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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte YURI HIRABAYASHI, CHIE FURUTA,
YOSHIHITO NOGUSA, KATSUYA SUZUKI, AND
HISAMINE KOBAYASHI¹

Appeal 2018-006896
Application 14/098,691
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and
JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Appellants identify Ajinomoto Co., Inc. as the real party-in-interest. App.
Br. 1.

SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Non-Final Rejection of claims 1, 2, 7–10, 15–17, and 21–32. Specifically, claims 1, 2, 7–10, and 24–28 stand rejected as unpatentable under 35 U.S.C. §101 as being directed to nonstatutory subject matter.

Claims 1, 2, 7–10, 15–17, 21–27, and 29–31 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Kuriki et al (JP 2003-169642, June 17, 2003)², Klein et al., *The Effects of Alanine Ingestion on Metabolic Responses to Exercise in Cyclists*, 37 AMINO ACIDS 673–80 (2009) (“Klein”), Vosloo et al. (US 2010/0099734 A1, April 22, 2010) (“Vosloo”), and F.Q. Nuttall et al., *The Metabolic Response to Ingestion of Proline With and Without Glucose*, 53(2) METABOLISM 241–46 (2004) (“Nuttall”).

Claims 1, 2, 7–10, 15–17, 21–27, and 29–32 also stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Klein, Vosloo, Nuttall, and Antrim et al. (US 2005/0048191 A1, March 3, 2005) (“Antrim”).

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellants' claimed invention is directed to amino acid compositions containing a carbohydrate and any one or more kinds of alanine, proline, and glycine, which can suppress a rapid increase in the blood glucose levels

² An English machine translation of this reference is of record.

immediately after ingestion and a decrease in the blood glucose level due to prolonged exercise, and can improve exercise performance. Abstr.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

Claim 1. An amino acid composition, comprising:

a carbohydrate comprising at least one of dextrin and reduction dextrin;

alanine; and

proline,

wherein a total concentration of the carbohydrate is 10 wt% to 90 wt%, based on the solid content of the amino acid composition,

the weight ratio of alanine to proline is 1:0.1 to 0.5,

the amino acid composition is free of amino acids other than alanine, proline, and glycine, and

the amino acid composition is in the form of a package of a unit ingestion amount of 2.5 g to 15 g in total of alanine and proline.

App. Br. 16.

ISSUES AND ANALYSES

We decline to adopt the Examiner's conclusion that the claims are directed to nonstatutory subject matter under 35 U.S.C. §101, and we reverse that rejection. However, we adopt the Examiner's findings, reasoning, and

conclusion that the claims on appeal are *prima facie* obvious over the cited prior art references. We address the arguments raised by Appellants below.

A. Rejection of claims 1, 2, 7–10, and 24–28 under 35 U.S.C. § 101

Issue

Appellants argue that the Examiner erred in concluding that the claims are directed to a judicial exception, *viz.*, a product of nature. App. Br. 13.

Analysis

The Examiner finds that the claims are drawn to a plurality of natural products: alanine and proline in combination with dextrin. Final Act. 4. The Examiner finds that dextrin is an excipient/food component that is conventional and routine in the field. *Id.* The Examiner states that, for claims comprising a plurality of judicial exceptions, the analysis is conducted for one of the exceptions, such as one of the specifically recited amino acids. *Id.* The Examiner finds that there is nothing in the record to suggest that the mixture of components has any characteristics (structural, functional or otherwise) that are different from the naturally occurring components. *Id.* The Examiner therefore concludes that, because there are no markedly different characteristics of the components from what occurs in nature, the mixture claimed by Appellants is a product of nature, and, therefore, a judicial exception to Section 101. *Id.*

We disagree. In performing an analysis of patentability under Section 101, we follow the framework set forth by the Supreme Court in *Mayo Collaborative Servc's v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012). We are also mindful of, and guided by, the United States Patent and Trademark

Office’s 2019 *Revised Patent Subject Matter Eligibility Guidance*, 84(4) Fed. Reg. 50–57 (January 7, 2019) (the “2019 Guidance”).

