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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAMELA McDONALD CASSIDY¹

Appeal 2019-000514
Application 15/052,825
Technology Center 1600

Before ERIC B. GRIMES, DEBORAH KATZ, and MICHAEL A. VALEK,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving a method of creating a nutrition and fitness plan, which have been rejected as indefinite, lacking adequate written description, patent-ineligible, and obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM the rejections for obviousness and patent-ineligibility.

¹ Appellant identifies the real party in interest as “Pamela McDonald CASSIDY.” Appeal Br. 3. We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

“The APO E gene variations occur naturally, and come in three major types— APO E2, E3, and E4. . . . Because you inherit two copies of the APO E gene, one from each parent, there are six possible combinations: E2/2, E2/3, E2/4, E3/3, E3/4, and E4/4.” Spec. 2:17–22.

“If you take an APO E gene blood test and are identified as APO E 3/3, the APO E genetic instructions in your body are considered neutral. However, if you are an APO E2 or APO E4 combination, you inherited an APO E gene with an alternative expression, which means your body handles foods and chemistry differently than an APO 3 individual does.” *Id.* at 2:24–28. “The invention is based upon the insight that knowing your APO E genotype can help you eat the right diet to maintain a safe optimal level of cholesterol in your system. The preferred embodiment of the invention provides a nutritional plan based on a person’s individual genetic APO E genotype.” *Id.* at 4:18–21.

Claim 24 is the only pending claim and reads:

24. A method for creating and optimizing a nutritional and fitness plan, comprising

performing a body composition bio-impedance test on a human individual to determine the individual’s caloric needs for activities of daily living for two basic activity levels, said activity levels comprising both a normal activities of daily living caloric requirement as is necessary to sustain said individual’s typical daily activity, and additional calories for daily activity of said individual that requires additional caloric use;

collecting a blood sample from said individual and submitting said blood sample for testing to determine said individual’s apolipoprotein E (APO E) genotype;

analyzing said blood sample to determine said individual's apolipoprotein E (APO E) genotype;

based upon both of said individual's APO E genotype and the results of said bioimpedance test:

applying a genotype specific nutritional plan and establishing optimal dietary levels of caloric content, fat content and type of fats, carbohydrate content and type of carbohydrates, and protein content and type of proteins, said nutritional plan establishing dietary levels of:

fat content and type of fats for said genotype selected from among inflammatory fats, comprising fats that come mainly from saturated and trans fat sources, and anti-inflammatory fats, comprising fats that come mainly from monounsaturated and polyunsaturated sources; and

carbohydrate content and type of carbohydrates for said genotype selected from among carbohydrates having various glycemic loads, and protein content and type of proteins for said genotype selected from among proteins coming from plant sources and proteins coming from fish and other animal sources;

said nutritional plan establishing a ratio of fat content to carbohydrate content based upon said individual's APO E genotype, said ratio comprising:

for APO E 2/2, 35% fat content, 15% protein content, and 50% carbohydrate content;

for APO E 2/3, 30% fat content, 15% protein content, and 55% carbohydrate content;

for APO E 3/3 and APO E 2/4, 25% fat content, 20% protein content, and 55% carbohydrate content; and

for APO E 3/4 and APO E 4/4, 20% fat content, 25% protein content, and 55% carbohydrate content; and

applying an exercise plan to maintain genotype specific body fat mass and lean mass, said exercise plan comprising:

for APO E 2/2 and APO E 2/3, 45% aerobic exercise and 55% anaerobic exercise;

for APO E 3/3 and APO E 2/4, 50% aerobic exercise and 50% anaerobic exercise; and

for APO E 3/4 and APO E 4/4, 75% aerobic exercise and 25% anaerobic exercise.

OPINION

Definiteness

Claim 24 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite, for the reasons discussed below. Ans. 6–8.

Appellant argues: “As noted by [MPEP § 2173.01], “a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.” Here, the M.P.E.P. does not allow the Examiner to reject the claims simply because of the language used.” Appeal Br. 9.

We agree with Appellant that the rejection should be reversed because the Examiner has not established that claim 24, contains words or phrases whose meaning is unclear. *See Ex parte McAward*, No. 2015-006416, 2017 WL 3669566, at *5 (PTAB Aug. 25, 2017) (precedential) (“[W]e apply the approach for assessing indefiniteness approved by the Federal Circuit in [*In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014)], i.e., ‘[a] claim is indefinite when it contains words or phrases whose meaning is unclear.’ 751 F.3d at 1310, 1314.”).

