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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID ALLAWAY and ADRIAN HEWSON-HUGHES

Appeal 2021-002898
Application 16/062,142
Technology Center 1700

Before JAMES C. HOUSEL, DONNAM. PRAISS, and
HUNG H. BUI, *Administrative Patent Judges*.

PRAISS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1–6. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ “Appellant” refers to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as MARS, Incorporated. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to a method of screening a food product for increasing blood levels of margoric acid in a cat. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A method of screening a foodstuff comprising:

(a) preparing a foodstuff comprising i) one or more of aspartic acid, serine, glutamic acid, glycine, alanine and praline, and ii) one or more of myristic acid, palmitic acid, stearic acid, palmitoleic acid, oleic acid and linolenic acid, the foodstuff further comprising a protein to fat ratio of 1:0.27 to 1:0.63 on a gram:gram as fed or dry matter basis;

(b) feeding a cat the foodstuff, and

(c) measuring the level of margoric acid in a blood sample from the cat before and after feeding the foodstuff,

wherein an increase in endogenous margoric acid levels post-prandially is indicative of a foodstuff effective to prevent or reduce the risk of coronary heart disease, type 2 diabetes and/or inflammation in the cat.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Stallings	US 2003/0086869 A1	May 8, 2003
Sunvold	US 2010/0303978 A1	Dec. 2, 2010
Hu	US 2012/0122981 A1	May 17, 2012
Hewson-Hughes	US 2014/0044825 A1	Feb. 13, 2014
Jenkins	A Review of Odd-Chain Fatty Acid Metabolism and the Role of Pentadecanoic Acid (C15:0) and Heptadecanoic Acid (C17:0) in Health and Disease, 20 Molecules 2425–2444	Jan. 30, 2015

REJECTIONS

The Examiner maintains the following rejections:²

Claims	35 U.S.C. §	Reference(s)/Basis
1–6	101	Eligibility
1, 3–6	103	Hewson-Hughes, Jenkins, Sunvold
2	103	Hewson-Hughes, Jenkins, Stallings

OPINION

Eligibility of Claims 1–6

Appellant argues the claims together. Appeal Br. 6–15. Therefore, we confine our discussion to claim 1, which we select as representative. Claims 2–6 stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Statutory Subject Matter/Revised Guidance Step 1

An invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101. We agree with the Examiner that claim 1 recites a “method,” which is within a statutory category of a process. *See* 35 U.S.C. § 101; Final Act. 4.

Alice Step One/Revised Guidance Step 2A, Prong One

“The [United States Supreme] Court has long held that [35 U.S.C. § 101] contains an important implicit exception. “[L]aws of nature, natural

² The Examiner withdrew the alternative rejection of claims 1 and 3–6 under 35 U.S.C. § 103 over Hewson-Hughes and Sunvold in combination with Hu (US 2012/0122981 A1, pub. May 17, 2012). Ans. 12; Final Act. 12.

phenomena, and abstract ideas’ are not patentable.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77–78 (2010) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)); *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014). In determining whether a claim falls within an excluded category, we are guided by the Court’s two-part framework, described in *Alice/Mayo*. *Alice*, 573 U.S. at 217–18 (citing *Mayo*, 566 U.S. at 75–77).

First, we determine whether a patent claim is “directed to” a patent-ineligible concept. *See Alice*, 573 U.S. at 217. If the claim is “directed to” a law of nature, natural phenomena, or abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where “we must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed [judicial exception] into a patent-eligible application.” *Alice*, 573 U.S. at 221 (internal quotation marks omitted). There is no need to proceed to the second step, however, if the first step of the *Alice/Mayo* test yields a determination that the claim is directed to patent-eligible subject matter.

The Federal Circuit has described the *Alice* step-one inquiry as looking at the “focus” of the claims, their “character as a whole,” and the *Alice* step-two inquiry as looking more precisely at what the claim elements add—whether they identify an “inventive concept” in the application of the ineligible matter to which the claim is directed. *See Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–36 (Fed. Cir. 2016); *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015).