Appellants’ claim 1 recites: “An amino acid composition, comprising...” Following the first step of the *Mayo* analysis, we find that the claims are directed to a composition of matter, and therefore falls into one of the broad statutory categories of patent-eligible subject matter under 35 U.S.C. § 101.

In the next step of the *Mayo* analysis, we determine whether the claims at issue are directed to a nonstatutory, patent-ineligible concept, i.e., a law of nature, a phenomenon of nature, or an abstract idea. *Mayo*, 566 U.S. at 70–71. If the claims are so directed, we next consider the elements of each claim both individually and “as an ordered combination” to determine whether additional elements “transform the nature of the claim” into a patent-eligible application. *Id.* at 78–79; *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015). Specifically, the Supreme Court considered this second step as determining whether the claims recite an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Mayo*, 566 U.S. at 72–73.

More specifically, in this second step of the *Mayo* analysis, we look to whether the claim recites one of the judicially-created exceptions to Section 101, i.e., an abstract idea, a law of nature, or a natural phenomenon. *See* 2019 Guidance 54 (step 2A, prong 1). If we determine that the claim recites a judicial exception, we then determine whether the limitations of the claim reciting the judicial exception are integrated into a practical application. *Id.* (Step 2A, Prong 2).

Finally, if we determine that the claim is directed to a judicially-created exception to Section 101, we evaluate the claim under the next step of the *Mayo* analysis, considering the elements of each claim both individually and “as an ordered combination” to determine whether additional elements “transform the nature of the claim” into a patent-eligible application. *Mayo*, 566 U.S. at 78–79; 2019 Guidance at 56 (Step 2B).

Claim 1 is directed to “an amino acid composition” containing dextrin, alanine, proline, and, optionally, glycine, in various concentrations and in prescribed ratios. We acknowledge the Examiner’s finding that all of these constituent elements are naturally occurring compositions, i.e., products of nature.

However, although each of these components alone may be naturally occurring, the combination of all the claimed elements does not occur naturally: the Examiner points to no examples of dextrin and the recited amino acids occurring, as claimed, as a natural product. *See, e.g., Ex parte Hennen*, Appeal No. 2016-002575, 2017 WL 2200423, at *4 (PTAB, May 10, 2017). Moreover, the Specification teaches that the combination of these components results in a composition that suppresses an increase of blood glucose level in an initial stage following ingestion and suppresses the decrease of blood glucose level during exercise for a prolonged interval. *See* Spec. 1. Appellants’ Specification thus discloses a composition that is “significantly more” than merely the natural products alone and markedly different than any of the natural products. *Id.*

We note that the Examiner has presented no evidence rebutting the Specification’s disclosure in this regard. We consequently conclude that the claimed composition is not a “product of nature.” Because the claim is not,

therefore, directed to judicial exception of Section 101 (2019 Guidance, Step 2A, prong 1), our analysis ceases at this step, and we reverse the Examiner's rejection of the claims upon this ground.

B. Rejection of claims 1, 2, 7–10, 15–17, 21–27, and 29–31 under 35 U.S.C. § 103(a) over Kuriki, Klein, Vosloo, Nuttall

Issue 1

Appellants argue that the Examiner erred because the cited references do not disclose or suggest suppressing an increase of blood glucose level immediately after carbohydrate ingestion by administering a composition containing 2.5 g to 15 g in total of alanine and proline. App. Br. 4.

Analysis

The Examiner finds that Kuriki teaches a sports drink composition comprising dextrin and, optionally, amino acids including alanine, proline, and glycine, to be administered to athletes in endurance exercise for supplying carbohydrates and preventing dehydration. Final Act. 4. The Examiner finds that Kuriki also teaches that its composition has utility in decreasing consumption of endogenous glycogen. *Id.* (citing Kuriki ¶¶ 2–4, 21). The Examiner also finds that Kuriki also teaches, in Example 6, that administration of dextrin provides a greater glycogen restorative effect during exercise *versus* other carbohydrates. *Id.* at 4–5.