The Examiner first finds claim 24 to be indefinite “because it lacks a positive active step relating back to the preamble.” Ans. 6. The Examiner reasons that the preamble of claim 24 “recites a method for creating and

optimizing a nutritional and fitness plan, however the last positive active step is drawn to applying a genotype specific nutritional plan.” *Id.* The Examiner states that it is therefore unclear “whether the method is drawn to creating and optimizing a nutritional and fitness regime or applying a genotype specific nutritional plan.” The Examiner also finds that “it is unclear how the nutritional and fitness regime is optimized.” *Id.*

We do not agree that claim 24 is indefinite on this basis. The Specification makes clear that “[t]he invention is based upon the insight that knowing your APO E genotype can help you eat the right diet to maintain a safe optimal level of cholesterol in your system.” Spec. 4:18–20. The Specification describes “a nutritional plan based on a person’s individual genetic APO E genotype,” and varies the content and type of fat, carbohydrate, and protein, as well as caloric content of the plan. *Id.* at 4:20–29. The Specification also describes “exercise recommendations related to the APO E genotypes.” *Id.* at 25:23, Table 2. Thus, the claim language, read in light of the Specification, would be understood to mean a nutrition and fitness plan that is optimized for an individual’s APO E genotype.

The Examiner also finds that “[i]t is unclear what is required of ‘additional calories for daily activity of said individual that requires additional caloric use.’” Ans. 6. The Specification, however, states that calculating individual daily caloric needs requires

add[ing] additional calories to your daily exercise session, such as an exercise program or energetic activity that requires additional caloric use. Examples of added exercise sessions: 30 minutes of running, 40 minutes of walking, or 60 minutes of biking. These are calories needed in addition to the calories of your normal activities of daily living.

Spec. 8:26–30. Thus, read in light of the Specification, the disputed limitation would be understood to mean the calories that are burned by an individual in exercise or energetic activity, in addition to activities of normal or typical daily living. *See id.* at 8:23–24.

The Examiner also finds that claim 24 is indefinite in its recitation of “applying a genotype specific nutritional plan and establishing optimal dietary levels of caloric content,” etc. Ans. 7. The Examiner states that “[i]t is unclear if optimal is with respect to fat loss, muscle gain, fat gain, etc.”; “it is unclear what is what is [sic] considered of a plan”; “it is unclear if regime is a dietary level of a single meal”; and “it is unclear if a plan is a menu, recipe, or merely number of calories.” *Id.*

We disagree that any of these issues renders claim 24 indefinite. As discussed above, the Specification makes clear that the nutritional optimization involved in the claimed method refers to varying the contents of an individual’s diet, based on their APO E genotype, in order to increase health benefits. In addition, claim 24 itself makes clear that the “nutritional plan establish[es] a ratio of fat content to carbohydrate content based upon said individual’s APO E genotype.” Whether that plan is followed based on each recipe, each meal, or each day does not affect the scope of claim 24 in creating the nutritional plan tailored to the individual’s APO E genotype.

Finally, the Examiner notes that claim 24 recites “inflammatory fats and anti-inflammatory fats” but concludes that the metes and bounds of these terms is unclear from the Specification. Ans. 7–8. Claim 24, however, expressly states that “inflammatory fats, compris[e] fats that come mainly

from saturated and trans fat sources, and anti-inflammatory fats, compris[e] fats that come mainly from monounsaturated and polyunsaturated sources.”

In summary, we reverse all of the bases of the rejection under 35 U.S.C. § 112, second paragraph.

Written Description

Claim 24 stands rejected under 35 U.S.C. § 112, first paragraph, for lack of adequate written description. Ans. 3. The Examiner finds that the Specification does not adequately describe the claim limitations reciting

“additional calories for daily activity of said individual that requires additional caloric use” or “based upon both of said individual’s APO E genotype and the results of said bio-impedance test: applying a genotype specific nutritional plan and establishing optimal dietary levels of caloric content, fat content and type of fats, carbohydrate content and type of carbohydrates, and protein content and type of proteins; and creating an exercise regime [sic, plan] to maintain a genotype specific percentage of body fat mass and lean mass.”

Id. at 4.

