Furthermore, "any orally accepted form" is restricted to "some embodiments."

Specification does NOT say, "these claim elements are not limiting" as alleged in the Opinion. Rather, Specification ¶106 Appx97 states, "It is intended that the following claims define the scope of the disclosure and that methods and structures within the Scope of these claims and their equivalents be covered thereby." Thus, Specification ¶ [0034] does not actually support the assertion that "the specification states that these [or any] claim elements are not limiting"; according to the specification, the invention's scope is to be determined by the claims.

Further, the features DO provide novel functionality to the formulations in "dosage of omega-6 and omega-3" and "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources". See #5-6 supra and Opening and Reply Briefs.

All patent specifications include broader embodiments and narrower embodiments. As a standard practice during prosecution, claims are delimited by

narrower embodiments over prior art. *Computer Dock Stat V. Dell*, 519 F.3d 1366, 1375 (Fed. Cir. 2008) (Holding that a patentee can limit the meaning of a claim term "by clearly characterizing the invention in a way to try to overcome rejections based on prior art"); *Intervet America V. Kee-Vet Laboratories*, 887 F.2d 1050, 1053-54 (Fed. Cir. 1989) (Noting that "[t]he claims themselves control"); *Maz Encryption Techs., LLC v. Lenovo (u.s.) Inc.*, C.A. No. 13-303-LPS (D. Del. Jun. 30, 2015) ("The Court [] will not read out of the claims an embodiment disclosed in the specification"; emphasis added).

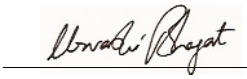
The Opinion changes the patent law by removing the provision that claims may be delimited over prior art by reciting narrower embodiments from specification in the claims, and sets forth a new legal and factual situation that a tribunal may reconstruct specification, for example by adding "these claim elements are not limiting", as convenient to reject an application.

Therefore, the Opinion should be reissued as precedential, as per IOP #10.4(h), because it sets forth a new legal and factual situation of interest to a wide spectrum of persons other than the parties to the case, for example various attorneys and other courts such as, United States District Court For The District Of Delaware.

Conclusion

In summary, the Opinion is improper therefore it should be vacated and the case should be reheard, otherwise, the Court should reissue the Opinion as precedential, treating the Appellant at par with other applicants. The Opinion may be revised, rather should be revised.

This application has been treated as a second-class citizen, given minimal thought and consideration causing delay and forcing the applicant to do a significant amount extra work and spend almost a decade in prosecution. The court must correct that. **It is extremely improper to single out the subject application for adverse treatment.** Consistent and evenhanded treatment of patents and patent applicants is essential for the integrity of the patent system. The Court must treat small companies at par with large corporations. If specification could be mutilated, as PTAB did and this Court adopted, and if claims could be mutilated as PTAB did and this Court adopted, then there is no motivation for the Appellant or any other inventor/applicant to disclose any invention and pursue any patents, because such mutilation could happen even at a later stage in life of the patent. We all lose if this is allowed to stand.



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

IN RE: URVASHI BHAGAT,
Appellant

2016-2525

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

Decided: March 16, 2018

URVASHI BHAGAT, Palo Alto, CA, pro se.

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

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

NEWMAN, *Circuit Judge.*

Urvashi Bhagat ("the Applicant") appeals the decision of the Patent Trial and Appeal Board ("the Board") affirming the examiner's rejection of claims 52, 61, 64, 65, 67–69, 73–75, 77, 78, 80, 82, 83, 90–102, 107, 116–122, 124,

and 128–145 of U.S. Patent Application No. 12/426,034 ("the '034 application").[1] We affirm the Board's decision.[2]

BACKGROUND

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

> 65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein
>
> > (1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or
> >
> > (2) omega-6 fatty acids are not more than 40 grams.

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.

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

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

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

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

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.

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.

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

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.

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.

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

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.

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.

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

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*

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.

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."

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

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

Analysis as that reference "teaches that walnuts contain sugars including disaccharides as required." Board Op. at *37. On this appeal the PTO does not discuss claim 136 with regard to olives, but argues that claim 136 is anticipated by the Walnut Nutrient Analysis and invalid under Section 101.

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

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. UBBr74.

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.

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

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.

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.

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

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.

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. UBBr76; UBRBr30. #14.

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

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. UBBr 76-77. Panel insincerely regurgitated PTAB Decision.

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.

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.

II

SECTION 101

The examiner and the Board also held that all of the claims are directed to non-statutory subject matter under Section 101, because the claimed fatty acid mixtures occur naturally in walnut oil and olive oil. The examiner found that the claimed "intermixture of lipids from different sources" is "structurally indistinct" from lipid formulations derived from a single source, as shown in the prior art. The examiner also found that the claims are directed to natural products of walnut oil and olive oil, and that the additional limitations in the claims do not change the characteristics of the products, or add "significantly more" to the claims.

The Applicant argues that it "disclaimed" the claim scope of compositions from a single source, thus avoiding not only anticipation, but also Section 101. The Applicant

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

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. Decision37 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 Decison37 to be safe. If Appellant had not, it could have been used against the Appellant.

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.

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.

claimed omega-3 and omega-6 fatty acids, from the omega-3 and omega-6 fatty acids that exist in nature, and that the Applicant has not provided evidence of such distinction.

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

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

AFFIRMED

No costs.

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.

Preponderance of evidence including five scientific publications (Appx6650-6707) and four PHOSITA testimonies have been subimtted 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.

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.

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.

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

FOLEY

FOLEY & LARDNER LLP

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

The PTAB upheld all rejections.

The Federal Circuit Decision

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

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.

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.

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:

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 Federa Circuit would do that.

> [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.

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).

OBLON

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

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.

ASSOCIATED PEOP

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- Life Sciences

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."

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.

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."

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.

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."

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.

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)

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

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

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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). Therefor 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

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."

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.

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.

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.

In the 101 analysis, the Examiner abbreviated, if not conflated, the 2A and 2b; apart from the finding that o-6 and 04 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.

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.

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.

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.

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 entirely 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.

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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PROOF OF SERVICE

I hereby certify that on May 14, 2018, I served a copy of the foregoing **APPELLANT'S MOTION PURSUANT TO FEDERAL RULE 32.1(e) TO REISSUE PANEL DECISION AS PRECEDENTIAL** via email on:

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