The Examiner finds that Klein teaches administration of 15 g or 30 g of alanine, either alone or in combination with sucrose (a carbohydrate), to athletes before and during exercise. Final Act. 5 (citing Klein 674). The Examiner finds that the addition of alanine suppresses the increase in blood

glucose level after carbohydrate ingestion. *Id.* (citing Klein Table 6, 678). The Examiner finds that Klein further teaches that it is well known in the art that alanine supplementation enhances exercise performance at a level similar to that which occurs with the provision of exogenous carbohydrate. *Id.* (see Klein 678).

The Examiner finds that Vosloo teaches proline supplementation of 20-1000 mg/kg of body weight to prevent dehydration due to exercise. Final Act. 5. The Examiner finds that Vosloo teaches that the proline may be mixed in a drink. *Id.*

The Examiner finds that Nuttall teaches that, in addition to the utility of proline in preventing dehydration, the administration of proline in combination with a carbohydrate attenuates the rise in blood glucose levels due to the ingestion of the carbohydrate. Final Act. 5 (citing Nuttall Abstr., Fig. 2). The Examiner further finds that Nuttall teaches that glycine similarly attenuates this response. *Id.* (citing Nuttall 245).

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to have modified the product of Kuriki by the addition of alanine and proline (with or without glycine) with a reasonable expectation of success. Final Act. 5–6. The Examiner concludes that a skilled artisan would have been motivated to make this modification for the metabolic benefits of the amino acids taught by the art. *Id.* at 6. The Examiner also finds that Klein teaches that alanine provides an additional energy source, in addition to other metabolic benefits, such as attenuating the blood glucose rise due to carbohydrate ingestion. *Id.* The Examiner finds that Nuttall teaches that the addition of proline has a similar effect, as well as utility in the prevention of dehydration. *Id.*

Appellants argue that Kuriki teaches amino acids that may be administered to a subject along with dextrin, but does not disclose or suggest the amount of amino acids, or the total amount of alanine and proline. App. Br. 4 (citing Kuriki ¶ 21).

Appellants argue that Klein teaches that a solution containing 6% of alanine is administered to a subject four times — 500 mL of the solution is administered 30 minutes before exercise, and 250 mL of the solution is administered at 15, 30, and 45 minutes during the exercise period. App. Br. 4 (citing Klein Abstr. 674). Appellants therefore calculate that Klein teaches that the subject is administered with 30 g or 15 g of alanine per administration, or 75 g in total. *Id.* (citing Klein 679).

Appellants further contend that Vosloo teaches that an effective amount of L-proline is between 20 mg/kg body mass and 1000 mg/kg, and particularly 100 mg/kg body. *Id.* (citing Vosloo ¶ 22).

Appellants argue that Nuttall teaches administration of 25 g of glucose and 1 mmol/kg of proline are to subjects. App. Br. 4 (*see* Nuttall 241). Appellants calculate that, given that the molecular weight of proline is 115.13 g/mol, the amount of proline administered to the subject is 0.12 g/kg in Nuttall. *Id.* Furthermore, assert Appellants, because the subjects in Nuttall have a body weight ranging from 58 to 107 kg (citing Nuttall 241), the subjects are therefore administered about 6.7 g to 12.3 g of proline in addition to 25 g of glucose. *Id.*

Appellants therefore argue that, based upon the teachings of these references, greater than 15 gms total of alanine and proline should be administered to a subject to obtain desirable effects. App. Br. 4. Appellants contend that a person of reasonable skill in the art would not have

reasonably expected that the total amount of alanine and proline administered to a subject for suppressing increase of blood glucose level could be within the range of 2.5 g to 15 g, as recited in claim 5.

We are not persuaded by Appellants' arguments. The sum teachings of the prior art references cited by the Examiner is that administration of a carbohydrate (e.g., dextrin) and alanine, proline, or glycine is useful in the suppression of a rapid rise in glucose post administration, and a sustained higher serum glucose level during prolonged exercise. Appellants' Specification acknowledges that it was known in the art at the time of invention that, *inter alia*: "[a]mino acids have been regularly used as supplement by general public and athletes, and are reported to provide various physiological actions," and that: "ingestion of proline suppresses an increase of blood glucose level after glucose ingestion in humans." Spec. 2.