Appellant points to the description in the Specification of additional calories required for low, medium, and high levels of activity. Appeal Br. 6, citing paragraphs 38–43 of the published application. Regarding a nutritional plan and exercise plan based on both APO E genotype and the results of a bio-impedance test, Appellant points to the published application’s paragraphs 38, 46–51, 59, and 105–107 for support. *Id.* at 7.

We conclude that a skilled artisan would have recognized that Appellant was in possession of a method meeting the disputed limitations based on the written description in the Specification. The Specification provides estimates of daily living calorie calculations for low level activity

(exercise 1–2 days/week), medium level activity (exercise 3–4 days/week), and high level activity (exercise 6–7 days/week). Spec. 10:11–26. We therefore agree with Appellant that the Specification adequately describes “additional calories for daily activity of said individual that requires additional caloric use.”

The Specification also states that the amount of energy needed by the body to maintain basic functions “is called a basal metabolic rate (BMr).” Spec. 9:10–11. A “practical way to calculate your BMr is to consider a bio-impedance test,” which evaluates body composition and “gives you your daily caloric requirement.” *Id.* at 9:15–17. “A bio-impedance test gives you your daily caloric requirements immediately.” *Id.* at 9:28–29. The Specification therefore describes using a bio-impedance test as part of the basis for establishing at least an optimal level of caloric content.

And the Specification describes optimizing the type and content of dietary fat, carbohydrate, and protein, as well as the type of exercise, depending on an individual’s APO E genotype. *See* Spec. 11:4 to 15:17, 25:21 to 27:27. Thus, when viewed as a whole, the Specification demonstrates possession of the disputed limitations.

We therefore reverse the rejection under 35 U.S.C. § 112, first paragraph.

Patent Eligibility

Claim 24 stands rejected under 35 U.S.C. § 101 on the basis that it is “directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more”; specifically, the “judicial exception of correlating genotype and basal metabolic rate determined by

bio impedance with prescribing exercise and nutritional regime. Further the analyzing and creating are abstract ideas.” Ans. 8–9. The Examiner also states that “the claims are based on the judicial exception of naturally occurring correlating [sic, correlating naturally occurring] APOE genotype and basal metabolic rate with prescribing exercise and nutritional regime. Further the analyzing and applying are abstract ideas.” *Id.* at 9.

The Examiner finds that the recited steps of performing a bio-impedance test and collecting a blood sample are “routine and conventional data gathering steps.” *Id.* at 11–12. The Examiner also finds that “[t]he recited steps only instruct the user to engage in well-understood, routine and conventional activity . . . since methods of analyzing nucleic acids . . . were conventional in the art at the time the invention was made.” *Id.* at 12. The Examiner therefore concludes that the claims do not “recite something significantly different than a judicial exception,” and are ineligible for patenting. *Id.* at 14.

Appellant argues that claim 24 is “a unique approach to creating and optimizing a nutritional and fitness plan and not ‘on the judicial exception of naturally occurring correlat[ion].’” Appeal Br. 10 (alteration in original). Appellant argues that the use of a bio-impedance test and APO E genotype “together to create and optimize a nutritional and fitness plan are not ‘a naturally occurring correlation between the APO E genotype and exercise and nutrition’ as asserted by the Examiner.” *Id.* Appellant also argues that “the determination of nutritional and fitness plan based on the APO E genotype and the result of the bio-impedance test is not well understood, routine or conventional.” *Id.*

An invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101.

However, the Supreme Court has concluded that “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable under 35 U.S.C. § 101.

See, e.g., Alice Corp. v. CLS Bank Int’l, 573 U.S. 208, 216 (2014).

To determine if a claim falls into an excluded category, we apply a two-step framework, described in *Mayo* and *Alice*. *Alice*, 573 U.S. at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). We first determine what the claim is “directed to.” *See Alice*, 573 U.S. at 219 (“On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk.”); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“Claims 1 and 4 in petitioners’ application explain the basic concept of hedging.”).

Patent-ineligible abstract ideas include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611), mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)), and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). In contrast, patent-eligible inventions include physical and chemical processes, such as “molding rubber products” (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); “tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores” (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1853))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claimed method employed a mathematical formula, but the Supreme Court held that “a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.” *Diehr*, 450 U.S. at 187; *see also id.* at 191 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”). The Supreme Court noted, however, that a claim “seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.” *Id.* (citing *Benson and Flook*); *see, e.g., id.* at 187 (“It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”).