In an effort to achieve clarity and consistency in how the Office applies the Supreme Court’s two-step framework, the U.S. Patent and Trademark Office (USPTO) published revised guidance on the application of § 101. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (“Revised Guidance”) effective as of January 7, 2019. Under the Revised Guidance, and further guidance issued on October 17, 2019,³ clarifying the Revised Guidance (“October 2019 Update”), only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look, under Step 2B, to whether the claim: (1) “adds a specific limitation beyond the judicial exception that is not ‘well-understood, routine, conventional’ in the field” or (2) “simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.” Revised Guidance, 84 Fed. Reg. at 52–56.

Applying this framework, we agree with the Examiner that claim 1 recites a judicially recognized exception, i.e., abstract ideas, laws of nature, or natural phenomena. Final Act. 4; Ans. 13.

According to the Examiner, determining an increase in endogenous margaric acid levels post-prandially in order to indicate a risk level of various diseases based on margaric acid blood levels measured before and after feeding falls within the mental process concepts grouping of abstract

³ The *October 2019 Update: Subject Matter Eligibility* is available at https://www.uspto.gov/sites/default/files/documents/peg-oct_2019_update.pdf). The Manual of Patent Examining Procedure (“MPEP”) now incorporates this Guidance and subsequent updates at § 2106 (9th ed. Rev. 10.2019, rev. June 2020).

ideas. Final Act. 4; Ans. 19; *see* Revised Guidance, 84 Fed. Reg. at 52; October 2019 Update at 7–8 (the mental process grouping includes “collecting information, analyzing it, and displaying certain results of the collection and analysis,” “collecting and comparing known information,” and “comparing BRCA sequences and determining the existence of alterations”); *see also* Spec. ¶ 19:5–9 (describing margoric acid as a known marker associated with lower risk of various diseases and describing increased endogenous levels of margoric acid observed in cats fed a certain protein to fat ratio diet as beneficial for lowering the risk of those various diseases).

Appellant contends claim 1 does not recite an abstract idea *per se* because claim 1 does not explicitly recite the terms “comparing” and/or “judging” which appear in the Revised Guidance. Appeal Br. 9–10.

Although claim 1 does not explicitly recite “comparing,” it does require a comparison to be made with its recitations “measuring the level of margoric acid in a blood sample . . . before and after feeding the foodstuff” and “an increase in endogenous margoric acid levels.” That is, the two recited measurements must be compared in order to obtain from the measured levels of margoric acid in a blood sample the recited “increase in endogenous margoric acid levels.” As such, the claim recites a mental process as the Examiner determines.

Additionally, claim 1 is directed to a judicial exception as a law of nature or natural phenomena. In particular, the claimed method is based on the law of nature or natural phenomenon that an increase in endogenous margoric acid levels is associated with a lower risk of various diseases. The focus of claim 1 is on an observed increase in measured margoric acid levels

before and after feeding foodstuff to a cat. This purpose is reflected in claim 1's preamble "method of screening a foodstuff" and recitation "wherein an increase in endogenous margoric acid levels post-prandially is indicative of a foodstuff effective to prevent or reduce the risk of [various diseases associated with margoric acid]." Appeal Br. 20 (Claims Appendix).

According to the Specification's example, differences were investigated in macronutrient compositions on post-prandial metabolite profiles in cats. Spec. 15: 26–28. The Specification describes the dietary protein to fat ratio of diet 4 exhibiting increased endogenous levels of margoric acid and, therefore, identifies diet 4 as beneficial for lowering the risk of various diseases associated with margoric acid as a marker. *Id.* at 19:5–9. The Specification's description of these steps confirms that they are based on the law of nature or natural phenomenon of increased endogenous margoric acid levels indicating a lower risk of various diseases.