Appellants acknowledge that Nuttall teaches administration of proline at concentrations (6.7–12.3 g) within the approximate prescribed total range recited in claim 1 (2.5–15 g) results in a 23% attenuation of the glucose area response. *See* Nuttall Abstr., 241. Vosloo teaches administration of, preferably 100 mg/kg L-proline, or, on average, approximately 6.2 g of proline; a concentration similar to the lower edge of the range taught by Nuttall.

Klein teaches the administration of alanine and carbohydrate also promotes sustained higher serum glucose concentrations during sustained exercise, as is also suggested by Kuriki for the combination of dextrin with the recited amino acids. We acknowledge that Klein teaches administration of greater amounts of alanine than are recited in the claims, nevertheless, we conclude that it would have been within the competence of a person of

ordinary skill in the art to adjust the ratio and absolute concentrations of amino acids to optimize the results and arrive at the claimed invention. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). This rule is limited to cases in which the optimized variable is a “result-effective variable.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (citing *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977); *see also In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) (“[D]iscovery of an optimum value of a result effective variable ... is ordinarily within the skill of the art”).

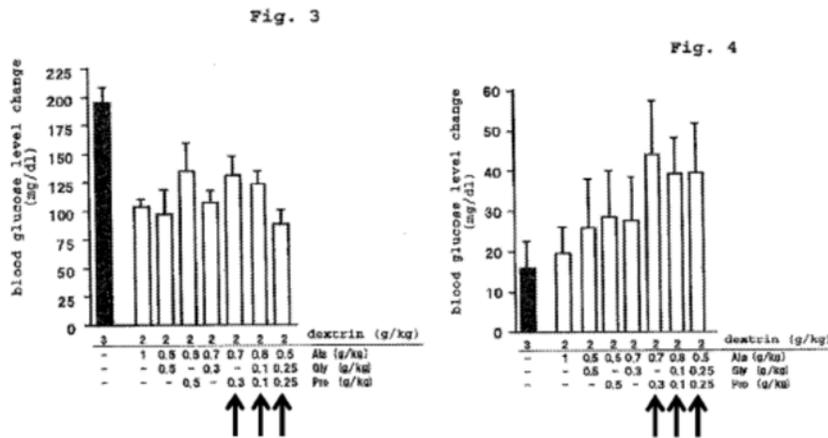
The prior art, notably Klein and Nuttall, and to a lesser extent, Kuriki, teach or suggest that the addition of amino acids, and specifically alanine and proline, help in maintaining sustained glucose levels during prolonged exercise and are, consequently, result effective variables. We therefore agree with the Examiner’s conclusion that the claims are *prima facie* obvious over the prior cited art.

Issue 2

Appellants argue that data presented in their Specification demonstrate the unexpected advantages obtained by administering a composition including alanine and proline in a weight ratio of 1:0.1 to 1:0.5. App. Br. 5.

Analysis

Appellants point to Example 2 of their Specification, in which compositions having varying mixing ratios of alanine, proline, and/or glycine were administered to subject mice. App. Br. 5. Fifteen minutes post administration, blood glucose levels were measured, and exercise was started: after 90 minutes of the exercise, the blood glucose level of the subjects was again measured. *Id.* (citing Spec. 21, ll. 7–21, 22, ll. 5–18). Appellants state that the change from the pre-administration blood glucose level to the blood glucose level measured after 15 minutes from the administration is shown in Figure 3 of the Specification; similarly, the change from the pre-administration blood glucose level to the blood glucose level measured after 90 minutes is shown in Figure 4. Figures 3 and 4 of the Specification, as annotated by Appellants, are reproduced below.



Figures 3 and 4 of Appellants’ Specification demonstrate blood glucose levels measured 15 minutes (Fig. 3) and 90 minutes (Fig. 4) post administration of the compositions listed on the x-axis. Arrows indicate compositions within the scope of the claims.