If the claim is “directed to” an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, and “examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (internal quotation marks omitted). “A claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Id.* (quoting *Mayo*, 566 U.S. at 77 (alterations in original)). “[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention.” *Id.*

The PTO has published revised guidance on the application of § 101. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50

(January 7, 2019) (“Revised Guidance”). Under that guidance, we first determine whether the claim recites:

- (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts; certain methods of organizing human activity such as a fundamental economic practice; or mental processes); and
- (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP §§ 2106.05(a)–(c), (e)–(h)).

See 84 Fed. Reg. at 54–55. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then determine whether the claim:

- (3) adds a specific limitation beyond the judicial exception that is not a “well-understood, routine, conventional activity” in the field (*see* MPEP § 2106.05(d)); or
- (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See 84 Fed. Reg. at 56.

Revised Guidance Step 2(A), Prong 1

Following the Revised Guidance, we first consider whether claim 24 recites a judicial exception, such as mental processes. We agree with the Examiner that the “applying” steps of claim 24 are abstract ideas, because they are mental processes. *See* Ans. 9 (“Further, the analyzing and applying are abstract ideas.”); *id.* at 31 (“[T]he step of applying is consistent with the prescribing step of claims of the parent” application.).

Claim 24 recites “applying a genotype specific nutritional plan.” The plan recites types of fats, carbohydrates, and proteins, and provides for a distribution of a person’s diet among those categories; e.g., for a person with an APO E 2/2 genotype, 35% fat content, 15% protein content, and 50% carbohydrate content. Claim 24 also recites “applying an exercise plan,” which provides for a distribution of exercise between aerobic and anaerobic exercise; e.g., for a person with an APO E 2/2 genotype, 45% aerobic exercise and 55% anaerobic exercise.

Both of these steps can be carried out mentally, because they only require associating a person’s genotype with a diet and exercise regimen that is suited to the type(s) of APO E that their cells express. The Specification makes clear that the claimed method simply recommends or prescribes a diet and exercise regimen; the method does not require actually eating or exercising in specific ways. The Specification states, for example, that “[t]he preferred embodiment of the invention provides an APO E gene micro and macronutrient nutritional recommendation, *i.e.* the APO E gene diet.” Spec. 5:8–9.

The Specification also states that “Fig. 1 is a chart showing a nutritional plan based on a person’s individual genetic APO E genotype according to the invention.” *Id.* at 6:1–2. Figure 1 shows a “SPECIFIC GENOTYPE DIETARY RECOMMENDATION” and an “EXERCISE PRESCRIPTION” for each of the six possible APO E genotypes. Thus, when the “applying” steps of claim 24 are read in light of the Specification, they require no more than looking at Figure 1 to see what dietary

recommendation and exercise prescription is appropriate for a particular individual, based on that individual's APO E genotype.

Revised Guidance Step 2(A), Prong 2

Following the Revised Guidance, we next consider whether “the claim as a whole integrates the recited judicial exception into a practical application of the exception”; i.e., whether the claim “appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception.” 84 Fed. Reg. at 54. This analysis includes “[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)” and “evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application.” *Id.* at 54–55.

Here, claim 24 requires the initial steps of

performing a body composition bio-impedance test on a human individual to determine the individual's caloric needs for activities of daily living . . . ;

collecting a blood sample from said individual and submitting said blood sample for testing to determine said individual's apolipoprotein E (APO E) genotype; [and]

analyzing said blood sample to determine said individual's apolipoprotein E (APO E) genotype.

Claim 24.

These steps determine (a) the number of calories an individual needs on a daily basis and (b) the individual's APO E genotype. *See Spec.* 9:15–17 (“[A] practical way to calculate your BMr [basal metabolic rate] is to consider a bioimpedance test. This is an accurate method and most convenient method of evaluating body composition, which gives you your

daily caloric requirement.”); *id.* at 11:6–8 (“To help you identify the correct diet type based on your APO E genotype: Find the recommendation for your specific APO E. If you have not yet been tested, consider getting a APO E genotype test.”).

The active steps recited in claim 24 thus provide the data for the recited mental process of “applying” a nutritional plan and an exercise plan. In other words, the “performing,” “collecting,” and “analyzing” steps of claim 24 are merely data-gathering steps, not a practical application of the mental process of “applying” a nutritional plan and an exercise plan. They therefore do not integrate the recited abstract idea into a practical application. *See* 84 Fed. Reg. at 55, n. 31 (“insignificant extra-solution activity” includes “mere data gathering such as a step of obtaining information about credit card transactions”); *see also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716 (Fed. Cir. 2014) (“‘[D]ata-gathering steps,’ *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1370 (Fed. Cir. 2011), . . . add nothing of practical significance to the underlying abstract idea.”).

Claim 24 does not include “an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition.” 84 Fed. Reg. at 55. As discussed above, the claimed method ends with “applying”—that is, recommending or prescribing—a diet and exercise regimen for an individual, but it includes no active step(s) in which the diet and exercise regimen are put into practice. The claimed method does not actually treat any individual, because it does not include any active steps of eating or exercising.

The claimed method is distinguished in this way from *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). In *Vanda*, the “claims [were] directed to a method of using iloperidone to treat schizophrenia.” *Id.* at 1135. Critically, the claims “require[d] a treating doctor to administer iloperidone in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day, depending on the result of a genotyping assay” in order to reduce the risk of a side effect called QTc prolongation. *Id.* Thus, the court held that the “claims [were] ‘a new way of using an existing drug’ that is safer for patients because it reduces the risk of QTc prolongation.” *Id.*

The claim here, by contrast, conveys information, in the form of dietary and exercise recommendations, to an individual but does not include any step comparable to *Vanda*’s step of administering an adjusted dose of iloperidone to a patient in order to treat schizophrenia more safely.

Because claim 24 recites an abstract idea and does not integrate the abstract idea into a practical application, it is directed to an abstract idea.

Revised Guidance Step 2(B)

Finally, the Revised Guidance directs us to consider whether claim 24 includes “additional elements . . . [that] provide[] ‘significantly more’ than the recited judicial exception.” 84 Fed. Reg. at 56. The Revised Guidance states that an additional element that “simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, . . . is indicative that an inventive concept may not be present.” *Id.*

Here, as discussed above, the additional elements recited in claim 24, beyond the abstract idea to which it is directed, are the data-gathering steps of “performing a body composition bio-impedance test,” “collecting a blood sample,” and “a blood sample.” The Revised Guidance instructs us to reevaluate additional elements that were found to be insignificant extra-solution activity under Step 2(A) of the analysis to determine whether those elements are “unconventional or otherwise more than what is well-understood, routine, conventional activity in the field.” 84 Fed. Reg. at 56. The Revised Guidance states, for example, that

when evaluating a claim reciting an abstract idea . . . and a series of data gathering steps that collect a necessary input . . . , an examiner might consider the data gathering steps to be insignificant extra-solution activity in revised Step 2A, and therefore find that the judicial exception is not integrated into a practical application. However, when the examiner reconsiders the data gathering steps in Step 2B, the examiner could determine that the combination of steps gather data in an unconventional way and therefore include an “inventive concept,” rendering the claim eligible at Step 2B.

Id. (footnote omitted).

Here, the Examiner points to Bernstein² and Kopelman,³ among other references, as evidence that the bio-impedance test and APO E genotyping step “are merely routine and conventional.” Ans. 30. Bernstein states that “[t]he sequence of the *apoE* gene and of its protein are well known, and the

² Martine S. Bernstein, *Physical Activity May Modulate Effects of ApoE Genotype on Lipid Profile*, *Arterioscler. Thromb. Vasc. Biol.* 22:133–140 (2002).

³ Peter G. Kopelman, *Obesity as a medical problem*, *Nature* 404:635–643 (2000).

complete DNA and mRNA nucleotide sequences are available on public databases.” Bernstein 134, right col. Bernstein also discloses using blood samples for APO E genotyping. *Id.* Thus, the steps of collecting a blood sample and analyzing it to determine an individual’s APO E genotype are routine and conventional activities.

Kopelman “review[s] the epidemiology and factors influencing obesity and the health consequences of excessive body fat.” Kopelman 635, left col. “Box 1 details the practical methods used in clinical practice to assess body fatness.” *Id.* at 635, right col. Kopelman’s Box 1 includes “Bioimpedance.” *Id.* at 635.

The evidence of record therefore supports the Examiner’s conclusion that claim 24 does not recite additional elements other than well-known, routine, and conventional activities. Ans. 11–12. We agree with the Examiner that the combination of elements recited in the method of claim 24 does not amount to significantly more than the judicial exception itself, and under 35 U.S.C. § 101 the claimed method is ineligible for patenting.

