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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* URVASHI BHAGAT

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Appeal 2019-000388  
Application 13/332,251  
Technology Center 1600

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

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal<sup>1,2</sup> under 35 U.S.C. § 134 involving claims to a method of preparing a lipid-containing formulation for a subject. The Examiner rejected the claims as indefinite, as anticipated, and as lacking patentable subject matter under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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<sup>1</sup> Appellant identifies the Real Party in Interest as Asha Nutrition Sciences, Inc. (App. Br. 3).

<sup>2</sup> We have considered and herein refer to the Specification of Dec. 20, 2011 (“Spec.”); Final Office Action of Dec. 21, 2016 (“Final Act.”); Appeal Brief of May 7, 2018 (“App. Br.”); Examiner’s Answer of Aug. 16, 2018 (“Ans.”); and Reply Brief of Oct. 15, 2018 (“Reply Br.”).

*Statement of the Case*

*Background*

“Linoleic acid (LA) and Alpha-linolenic Acid (ALA) are the precursors for all omega-6 and omega-3 fatty acids. It is well established that LA and ALA are ‘essential’ fatty acids” (Spec. ¶ 4). “Dietary deficiency or excess of the two essential fatty acids may cause many illnesses” (*id.*). “Numerous studies provide evidence for the prophylaxis and treatment of medical conditions using supplementation with omega-3 fatty acids and recommendations to reduce omega-6 consumption” (*id.* ¶ 6). “The traditional emphasis on increasing omega-3 and reducing omega-6 consumption often does not result in satisfactory relieves because of the uncertainties introduced by dietary and demographic factors” (*id.* ¶ 7).

The Specification teaches “methods for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids within context of other factors” (Spec. ¶ 8). The Specification teaches “methods that use more advantageous sources of omega-6 fatty acids, in the presence of nutritionally adequate omega-3 fatty acids” (*id.*).

*The Claims*

Claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145–150, 153–166, 168, 171, 177, and 178 are on appeal.<sup>3</sup> Claim 94 is representative and reads as follows:

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<sup>3</sup> We note that claim 172 is listed as “previously presented” in the Claims Appendix. However, claim 172, added in the Amendment filed Jan. 4, 2013, was identified as withdrawn in the Final Action mailed Apr. 16, 2013 (*see* Final Act. 4/16/2013 at 2 “Claims 95, 102–104, 107–108, 112–114, 116, 118–119, 121–125, 128–137, 139–140, and 142–172 are withdrawn as being drawn to nonelected species.”).

94. A method of preparing a lipid-containing formulation for a subject, comprising:

combining daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,

wherein the formulation comprises omega-6 and omega-3 fatty acids, and wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:

4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or

1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or

4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or

2:1 to 30:1 if the subject has a diet of high seafood; or

1:1 to 45:1 based on lipid tolerance of the subject; or

1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

*The Rejections*

A. The Examiner rejected claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145–150, 153–166, 168, 171, 177, and 178 under 35 U.S.C. § 112, second paragraph (Ans. 4–5).

B. The Examiner rejected claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145, 147–149, 153–157, 159–162, 164–166, 168, 171, 177, and 178 under 35 U.S.C. § 101 (Ans. 6–13).

C. The Examiner rejected claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145, 147–149, 153–157, 159–162, 164–166, 168, 171, 177, and 178 under 35 U.S.C. § 102(b) as anticipated by Olive Oil<sup>4</sup> and Olive Oil Nutritional Profile<sup>5</sup> (Ans. 14–20).

A. *35 U.S.C. § 112, second paragraph*

The Examiner finds:

The terms “high” and “low” are relative terms and it is unclear to the Examiner how high or low the amounts of antioxidants, phytochemicals and or seafood is required in the diet of a subject to meet said limitations. The claims do not recite any amounts of antioxidants, phytochemicals or seafood. As such, one of ordinary skill would be unable to discern whether an amount of antioxidants, phytochemicals or seafood in the diet of a subject as disclosed in the prior art falls within the scope of “high” or “low.”

(Ans. 5.)

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<sup>4</sup> Olive Oil, <http://web.archive.org/web/20070713174214/http://www.whfoods.com/genpage.php?pfriendly=1&tname=foodspice&dbid=132> (2007).

