IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

URVASHI BHAGAT,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 1:20-cv-1515
	)	
	)	
THE UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,	)	
	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Defendant's Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56 and Plaintiff's Motion to Strike Defendant's Motion for Summary Judgement.

The Court first addresses Plaintiff's Motion to Strike Defendant's Motion for Summary Judgement or Stay Briefing of the Motion Pending the Outcome of Plaintiff's Appeal. The Motion for Summary Judgement is not premature. Plaintiff has had over four months to conduct discovery and has used that time to conduct her discovery. The Motion to Strike should be denied.

The Fourth Circuit's February 23, 2023 Order that consolidated Plaintiff's appeals also dismissed as moot Plaintiff's Motion for a Stay of the District Court proceedings. This Court finds Plaintiff has failed to carry the burden to

support a stay pending interlocutory appeal of discovery matters.

Plaintiff is the inventor of the United States Patent Application No. 13/877,847 (the "Application"). The Application describes nutritional formulations as supplements, meal components, or meals, that may be administered in any orally acceptable form, including, capsules, tablets, liquid formulations, or whole foods. This includes specifying that the nutritional formulation may comprise one or more nuts, including almonds, and that nuts are a source of omega-6 fatty acids, antioxidants, and polyphenols. The Application discusses administering the formulations at various frequencies including one to three times a day.

The Application also includes that different formulations may be packaged together or in single units and in different types of packaging including in a gelatinous case, a vial, a bottle, a pouch or a foil, or plastic or card-board box. It further states that formulations may be marked to indicate the intended consumer, the frequency of consumption, the suitability for consumption according to a general diet plan, or the maximum amounts for average daily consumption.

There are "method of using" claims included in the Application. This includes Claim 88 which recites steps to administer a dosage to an individual selected from a diet cohort

that is based on gender, age, genetic profile, family history, climactic temperature, or medical condition. Claims 97 and 116 relate to methods of treatment of either unspecified medical conditions or diseases, or any of a long list of widely divergent conditions and diseases, through administering nutritional formulations. One of the examples included in the Application is a subject given a composition that included a combination of vegetable oils, nuts, and seeds. Claim 99 relates to methods of preparing a product comprising nutritional formulations, including the steps of determining the individual's diet cohort and selecting and preparing at least one formulation that provides 1 to 40 g of omega-6 fatty acids, 25 mg to 10 g of antioxidants, and greater than 5 mg of polyphenols.

However, none of the Application's method claims include tailoring the nutrient dosages in the product to the diet cohort or restricting the total daily intake of any of the claimed nutrients.

Claim 112 deals with a computer system to implement the method of Claim 99 and recites a system that outputs a nutritional plan for an individual based on their dietary preferences and dietary guidelines.

The United States Patent and Trademark's Patent Trial and Appeal Board (the "Board") affirmed the rejection of the

Plaintiff's Application claims because they were obvious in light of numerous past expert studies and disclosures. In particular, the Board used a work by inventor Claudia R. Morris, US Published Patent Application Number 2008/0213239 A1 (hereinafter "Morris"), which discloses preparing and administering dietary formulations comprising omega-6 fatty acids and Vitamin E to children and adults for treating various conditions such as cardiovascular disease. The formulations may be in the form of tablets, capsules, food bars, or drinks. Morris discloses that the formulations comprise omega-6 fatty acids, such as linoleic acid, in dosages and amounts overlapping the dosages in Plaintiff's claims. Morris shows that the formulations comprise from about 50 mg to about 500 mg omega-6 fatty acids that may be administered once, twice, or three times daily, which would equal a dosage ranging from 50 mg to 1,500 mg of omega-6 fatty acids a day. There is further overlap where Morris shows that the formulation comprises Vitamin E in amounts and dosages that overlap the Plaintiff's claimed dosages.

The Board further found that Morris discloses packaged formulations comprising omega-6 fatty acids, Vitamin E, and polyphenols. Morris also discloses dosages of omega-6 and Vitamin E overlapping the claimed ranges. The Board determined the claimed dosages were obvious due to Morris's disclosure that dosages are a result-effective variable and may be optimized for

an individual. Morris also discusses preparing formulations based on an individual's age, weight, genetic makeup, etc., which equates to Plaintiff's Claim 99 limitation of preparing a formulation based on the diet cohort of an individual.

The only difference the Board found between Morris and the Plaintiff's claimed formulation was an explicit disclosure of using nutrients from different sources. However, this would have been obvious in light of another expert's teachings of oil blends from different sources.

Plaintiff brought this suit pursuant to 35 U.S.C. § 145 the Board affirmed the rejection of all pending claims of Plaintiff's Application.