Appellant’s Arguments

Appellant argues that the claim is

a unique approach to creating and optimizing a nutritional and fitness plan and not “on the judicial exception of naturally occurring correlat[ion]” as indicated by the Examiner. The use of a bio-impedance test is not the preemption of the law of nature concerning basal metabolic rate, and the determining of APO E genotype is not the preemption of the law of nature concerning the APO E genotype itself. The use of both together to create and optimize a nutritional and fitness plan are not “a naturally occurring correlation between the APO E genotype and exercise and nutrition” as asserted by the Examiner.

Appeal Br. 10 (alteration in original).

This argument is unpersuasive. Even assuming that the claims do not recite a naturally occurring correlation, they nonetheless recite the mental processes of “applying” nutritional and exercise plans, as discussed above. The argument that the claimed method does not preempt either bio-impedance tests or APO E genotyping is unpersuasive because,

[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent’s claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1379 (Fed. Cir. 2015).

Appellant also argues that “the determination of nutritional and fitness plan based on the APO E genotype and the result of the bio-impedance test is not well understood, routine or conventional.” Appeal Br. 10. Appellant argues that “the inventor discovered an optimized nutritional and fitness plan customized to patients based on results of bio-impedance testing. The claimed subject matter significantly adds details that are not known or suggested by the alleged laws of nature as they are understood.” *Id.* at 10–11.

This argument is unpersuasive because the issue is not whether the claimed process as a whole was known, but whether, *in addition to* the judicial exception, the claimed process includes elements that go beyond well-understood, routine, and conventional activity known to those in the field. *See Alice*, 573 U.S. at 217 (If “the claims at issue are directed to one of

th[e] patent-ineligible concepts . . . we consider 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.”) (internal citation omitted).

Here, as discussed above, the evidence shows that bio-impedance testing and APO E genotype analysis were routine and conventional activities. To the extent that considering both bio-impedance test results and APO E genotype when recommending a diet and exercise regimen is an improvement over conventional approaches to diet and exercise, the improvement is in the mental process of deciding on the foods and exercises that would benefit an individual. *Cf. SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (An “advance [that] lies entirely in the realm of abstract ideas, with no plausibly alleged innovation in the non-abstract application realm . . . is ineligible for patenting.”).

Obviousness

Claim 24 stands rejected under 35 U.S.C. § 103(a) as obvious based on Roberts,⁴ Bernstein, Kopelman, Singhal,⁵ Brooks,⁶ and Sakata.⁷ Ans. 14. The Examiner finds that Roberts teaches “a method for selecting an optimal diet and exercise regimen for a patient, comprising considering,” among

⁴ Roberts et al., US 2005/0009193 A1, pub. Jan. 13, 2005.

⁵ Atul Singhal et al., *Programming of lean body mass: a link between birth weight, obesity, and cardiovascular disease?*, *Am. J. Clin. Nutr.* 77:726–730 (2003).

⁶ George A. Brooks et al., *Exercise Physiology: Human Bioenergetics and Its Applications*, 2nd ed., Mayfield Publishing Company, p. 525(1996).

⁷ Sakata et al., US 6,477,409 B2, iss. Nov. 5, 2002.

other factors, “APO E genotype; and selecting a diet and exercise regimen” based on these factors. *Id.* The Examiner finds that Roberts recommends “a diet moderate in fat content, consisting of 30–35% of total calories,” for individuals with APO E 2/2 and 2/3 genotypes. *Id.* at 14–15. “Roberts teaches a diet for subjects with APO E3 and APO E2/4 should have fat providing 25–30%[] of total calories.” *Id.* at 16.

The Examiner finds that Roberts does not teach testing an individual to determine APO E genotype or “determining a specific exercise regime based on the individual[']s APO E genotype.” *Id.* at 17–18. The Examiner finds, however, that “Bernstein teaches DNA was extracted from individuals and Apo E genotypes were determined.” *Id.* at 18. The Examiner finds that Bernstein also teaches that different intensities of exercise had different effects on individuals’ HDL and triglyceride levels, depending on APO E genotypes. *Id.*

The Examiner finds that “Kopelman teaches bio-impedance,” “Singhal suggest that body composition is a more accurate determination of obesity that surrogate markers such as BMI,” and Brooks “teaches ideal body composition for men is 20% or less body fat . . . [and] for women is between 16 and 25% body fat.” *Id.* at 19.