Appellant's method for screening a foodstuff for an optimal level of endogenous margoric acid is analogous to the claimed method in *Mayo* for optimizing therapeutic efficiency for treating a gastrointestinal disorder. The claimed method in *Mayo* (1) administered a drug to a subject, (2) determined the drug level in a subject, and (3) correlated the drug level with either a need to increase or decrease the amount of drug administered to the subject. *Mayo*, 566 U.S. at 74–75. The Supreme Court determined that the claims set forth a relationship between concentrations of certain metabolites in the blood and the likelihood administered doses would be ineffective or produce toxic side effects. *Id.* at 77. The Court determined that such a relationship is a consequence of the body's metabolism, which is an entirely natural process, thus, a claim to the relation sets forth a natural law. *Id.*

Like the claimed method in *Mayo*, Appellant’s claim (1) feeds foodstuff to a cat, (2) measures the cat’s endogenous margaric acid levels, and (3) correlates a post-prandial increase in the margaric acid level with “a foodstuff effective to prevent or reduce the risk of coronary heart disease, type 2 diabetes and/or inflammation in the cat.” Accordingly, we determine that claim 1 recites the judicially recognized exception of a law of nature or natural phenomenon because the relationship between margaric acid level and effectiveness is a consequence of the cat’s metabolism, which is an entirely natural process.

Alice Step One/Revised Guidance Step 2A, Prong Two

We next consider whether claim 1 recites any additional elements that integrate the judicial exception into a practical application. Revised Guidance, 84 Fed. Reg. at 54. We determine that the recited foodstuff in claim 1 does not integrate the judicial exception into a practical application. The foodstuff is a component used to apply the judicial exception as the Examiner finds. Ans. 14. Claim 1 applies the natural phenomenon of endogenous margaric acid levels indicating lower risk of various diseases to the foodstuff consumed by a cat to observe the foodstuff’s effectiveness as a particular treatment or prophylaxis for a medical condition or disease. The additional element, thus, is not improved or transformed by the natural phenomenon.

The Specification provides that the foodstuff to be used in the method is “a complete nutritionally balanced pet foodstuff” preferably for a cat. Spec. 4:20–22; *see also id.* at 7:36 (“The pet foodstuff can be a complete and nutritionally balanced pet food product.”). The Specification states “[t]he

purpose of the method of the invention is to provide a diagnosis that the pet foodstuff is the factor providing the effect of increasing the endogenous margaric acid levels in the companion animal.” *Id.* at 6:4–6. The Specification acknowledges that margaric acid is a known marker associated with lowering the risk/incidence of insulin resistance, type 2 diabetes, inflammation and coronary heart disease. *Id.* at 6:16–17. The Specification states that the foodstuff “can be made according to any method known in the art” and the measurement of margaric acid levels is made “using standard assays, known in the art, to determine the concentration levels of endogenous margaric acid.” *Id.* at 9:25–26, 11:7–8. Thus, the claimed method measures a known marker in a companion animal that is attributable to known pet foodstuffs.

Accordingly, we determine that claim 1 lacks any additional elements that are sufficient to integrate the judicial exception into a practical application.

Alice Step Two/Revised Guidance Step 2B

We next consider whether claim 1 recites additional elements that, when considered individually or as an ordered combination, provide an inventive concept that is significantly more than the judicial exception. *Alice*, 573 U.S. at 217–18. This step is satisfied when the limitations involve more than well-understood, routine, and conventional activities known in the industry. *See Berkheim v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018).

Appellant contends the Examiner’s analysis under this step is insufficient “because the Examiner has not established that the preparation of the recited food is routine or conventional.” Appeal Br. 15. However, the

Specification itself acknowledges that the preparation of the foodstuff is “made according to any method known in the art” and that “[t]he pet foodstuff can be a complete and nutritionally balanced pet food product.” Spec. 7:36, 9:25–26. The cited prior art references likewise show that it was known in the art to prepare cat food with a protein to fat ratio that overlaps the claimed range and to include the recited functional ingredients (amino acids as active ingredients and myristic acid, palmitic acid, stearic acid, and oleic acid to reduce water transmission in kibble). Hewson-Hughes ¶¶ 7, 42; Sunvold ¶¶ 20, 37, 56. Thus, the additional elements, considered individually or as an ordered combination, are merely sample preparation and data gathering as the Examiner determines. Ans. 14–15.