According to Appellants, Figure 3 shows that degree of increase in the blood glucose level is suppressed when the compositions recited in the claims are administered (as indicated by the arrows), compared to when a carbohydrate (dextrin) alone is administered (as indicated by the solid black bar at right). App. Br. 6. Similarly, Appellants argue, Figure 4 demonstrates that blood glucose levels increased by the administration of the claimed composition remains higher than the control blood glucose level after 90 minutes of exercise. *Id.*

Appellants argue that Figure 4 shows that the degrees of the blood glucose level change vary depending on the mixing ratio of alanine, proline, and/or glycine. App. Br. 6. Specifically, argue Appellants, Figure 4 indicates that when the weight ratio of alanine to proline is 0.7/0.3, 0.8/0.1, or 0.5/0.25 — that is, when the weight ratio of alanine to proline is 1:0.43, 1:0.125, or 1:0.5, the blood glucose level after 90 minutes of exercise remains relatively high, as compared to when 1 g/kg of alanine alone is administered (i.e., when the weight ratio of alanine to proline is 1:0) or when 0.5 g/kg of alanine and 0.5 g/kg of proline are administered (i.e., when the weight ratio of alanine to proline is 1:1). *Id.* Appellants assert that these results demonstrate that, by setting the weight ratio of alanine to proline in the composition within the range of 1:0.1 to 0.5 as recited in the claims, blood glucose level raised by the administration of the composition can be relatively high, and rapid decrease in blood glucose level due to exercise can be prevented. *Id.* Appellants contend that the different degrees of glucose level change shown in Figure 4 of the Specification are attributable to the difference in the mixing ratio of alanine and proline, since all conditions other than the mixing ratio are identical. *Id.* (citing Spec. 22, ll. 4–33).

Appellants note that the changes in the blood glucose level in Figure 4 are shown with an error bar. App. Br. 9. According to Appellants, the size of the error bars (the variation in the blood glucose level) can be relatively large after the exercise, because the effect of exercise may vary from individual to individual even when the subjects performed the same exercise under the same conditions. *Id.* However, Appellants contend, all of the error bars in Figure 4 have similar lengths, indicating that all measurements have similar variation ranges. *Id.* Appellants argue that, because Figure 4 shows that the blood glucose level after 90 minutes of exercise is significantly higher in the rightmost three measurements as compared to the others, it would be understood that a meaningful improvement is observed when a composition including alanine and proline in the claimed mixing ratios is administered. *Id.*

Appellants argue further that the experimental results presented in Example 2 of the Specification also show the unexpected advantages of the claimed method over those taught by the cited prior art. App. Br. 7. By way of example, Appellants point out that, in Example 2, some mouse test groups were administered dextrin alone, or dextrin and amino acid(s). *Id.* Appellants contend that these mice are similar to the subjects in Kuriki. *Id.* (citing Kuriki ¶¶ 14, 21). Similarly argue Appellants, the test group to which 2 g/kg of dextrin and 1 g/kg of alanine were administered are closer to the claimed composition than to that taught by Klein, since sucrose rather than dextrin is administered in Klein. *Id.* Appellants further assert that, as shown in Figure 4, the blood glucose level remains relatively high when the alanine and proline are administered in the claimed concentration ratio

compared to when different ratios or combinations of amino acids are administered to the subject, as described in the cited references. *Id.*

Appellants therefore argue that the prevention of a rapid decrease in blood glucose level due to exercise (i.e., the maintenance of relatively high blood glucose levels after exercise), as shown in Figure 4, would have been Unexpected by a person of ordinary skill in the art. App. Br. 7. Appellants assert that none of the cited references describes administering alanine and proline in a prescribed ratio to control the blood glucose level after sustained exercise. *Id.*

We are not persuaded by Appellants' arguments. With respect to its Figures 3 and 4, Appellants' Specification discloses:

Figure 3 shows changes in the blood glucose level 15 minutes after the administration from that before administration, and Figure 4 shows changes in the blood glucose level after 90 minutes exercise loading from that before administration. Irrespective of dose, simultaneous administration of dextrin and, Ala alone, two kinds of Ala and Gly, two kinds of Ala and Pro, or three kinds of Ala, Gly and Pro, suppressed the increase of blood glucose level 15 minutes after the administration, and the decrease of blood glucose level after the exercise loading, as compared to an administration of an isocaloric dextrin alone. The results show that the amino acid-containing composition of the present invention is useful since it has a suppressive action on the increase of blood glucose level and an action to maintain the blood glucose level during exercise loading.

Spec. 22. In sum, this passage of Appellants' Specification discloses that there are differences between control and all experimental groups at 15 minutes post administration and after 90 minutes of exercise loading. The Specification makes no analysis of inter-experimental group differences, nor does it disclose any statistical analysis to demonstrate such differences.

Appellants point to the “error bars” on the experimental groups (Standard deviation? Standard error of the mean?), without demonstrating any evidence of statistical difference. Lacking such objective scientific validation of the inter-experimental group differences, either in the disclosures of the Specification, or even, *post hoc*, in their Appeal Brief, other than a mere assertion that the differences between the various experimental groups are “significant,” Appellants’ arguments lack the evidentiary support to sustain an argument of unexpected results. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (“It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements ... [do] not suffice” (citation omitted)).

Furthermore, even were we to acknowledge, *arguendo*, that the results between those experimental groups that fall within the scope of the claims and those that do not is statistically significant, and that the claimed compositions demonstrated better results in Figure 4 (but not in Figure 3), that would not, in itself, be sufficient evidence of unexpected results to overcome the Examiner’s *prima facie* case of obviousness. When we consider that it was well known in the prior art that administration of the claimed amino acids could generate the effects exemplified in Figures 3 and 4 of Appellants’ Specification, Appellants’ balancing of the various amino acids to obtain more effective results resembles the sort of routine optimization that would be well within the abilities of a person of ordinary skill in the art. *See Aller*, 220 F.2d at 456.

In short, we are not persuaded that Appellants’ arguments with respect to unexpected results are sufficient to overcome the Examiner’s conclusion that the claims are *prima facie* obvious. In the instant appeal, we find that

the alleged improvement in serum glucose elevation after exercise caused by the claimed invention does not represent the “difference in kind” that is required to show unexpected results, and therefore does not overcome the Examiner’s conclusion that the claims are obvious over the combined cited prior art. *See In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005); *see also Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) (holding that: “Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion”). We consequently affirm the Examiner’s rejection of the claims.

Furthermore, Appellants argue claims 16, 17, and 1 separately, but rely upon essentially the same arguments presented by Appellants *supra*. *See* App. Br. 10–12. For the same reasons, we similarly affirm the Examiner’s rejection of these claims.

C. Rejection of claims 1, 2, 7–10, 15–17, 21–27, and 29–32 under 35 U.S.C. § 103(a) over Klein, Antrim, Vosloo, Nuttall

Analysis

Appellants reprise their arguments presented *supra*, arguing further that Antrim does not cure the alleged deficiencies of Klein, Vosloo, and Nuttall. App. Br. 13. According to Appellants, Antrim is directed to dextrans, and does not disclose or suggest the total amount of alanine and proline that may be administered to a subject. *Id.*

We have explained *supra* our reasoning as to why we conclude that the Examiner’s combination of Kuriki, Klein, Vosloo, and Nuttall is sufficient to establish that the claim are *prima facie* obvious. As with Kuriki, which only teaches administration of amino acids in passing and

without teaching the concentrations, the Examiner relies upon Antrim as teaching the preparation of dextrans that have utility in the preparation of food products, including sports drinks (liquid or powder concentrate) and energy bars, which may include other nutritional components, such as amino acids, including alanine, proline, and lysine. *See* Final Act. 8 (citing Antrim ¶¶ 18, 22–26, 45). For the reasons we have explained, we agree with the Examiner’s reasoning and conclusion that the claims are *prima facie* obvious over the combined cited prior art, and we affirm the Examiner’s rejection of the claims upon this ground.

DECISION

The Examiner’s rejection of claims 1, 2, 7–10, and 24–28 under 35 U.S.C. § 101 is reversed.

The Examiner’s rejection of claims 1, 2, 7–10, 15–17 and 21–27, and 29–32 under 35 U.S.C. § 103(a) is affirmed.

AFFIRMED