The Examiner finds that “[t]he prior art of record (Bernstein and Kopelman) suggests determining a basal metabolic rate as part of exercise plans, but does not provide specific guidance.” *Id.* at 20. The Examiner finds that Sakata teaches “an apparatus for measuring basal metabolism” that includes “a device to measure bioelectrical impedance” of a subject and provides an improved method of determining basal metabolism. *Id.* at 21.

The Examiner concludes that it would have been obvious “to use the genotyping methods taught by Bernstein in the method of Roberts . . . because Roberts suggest[s] genotyping APO E and determination of diet based on APO E genotype . . . [and] Bernstein teaches methods of genotyping APO E were known.” *Id.* at 19. The Examiner concludes that it would also have been obvious “to improve the method of Roberts to include providing a genotype specific exercise regime as Bernstein teaches that different exercise intensities have different effects on blood triglyceride and HDL-cholesterol profiles based on APOE genotype.” *Id.*

The Examiner further concludes that it would have been obvious “to use additional determination of body fat mass and lean fat mass in the determinations of exercise and nutrition programs based on APO E genotypes as taught by Roberts and Bernstein” with a “reasonable expectation of success using known methods of determining percentage body mass and lean body mass and Singhal teaches these methods were known.” *Id.* at 20. Finally, the Examiner concludes that it would have been obvious to use “the bioimpedance method of Sakat[a] to estimate caloric intake required for additional activities. The artisan would be motivated to determine basal metabolic rate and provide more concise exercise and dietary regime.” *Id.* at 21.

Appellant argues:

The cited art does not mention an individual’s APO E genotype and the result of a bio-impedance test, and therefore cannot teach “applying a genotype specific nutritional regime plan and establishing optimal dietary levels of caloric content, fat content and type of fats, carbohydrate content and type of carbohydrates, and protein content and type of proteins” based

on the “both of said individual’s APO E genotype and the result of said bio-impedance test.”

Appeal Br. 13. Appellant also argues that “[t]he Examiner failed to indicate a reason a person of ordinary skill in the art would be motivated to combine the six references, none of which measure an individual’s APO E genotype and bio-impedance to create a nutritional plan based on them.” *Id.* at 14.

We conclude that the cited references support a prima facie case of obviousness. Roberts discloses “a method for selecting an optimal diet and exercise regimen for a patient,” based on the patient’s APO E genotype, among other factors. Roberts ¶ 10. For example, Roberts states that “APO E 2/2 and 2/3 individuals . . . ha[ve] a better outcome when diet is higher in fat rather than sugar. . . . Therefore, a diet moderate in fat content, consisting of 30–35% of total calories, is recommended.” *Id.* ¶ 18.

Roberts also states that “[i]ndividuals who are homozygous for the APO E3 allele (and APO E 2/4 . . .) should follow a basic preventive diet. Therefore, daily fat intake for prevention of cardiovascular disease should be low, consisting of 25–30% of daily total calories.” Roberts ¶ 28. Roberts also states that “[c]alorie content of preventive diet must be appropriate for weight maintenance or weight loss depending on calculated goal weight or % body fat.” *Id.*

Roberts states that “[i]ndividuals with at least one APO E4 allele (i.e., APO E 4/4 or 3/4, but excluding APO E 2/4) are most responsive to dietary intervention and are particularly sensitive to fat intake. A diet very low in fat (less than 20%) is recommended for this reason.” *Id.* ¶ 35.

Roberts does not disclose collecting a blood sample and analyzing it to determine an individual’s APO E genotype, as recited in claim 24. And,

although Roberts states that “[p]hysical activity can positively influence plasma lipid and lipoprotein concentration and reduce coronary artery disease risk levels,” *id.* ¶ 97, it does not provide exercise recommendations based on individuals’ APO E genotypes.

Bernstein, however, discloses both of these elements of the claim. Bernstein assessed whether “lipid profile levels observed across *apoE* genotype groups differed between more sedentary versus more active subjects.” Bernstein 133, right col. Bernstein discloses that blood was collected from participants, genomic DNA was extracted, and APO E genotype was determined. *Id.* at 134, right col.; 135, Table 1. Thus, it would have been obvious to a skilled artisan to include collecting a blood sample and analyzing APO E genotype in Roberts’ method, because Roberts discloses that an individual’s optimal diet depends on their APO E genotype.