Accordingly, we determine that claims 1–6 are directed to a patent ineligible abstract idea under 35 U.S.C. § 101 without significantly more.

Obviousness Rejections of Claims 1–6

The Examiner finds Hewson-Hughes teaches a foodstuff having overlapping protein and fat ratios for use in preventing or reducing the risk of disease such as diabetes. Final Act. 6–7. The Examiner finds Hewson-Hughes does not disclose the foodstuff comprises amino acids and one or more of myristic acid, palmitic acid, stearic acid, palmitoleic acid, oleic acid, and lineolenic acid as required by claim 1, but finds Sunvold teaches a pet food in the form of a coated kibble that improves vitamin retention which contains amino acids and fatty acids as active ingredients and that myristic acid, palmitic acid, stearic acid, and oleic acid components can assist in reducing water transmission within the coated kibble. *Id.* at 8–9. The Examiner determines it would have been obvious to incorporate amino acids

and fatty acids into the foodstuff for the benefit of incorporating further active ingredients as taught by Sunvold. *Id.* at 9. The Examiner also finds Jenkins discloses measuring margoric acid levels in a blood sample wherein an increase post-prandially is indicative of a foodstuff useful in preventing and/or reducing the risk of coronary heart disease, type 2 diabetes, and/or inflammation. *Id.* at 9–10. The Examiner determines it would have been obvious to measure the level of margoric acid in a blood sample before and after feeding the foodstuff as taught by Jenkins because both Hewson-Hughes and Jenkins are direct to control of diabetes through improved diet. *Id.* at 10.

Appellant does not separately argue the obviousness rejections nor separately argue the claims. Appeal Br. 15–18. Therefore, we confine our discussion to claim 1, which we select as representative. Claims 2–6 stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Appellant argues that the Examiner’s prior art combination is based on impermissible hindsight because a person having ordinary skill in the art at the time of the invention would have had to pick and choose at least one of aspartic acid, serine, glutamic acid, glycine, alanine, and proline from 225 possibilities listed in Sunvold’s paragraph 37 and one of myristic acid, palmitic acid, stearic acid, palmitoleic acid, oleic acid, and linolenic acid from more than 283 possibilities listed in paragraphs 37 and 56, which Appellant asserts amount to 39,903 possible combinations of two. Appeal Br. 16–17.

Appellant’s argument is not persuasive of error because Sunvold teaches it would be beneficial to incorporate further active ingredients into the foodstuff as the Examiner finds. Ans. 17; Sunvold ¶ 37. Claim 1 does not

require one component from group (a) and one component from group (b) as Appellant asserts. Rather, claim 1 recites “one or more” of the components in groups (a) and (b), which Sunvold groups together as amino acids and components for assisting in reducing water transmission within a coated kibble. Sunvold ¶¶ 37, 56. Thus, it would have been within the level of skill of a person having ordinary skill in the art to combine one or more of these components according to known methods to yield predictable results as shown by Sunvold, which lists the components of groups (a) and (b) together with equivalents. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.”).

Accordingly, we affirm the rejection of claim 1 under 35 U.S.C. § 103.

CONCLUSION

The Examiner did not err in rejecting claims 1–6 under 35 U.S.C. §§ 101 and 103.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1-6	101	Eligibility	1-6	
1, 3-6	103	Hewson-Hughes, Jenkins, Sunvold	1, 3-6	
2	103	Hewson-Hughes, Jenkins, Stallings	2	
Overall Outcome			1-6	

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