<sup>5</sup> Olive Oil Nutritional Profile, <http://web.archive.org/web/20070714054939/http://www.whfoods.com/genpage.php?pfriendly=1&tname=nutrientprofile&dbid=110> (2007).

Appellant contends the Specification “provides guidance for recognizing high-antioxidant diets, high-phytochemical diets, high seafood diets. The specification also teaches that omega-6 and omega-3 fatty acid metabolism and requirements are affected by a number of antioxidants and phytochemicals, and how to adjust the formulation accordingly” (App. Br. 11 (citing Spec. ¶ 33)). Appellant also points to teachings in the art regarding the use of “high” and “low” (*see* App. Br. 11–12) as well as a statement by Dr. Erickson regarding “high” and “low” (*see* App. Br. 13).

We agree with Appellant. The Supreme Court articulated the test for indefiniteness as “requir[ing] that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). “As long as claim terms satisfy this test, relative terms and words of degree do not render patent claims invalid.” *One-E-Way, Inc. v. International Trade Commission*, 859 F.3d 1059, 1063 (Fed. Cir. 2017). “To determine whether a particular term is indefinite, ‘[o]ne must bear in mind . . . that patents are “not addressed to lawyers, or even to the public generally,” but rather to those skilled in the relevant art.’” *Id.* (citing *Nautilus*, 572 U.S. at 909).

The Examiner provides no evidence that the terms “high” and “low” in relation to dietary components would have been indefinite to one of ordinary skill in the art. In contrast, as explained in more detail below, Appellant provides several references that use the terms “high” and “low” with respect to dietary compositions and statements by Dr. Erickson specifically assert that the skilled artisan would have understood the meaning of these relative terms.

The Specification uses the terms “high” and “low” relative to dietary components, for example teaching “an individual with a low-antioxidant low-phytochemical herbivorous diet, a low-antioxidant low-phytochemical ovo-lacto vegetarian diet, a low-antioxidant low-phytochemical vegan diet, or a low-antioxidant low-phytochemical omnivorous diet may be administered related compositions” (Spec. ¶ 33).

Table 1 of Simopolous,<sup>6</sup> reproduced in part below, shows specific values given for the terms “high” and “low” in the context of omega 6 and omega 3 fatty acids, as well as for other dietary elements:

Table 1  
 Characteristics of hunter-gatherer and western diet and lifestyles

Characteristic	Hunter-gatherer diet and lifestyle	Western diet and lifestyle
Fiber	High	Low
Fat	Low	High
Animal	Low	High
Vegetable	Very low	Moderate to high
Total long-chain ω6 + ω3	High (2.3 g/d)	Low (0.2 g/d)
Ratio ω6/ω3	Low (2.4)	High (12.0)
<i>Vitamin, mg/d</i>	<i>Paleolithic period</i>	<i>Current US intake</i>
Riboflavin	6.49	1.34–2.08
Folate	0.357	0.149–0.205

Dr. Erickson stated, in Applicant’s Interview Summary:

The concept of “high” and “low” of nutrients and food types is well known in the field of nutrition and the terms often appear in scientific and medical publications in the field. This is frequently the case in nutritional surveys and nutritional epidemiology. The relative amounts of “high” and “low” of various nutrients and food types are well known.

(Applicant’s Interview Summary 4/25/17 at 9.)

Thus, the evidence shows that the ordinary artisan in the nutritional arts would have understood the meaning of “high” and “low” as it relates to

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<sup>6</sup> Simopoulos, *The importance of the ratio of omega-6/omega-3 essential fatty acids*, 56 BIOMED. PHARMACOTHER. 365–79 (2002).

amounts of nutritional components, and omega fatty acids in particular, with reasonable certainty. We therefore reverse the indefiniteness rejection.

*B. 35 U.S.C. § 101*

The Examiner finds that the claims on appeal are “directed to a judicial exception (i.e. a law of nature, a natural phenomenon, or an abstract idea) without significantly more” (Ans. 6). The Examiner finds that the claims recite a “process of making a lipid-containing formulation (i.e. a combination of products or elements), wherein the product formed by said process is a combination of products of nature” (*id.*). Specifically, the Examiner finds “[b]ecause each compound in olive oil is naturally occurring, and, further, because the recited combination of compounds is known to occur together in nature (i.e. is present in olive oil), said combination formed by combining daily amounts of fatty acids is considered a ‘product of nature’” (*id.* at 10). The Examiner also finds the claim steps basing dosage on particular factors “is a mental step that merely equates to gathering information, correlating or making a determination and is thus an abstract idea which is a judicial exception” (*id.* at 13).

Appellant contends:

[T]he claims require more than merely providing some quantity of the recited formulation. The claims require that the “combining” is done such that “the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors.” This amounts to more than an abstract idea because the abstract idea is applied to the formulation such that the formulation’s composition varies as a function of the factors considered.

(App. Br. 21.)

We apply the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), based on the two-step *Alice* framework. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014).

In *Alice* step one, we ask whether the claims are directed to a patent ineligible concept, such as natural phenomena or an abstract idea. *Alice*, 134 S.Ct. at 2355; *Mayo*, 566 U.S. at 75–77; *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015). While method claims are generally eligible subject matter, method claims that are directed only to abstract ideas and/or natural phenomena are directed to patent ineligible concepts. *Ariosa*, 788 F.3d at 1376. In *Alice* step two, we examine the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application. *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 566 U.S. at 71–72).

*Alice Step One*

Claim 94 is directed to a process of designing a lipid formulation based on three overlapping types of parameters: (a) personal characteristics such as age, gender, diet, and weight (*cf.* Spec. ¶ 9); (b) dietary intake such as amounts of antioxidants, phytochemicals, and seafood (*cf.* Spec. ¶ 33); and (c) climate conditions at the subject's location (*cf.* Spec. ¶¶ 43–44).

The claim is directed to a method of preparing a lipid containing formulation for a subject. Thus, the method, itself, is not a natural phenomenon or natural law because the claim does not read on only the composition, itself, but rather is directed to making the composition.

Therefore, the method of combining lipids based on these parameters is not reasonably interpreted as a natural phenomenon.

Moreover, the instant facts differ from those in *Mayo*, where the natural correlation between 6-thioguanine levels and therapeutic efficacy was a relationship that “exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes.” *Mayo*, 566 U.S. at 77. Here, even if there is a correlation between a particular amount of fatty acids and a particular therapeutic effect in a patient, the claim is not drawn to that correlation, but rather is directed to a method of making such a composition.

As to patent ineligibility based on abstract ideas, claim 94 is not directed to an abstract idea but rather to a specific process for combining omega-6 and omega-3 fatty acids based on the three overlapping types of parameters relating to specific characteristics of a subject individual. We can analogize the instant facts to *Cellzdirect*, where a claim to a process of producing cryopreserved hepatocytes that survive multiple freeze/thaw cycles using a particular process was “directed to a new and useful method of preserving hepatocyte cells.” *Rapid Litigation Management Ltd. v. Cellzdirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016). *Cellzdirect* noted:

[The] claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to *undergo* the process does not make the claim “directed to” that natural ability.

*Id.* at 1048–1049.

Similarly, the claims as a whole are not abstract. “That a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction.” *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017). The instant claims seek to protect only the process of combining omega-6 and omega-3 fatty acids for a particular subject based on a number of specific characteristics that must be considered together including personal characteristics, dietary intake, and climate conditions at the subject’s location. Therefore, rather than claiming an abstract idea such as merely “gathering information, correlating or making a determination” (*see* Ans. 13), the claims specify forming a particular combination of omega-6 and omega-3 fatty acids based on the information for preparation of dietary supplements for a particular subject. *See Thales*, 850 F.3d at 1349 (“The claims specify a particular configuration of inertial sensors and a particular method of using the raw data . . . . Far from claiming the equations [e.g. abstract idea] themselves, the claims seek to protect only the application of physics to the unconventional configuration of sensors as disclosed.”).

Because the claims are not directed to either a natural phenomenon or an abstract idea, we need not turn to the second step of the *Alice* framework.

We therefore conclude that all of the claims on appeal are directed to patent-eligible subject matter and reverse the § 101 rejection.

C. 35 U.S.C. § 102(b)

The Examiner finds “‘Olive Oil’ teaches that 2 tablespoons a day of olive oil added to an otherwise unchanged diet in 28 outpatients, ranging in age from 64 to 71, resulted in significant drops in total- and LDL cholesterol” (Ans. 14). The Examiner finds:

[O]ne can clearly envisage that the reference teaches the amounts of the fatty acids in two tablespoons of olive oil, when provided by combining two one tablespoon servings, is “based on” “diet of the subject”, “medical conditions of the subject”, “gender of the subject” and “age of the subject”. Moreover, the reference indicates that olive oil is part of a diet from the Mediterranean region, a region which has a specific climate (ambient temperature range), and thus qualifies as a method of combining two one tablespoon servings of olive oil “based on” the elected factor (the ambient temperature range of a subject's living area).

(Ans. 19.)

Appellant contends the rejection erred by not giving patentable weight to the following claim elements recited in claims 94 and 101; effectively ignoring a large part of the claim language.

wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors . . . (claim 94)

evaluating the subject on the basis of one or more factors selected from . . . (Claim 101)

wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors . . . (Claim 101)

(App. Br. 25.) Appellant contends the prior art fails “to disclose and enable how to prepare, select, and control omega-6 and omega-3 ‘based on’ ‘age’, ‘gender’, ‘diet’, ‘medical condition’, or the ‘ambient temperature range’ of the subject” (App. Br. 26).

We agree with Appellant that the method of preparing a formulation as specified in the claim is not anticipated by the so-called “Olive Oil” publication. As indicated by Appellants, Olive oil does not teach controlling

the amounts of omega-6 and omega-3 based on one of the recited factors, but rather teaches the same olive oil composition irrespective of the patient's diet or other factors.

We agree with Appellant because there is no evidence that the subjects discussed in the "Olive Oil" reference necessarily were prepared using fatty acid ratios consistent with the individual correlations between personal characteristics, dietary intake, and climate conditions as recited in claim 94.

This reasoning that the patient population in claim 94 may differ from the patient population in "Olive Oil" is consistent with *Perricone*, which distinguished between the topical application of a lotion to skin generally to prevent sunburn, and the topical application of a lotion to treat sunburned skin. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). *Perricone* found that the "issue is not . . . whether [the prior art] lotion if applied to skin sunburn would inherently treat that damage, but whether [the prior art] discloses the application of its composition to skin sunburn. It does not." *Id.* at 1378 (emphasis omitted).

The same analysis applies here. There is a general teaching in "Olive Oil" to provide olive oil that will inherently contain a particular ratio of omega-6 to omega-3 fatty acids to patients (*see* Olive Oil 2). If the subjects in "Olive Oil" also happened to have the particular dosages based on personal characteristics and dietary intake as shown in tables 9–11 of the Specification (*see* Spec. ¶¶ 47–49), as well as the climate conditions of Table 6 of the Specification (*see* Spec. ¶ 43), the "Olive Oil" composition might also necessarily satisfy the three requirements of personal characteristics, dietary intake, and climate conditions, analogous to the skin

treatment at issue in *Perricone*. However, the Examiner has not identified any teaching or suggestion in “Olive Oil” to modify the composition to satisfy the three requirements of personal characteristics, dietary intake, and climate conditions. In the same manner that not everyone who applies lotion to his or her skin will necessarily have sunburn, not all subjects taking olive oil have been demonstrated to necessarily satisfy the three requirements of personal characteristics, dietary intake, and climate conditions recited in the Specification. Therefore, the evidence of record in “Olive Oil” does not demonstrate that olive oil will necessarily result in the required subject specific formulations. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” (citation omitted)).

This situation is different than the product claims at issue in *In re Bhagat*, 726 F. App’x 772 (Fed. Cir. 2018), where the claims were all directed to formulations and compositions and the prior art disclosed products that contained “a dosage of lipids within the scope of the claims.” *Id.* at 776. Here, the claims are drawn to specific methods with specific steps and required considerations that have not been shown to be necessarily present in the “Olive Oil” reference.

We therefore reverse the anticipation rejection.

#### SUMMARY

In summary, we reverse the rejection of claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145–150, 153–166, 168, 171, 177, and 178 under 35 U.S.C. § 112, second paragraph.

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We reverse the rejection of claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145, 147–149, 153–157, 159–162, 164–166, 168, 171, 177, and 178 under 35 U.S.C. § 101.

We reverse the rejection of claims 94, 95, 101, 108, 116, 119, 122–125, 128–132, 134, 137, 139, 140, 145, 147–149, 153–157, 159–162, 164–166, 168, 171, 177, and 178 under 35 U.S.C. § 102(b) as anticipated by Olive Oil and Olive Oil Nutritional Profile.

REVERSED