Bernstein also discloses that “basal metabolic rate (BMR) . . . was calculated for each participant. Each physical activity was previously assigned a score indicating its intensity in terms of BMR multiples. For example, when sleeping, an individual expends 1 time the energy required by the BMR.” Bernstein 134, left col. “[M]oderate intensity activities expend[ed] 3 to 3.9 times the BMR High-intensity and very high-intensity activities expend[ed] ≥ 4 times the BMR.” *Id.* Bernstein reports that “[a]mong men, the *apoE4* group had significantly greater beneficial effects of increased %high-intensity activity on HDL cholesterol . . . and triglycerides . . . than either the *apoE2* group . . . or the *apoE3* group.” *Id.* at 135, right col. (Bernstein defines the *apoE* groups as follows: “*ApoE[2]*” means APO E 2/2 and APO E 2/3; “*ApoE3*” means APO E 3/3; and

“*ApoE4*” means APO E 3/4 and APO E 4/4. *Id.* at 136, legend to Table 2. Participants with APO E 2/4 genotypes were excluded. *Id.*)

Based on Bernstein, therefore, it would have been obvious to modify Roberts’ method to include recommending higher intensity (i.e., more aerobic) exercise to individuals having an APO E 3/4 or 4/4 genotype, as compared to those having APO E 2/2, 2/3, or 3/3 genotypes.

Bernstein does not disclose performing a bio-impedance test to calculate the basal metabolic rate (BMR) for an individual. However, Sakata discloses “an apparatus for measuring basal metabolism.” Sakata 1:11–12. Sakata’s apparatus includes “a device to measure bioelectrical impedance of [a] subject” and “a device for calculation of basal metabolism of the subject.” *Id.* at 2:10–14. Sakata states that its device “improves the accuracy of an arithmetic method used to determine basal metabolism.” *Id.* at 2:17–18.

Because Bernstein teaches that higher-intensity exercise, as determined based on BMR multiples, is more beneficial to individuals with APO E4 genotypes, it would have been obvious to modify the method made obvious by Roberts and Bernstein to use Sakata’s device—which includes measuring bioelectrical impedance, or bio-impedance—to determine an individual’s BMR, because Sakata teaches that its device improves the determination of basal metabolism.

The Examiner cites Kopelman, Singhal, and Brooks as evidence that obesity is unhealthy and “body composition is a more accurate determination of obesity than surrogate markers such as BMI.” Ans. 19. These references thus show that a skilled artisan would have had a reason to

modify Roberts, Bernstein, and Sakata to optimize dietary and exercise recommendations for an individual to promote a healthy weight.

Appellant argues that

[t]he cited art fails to teach “based upon both of said individual’s APO E genotype and the result of said bio-impedance test . . . applying a genotype specific nutritional regime plan and establishing optimal dietary levels of caloric content, fat content and type of fats, carbohydrate content and type of carbohydrates, and protein content and type of proteins.”

Appeal Br. 11–12. Appellant also argues that

[t]he cited art does not mention an individual’s APO E genotype and the result of a bio-impedance test, and therefore cannot teach “applying a genotype specific nutritional regime plan and establishing optimal dietary levels of caloric content, fat content and type of fats, carbohydrate content and type of carbohydrates, and protein content and type of proteins” based on the “both of said individual’s APO E genotype and the result of said bio-impedance test.”

Id. at 13. Similarly, Appellant argues that “[t]he Examiner failed to indicate a reason a person of ordinary skill in the art would be motivated to combine the six references, none of which measure an individual’s APO E genotype and bio-impedance to create a nutritional plan based on them.” *Id.* at 14.

These arguments are unpersuasive because the rejection is based on what the cited references, when read together, would have suggested to those skilled in the art. The Examiner provided reasons, based on the evidence, that a skilled artisan would have combined their teachings. Ans. 19–21. For the reasons discussed above, we agree with the Examiner that a person of ordinary skill in the art would have had a reason to combine APO E genotyping, as disclosed by Bernstein, and bio-impedance testing, as

disclosed by Sakata, with Roberts' APO E genotype-based diet recommendations and Bernstein's recommendation for more high-intensity exercise for individuals with APO E4 genotypes, resulting in the claimed method.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
24	112, second paragraph	Indefiniteness		24
24	112, first paragraph	Written Description		24
24	101	Eligibility	24	
24	103(a)	Roberts, Bernstein, Kopelman, Singhal, Brooks, Sakata	24	
Overall Outcome			24	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED