

NOTE: This disposition is nonprecedential.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”) 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”).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-

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

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

I

ANTICIPATION

A. The Mark reference

The Board affirmed the examiner's rejection of claims 52, 61, 64, 65, 67–69, 73, 75, 77, 78, 80, 83, 90, 92–96, 98, 100, 129–131, 133, 135–137, 142 and 144 on the ground of anticipation by U.S. Patent No. 5,549,905 (“Mark”). Mark describes a nutritional composition for pediatric patients, including a protein source, carbohydrate source, and lipid source containing omega-6 and omega-3 fatty acids in a ratio of “approximately 4:1 to 6:1.” Mark, col. 2, ll. 32–38; col. 4, ll. 21–23. Mark states that the omega-6 fatty acid “is present in a range of approximately 4–6% of the total calories” of the pediatric composition, and the omega-3 fatty acid “is preferably present in the range of approximately 0.8–1.2% of the total calories.” *Id.* at col. 4, ll. 27–31. Mark describes a specific composition containing 38.5 grams of total lipids, *id.* at col. 6, l. 9, administered intra-

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

infants and children.” Board Op. at *26. We discern no error in the finding that claim 137, which includes “human infants,” is anticipated by Mark’s reference to children ages 1–10.

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

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

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

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

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

B. *The Olive and Walnut Nutrient Analyses*

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

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

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

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

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

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

references. The Board's finding that the references' serving sizes of olives and walnuts meet the "dosages" in the claims is supported by substantial evidence in the record.

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

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

For claims 67 and 68 the Board found that the protein in walnuts and olives meets the "protein source" designated in these claims. The Board found that the Walnut Nutrient Analysis includes protein and carbohydrates as recited in claim 67, and "the protein in walnuts is not derived from the prohibited sources of claim 68." Board Op. at *35-36. Claim 78 recites "steady" delivery, e.g., "[t]he formulation of claim 65, whereby the formulation provides gradual and/or steady delivery so that any

omega-3 withdrawal is gradual, and/or any omega-6 and/or other fatty acid increase is gradual.” Claims 73, 74, 98, 118, 122, 137 and 140 add limitations directed to intended use. Claims 96 and 97 include limitations of additional nutrients and polyphenols.

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

II

SECTION 101

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

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

states that the Board erred in rejecting all of the claims as directed to a product of nature, arguing that the claimed “intermixture of lipids from different sources” does not occur in nature, and that the properties of the claimed formulations from different lipid sources are different from the properties of single source natural products.

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

Claim 128

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

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

Claims 102, 107, and 119

The examiner and the Board did not specifically include claims 102, 107, and 119 in the rejection for 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

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.