A Section 145 appeal is a hybrid action because it is partially an appeal from an administrative body and partially a new evidentiary proceeding. See Hyatt v. Kappos, 625 F.3d 1320, 1322 (Fed. Cir. 2010); Halozyme, Inc. v. Iancu, 320 F. Supp. 3d 788, 801-02 (E.D. Va. 2018) (Hilton, J.). New evidence may be presented but the Board's decision remains at the center of the case. Hyatt, 625 F.3d at 1322. When a party presents new evidence not previously before the Board, the court makes a de novo finding on any disputed questions of fact. Kappos v. Hyatt, 566 U.S. 431, 433- 434 (2012). The issue of patent eligibility is a question of law for the court.

Under Federal Rule of Civil Procedure 56, a court should grant summary judgment if the pleadings and evidence show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In reviewing a motion for summary judgment, the court views the facts in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Once a motion for summary judgment is properly made, the opposing party has the burden to show that a genuine dispute of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

The Court finds there are no issues of material fact as to any of Plaintiff's claims and their patent ineligibility under 35 U.S.C. §§ 101 and 103.

The two-step framework for determining whether claims that are within a statutory category nevertheless fall within a patent-ineligible exception, is set out by the Supreme Court in Alice Corp. Pty. Ltd.v. CLS Bank Int'l, 573 U.S. 208 (2014). Step one is "whether the claims at issue are directed at one of [the] patent-ineligible concepts." Id. at 217. The patent-ineligible concepts include laws of nature, natural phenomena, and abstract ideas. If claims are directed at one of the patent-ineligible concepts, then the court moves to step two and

considers the elements of each claim "both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Id. at 217-218.

Each of Plaintiff's claims of the Application at issue deal with products of nature or abstract ideas that are patent ineligible under 35 U.S.C. § 101.

Plaintiff's claims 82-89, 91-104, 107-110, and 113-120 of the Application contain a recitation of the combination of nutrients naturally present in almonds and thus are a natural product. Further, the claims do not have any limitations that transform the natural product into patent-eligible subject matter.

Independent claims 82, 99, 115, and 116 recite nutritional formulations with a combination of nutrients in various specified dosages. These claimed nutrients are naturally present in almonds, making the claims about a natural product. Since almonds contain all of the claimed nutrients, the claims do not recite a product with any markedly different characteristics from those found in nature.

The court begins with step one to determine if the claims fit into a patent-ineligible statutory category. Independent claim 82 is a product claim, and its patentability depends on the product. The claim's recitation of the nutrients coming from

an intermixture process using different sources does not change the conclusion that it is a natural product. The patentability of a product claim depends on the product and not the process of making it.

Independent claim 82's dependent claims 95, 103, 109, and 110 clarify that the independent claim's formulation encompass nuts. Dependent claims 88, 91, 96-98, 102, and 104 do not make any attempt to further limit the nutrient composition. Dependent claims 83, 84, 100, and 115-118 merely recite the same nutrients which almonds comprise. Also, almonds contain the dosages of omega-6 fatty acids recited in claims 92, 107, 113, and 119, and the polyphenol dosage recited in claim 120. Almonds further comprise phytosterols as required by claim 85, in the dosages recited in claims 86, 93, 108, and 114.

Claim 94's requirement that one formulation provide omega-6 fatty acids in a dosage less than 1 g, but that a plurality collectively provide 1 to 40 g of omega-6 merely encompasses a product of 100 g of almonds broken into 5 g increments. Almonds also contain the phytochemicals, lipids, antioxidants, vitamins, minerals, and fiber recited in claims 87 and 101. Finally, claim 89 encompasses a mixture of one or more food items, which includes a mixture of 100 g of almonds with other nuts.

Having determined that the product and method claims of the Application are about a natural product under the first step of

the Alice inquiry, the court now moves to step 2 to determine if the additional claim elements transform the natural product into a patent-eligible application. Transformation of a natural product into eligible subject matter requires the additional features be more than "well-known understood, routine, conventional activit[ies]." See Alice at 225.

Plaintiff's independent product claim 82, simply recites well-known routing and conventional activity of packaging and labeling the formulations. This includes basic packaging such as in "a vial, a bottle, a pouch or a foil, or plastic and/or card-board box, and the like." This type of basic, common-place packaging is a conventional activity.

Claim 82's dependent claims, 91 and 95, fail to add any transformative claim limitations. Claim 91 limits the formulations into particular forms like powder. Unfortunately, it is well known that nuts can be crushed into a powder. Claim 95 recites that the formulation is in a "kit" which is nothing more than conventional packaging of the formulation.

Claims 83-87, 89, 92-94, 113-114, 117, and 119-120 are also dependent claims from claim 82, but do not recite any limitations beyond the natural product itself or additional natural products.

Independent claim 115 is also directed to just the natural product. Therefore, all of the product claims of the Application are patent ineligible.

Claims 88, 96-98, and 116 recite methods of administering the natural product. Beyond the natural product itself, the only limitation recited in claim 88 is the step of administering to an individual that belongs to a specified diet cohort. Administering, which includes eating or feeding, almonds to an individual is a conventional activity. The "diet cohort" limitation just identifies the intended recipient of the natural product and does so in a generic manner that all humans would qualify. Claims 96-98 and 116 are methods of treating either unspecified medical conditions or a long list of widely divergent conditions by administering the natural product and administering is still a routine and conventional activity.

Independent claim 99 and its dependent claims recite methods of preparing nutritional formulations for an individual which include "determining," "selecting," and "preparing" steps. Each step, however, is insufficient to transform the naturally-occurring nutritional formulation, almonds, into patent-eligible subject matter. First, the "determining" step simply groups the individuals into diet cohorts, which the Application explains broadly includes a grouping based on food preference, dietary habits, age, or gender. Grouping individuals on the basis of

these generic and broad categories is well-known and conventional. Second, the "selecting and preparing" step simply links the choice of nutritional formulation to the grouping. The additional limitations of claim 99 are therefore nothing more than post-solution activities related to preparing a natural product for consumption that do not transform the claims from being directed to the ineligible natural product.

Dependent claims 102, 104, 109, and 110 recite more limitations on the method of preparing but are not directed to anything more than the natural product itself.

Claim 112 deals with a computer system that implements the method of preparing the product from claim 99. It takes dietary preferences and guidelines to generate a nutrition program. This is a type of meal planning that is a method for organizing human activity and thus an abstract idea. Further, the additional elements given in claim 112 only add conventional computer components and are not sufficient to transform the claimed computer system into a patent-eligible invention.

Further showing the Application's patent-ineligibility, Plaintiff's claims of the Application are obvious under 35 U.S.C. § 103.

A claim is unpatentable under § 103 if the differences between the claims and the prior art would have been obvious to a person of ordinary skill in the art at the time of the

invention. A presumption of obviousness exists if the claims recite a range that overlap with what is disclosed in the prior art. Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006). Here, the prior art teaches all the claimed nutrients in dosages overlapping the claimed ranges, thereby establishing such a presumption.

As the Board correctly found, claims 82-89, 91-104, 107-110, and 113-120 of the Application would have been obvious given the teachings of Morris and inventors Joshua C. Anthony et al., US Published Patent Application Number 2007/0166411 A1 (hereinafter "Anthony"). The Board treated claim 82 as representative, finding Plaintiff did not separately argue the patentability of any dependent claims as required under 37 C.F.R. § 41.37(c)(1)(iv). As the party that "seeks to change an administrative result," Plaintiff bears the "burden" of showing error in that determination. Cal. Rsch. Corp. v. Ladd, 356 F.2d 813, 819 (D.C. Cir. 1966).

The Board further found that Morris teaches preparing and administering a packaged dietary formulation comprising omega-6 fatty acids, Vitamin E, and polyphenols. It also found that Morris teaches dosages of omega-6 fatty acids and Vitamin E overlapping the claimed range.

As Defendants' expert witness Dr. William S. Harris explained, in addition to being obvious over Morris and Anthony,

the benefits of consuming the claimed nutrients were well-known in the art as of 2010. This is reflected in an additional three combinations of references that also render claims 82-89, 91-104, 107- 110, and 113-120 obvious. These additional reference combinations disclose the claimed omega-6 fatty acid, antioxidant, and polyphenol dosages that have been the focus of Plaintiff's arguments throughout this proceeding. Plaintiff has not argued with particularity why this prior art does not disclose any additional limitations in the dependent claims.

Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids and its antioxidant range. However, Plaintiff fails to establish unexpected results to rebut the presumption of obviousness based on the overlapping ranges of the prior art and Plaintiff has not shown any additional teaching away to rebut the presumption of obviousness.

Lastly, Plaintiff attempts to argue the prior art is not relevant because it does not address the problem solved by her Application. However, the prior art is from the same field of endeavor in nutritional formulations as the Application and therefore is relevant art in this case.

For the foregoing reasons, Defendant's Motion for Summary Judgment should be granted.

An appropriate Order shall issue.

Alexandria, Virginia
March 30, 2023

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE