United States Court of Appeals for the Federal Circuit

NATURAL ALTERNATIVES INTERNATIONAL, INC.,
Plaintiff-Appellant

v.

CREATIVE COMPOUNDS, LLC,
Defendant-Appellee

DOES 1-100, CORE SUPPLEMENT TECHNOLOGIES, INC., HONEY BADGER, LLC, MYOPHARMA, INC.,
Defendants

2018-1295

Appeal from the United States District Court for the Southern District of California in No. 3:16-cv-02146-H-AGS, Judge Marilyn L. Huff.

Decided: March 15, 2019

KEVIN M. BELL, Porzio, Bromberg & Newman, PC, Washington, DC, argued for plaintiff-appellant. Also represented by SCOTT A. M. CHAMBERS, BILLY DELL CHISM, CAROLINE COOK MAXWELL, RICHARD J. OPARIL; MATTHEW ZAPADKA, Bass, Berry & Sims, PLC, Washington, DC.

KEVIN JOHN O'SHEA, O'Shea Law LLC, Jackson, MO, argued for defendant-appellee.

MELISSA A. BRAND, Biotechnology Innovation Organization, Washington, DC, for amicus curiae Biotechnology Innovation Organization. Also represented by HANSJORG SAUER; BRIAN PAUL BARRETT, Eli Lilly and Company, Indianapolis, IN.

KEVIN EDWARD NOONAN, McDonnell, Boehnen, Hulbert & Berghoff, LLP, Chicago, IL, for amici curiae Christopher Michael Holman, David Lund, Adam Mossoff, Kristen J. Osenga, David O. Taylor. Also represented by AARON VINCENT GIN.

Before MOORE, REYNA, and WALLACH, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* MOORE.

Opinion concurring-in-part and dissenting-in-part filed by *Circuit Judge* REYNA.

MOORE, *Circuit Judge*.

Natural Alternatives International, Inc., appeals a decision of the U.S. District Court for the Southern District of California granting Creative Compounds, LLC's motion for judgment on the pleadings that the asserted claims of U.S. Patent Nos. 5,965,596, 7,825,084, 7,504,376, 8,993,610, 8,470,865, and RE45,947 are not patent eligible. Because Creative Compounds has failed to demonstrate under Natural Alternatives' proposed claim constructions that the claims are not patent eligible, we reverse and remand.

BACKGROUND

Natural Alternatives owns a number of patents that relate to dietary supplements containing beta-alanine and have substantially similar specifications. Beta-alanine is

an amino acid. Together with histidine, another amino acid, it can form dipeptides that are found in muscles. *E.g.*, '596 patent 1:59–64. The dipeptides are involved in the regulation of intra-cellular pH during muscle contraction and development of fatigue, and variations in dipeptide concentrations affect the anaerobic work capacity of individual athletes. *Id.* at 4:58–62, 5:1–3. One of these dipeptides is carnosine, which contributes to hydronium ion buffering. *Id.* at 2:11–13. During certain sustained exercise, hydronium ions and lactate can accumulate and severely reduce intracellular pH. *Id.* at 1:50–54. The reduced pH interferes with the creatine-phosphorylcreatine system, a part of the process by which energy is generated in cells, particularly muscle cells. *Id.* at 1:31–43, 1:54–55. The claimed patents generally relate to the use of beta-alanine in a dietary supplement to "increas[e] the anaerobic working capacity of muscle and other tissue." *Id.* at 2:16–18.

Natural Alternatives has asserted its patents in multiple suits in the Southern District of California. Creative Compounds moved for judgment on the pleadings, which the district court granted. Applying the two-part test from *Alice Corp. Party Ltd. v. CLS Bank International*, 573 U.S. 208, 217 (2014), it held all of the asserted claims were directed to patent ineligible subject matter under 35 U.S.C. § 101 and lacked an inventive concept sufficient to render them patent eligible. The district court granted judgment in favor of Creative Compounds, and Natural Alternatives timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

LEGAL STANDARDS

Section 101 of the Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

35 U.S.C. § 101. The term "process" "includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b). The Supreme Court has explained that under § 101, patent protection does not extend to the patent ineligible concepts of laws of nature, natural phenomena, and abstract ideas, which are "building blocks of human ingenuity." *Alice*, 573 U.S. at 216–17. We must therefore distinguish between claims to patent ineligible subject matter and those that "integrate the building blocks into something more." *Id.* at 217.

In doing so, we first determine whether the claims at issue are "directed to" a patent ineligible concept. *Id.* As the Supreme Court has cautioned, we must be careful in this analysis as "too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012). If we determine that the claims are directed to a patent ineligible concept, "we 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," i.e., whether there is an "inventive concept." *Alice*, 573 U.S. at 217 (*quoting Mayo*, 566 U.S. at 78–79).

Eligibility under § 101 is a question of law based on underlying facts that, ultimately, we review de novo. *SAP Am. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018). It may be resolved on a motion to dismiss where "there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law." *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018).

DISCUSSION

The district court held that the claims at issue are not patent eligible and dismissed. We review a district court's Rule 12(c) dismissal for judgment on the pleadings under the law of the regional circuit. *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1293 (Fed. Cir. 2016). The Ninth Circuit reviews a court's grant of judgment on the pleadings de novo. *Newton v. Parker Drilling Mgmt. Servs., Ltd.*, 881 F.3d 1078, 1083 (9th Cir. 2018). This analysis is "functionally identical" to the standard for deciding a motion to dismiss. *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 n.4 (9th Cir. 2011) (quoting *Dworkin v. Hustler Magazine Inc.*, 867 F.2d 1188, 1192 (9th Cir. 1989)). In doing so, the court "inquire[s] whether the complaint's factual allegations, together with all reasonable inferences, state a plausible claim for relief." *Id.* at 1055. In the Ninth Circuit, a court deciding a motion under Rule 12 may consider "material which is properly submitted as part of the complaint," including documents that are not physically attached to the complaint, if their authenticity is not contested and the complaint necessarily relies on them, and it may take judicial notice of matters of public record. *See Lee v. City of L.A.*, 250 F.3d 668, 688–89 (9th Cir. 2001).

The district court stated that in performing its eligibility analysis, it accepted Natural Alternatives' proposed claim constructions. J.A. 7 n.3. This was proper given the stage of the litigation. Applying the proposed claim constructions, we hold that the complaint's factual allegations, together with all reasonable inferences, plausibly establish the eligibility of the representative claims.[1]

---

[1] Though the dissent suggests disagreement with those constructions, we note that neither party argued for

I.

Several of the asserted patents claim methods of treatment using beta-alanine ("the Method Claims"). Claim 1 of the '596 patent and claim 1 of the '865 patent have been treated as representative of the claims in those patents. Claim 1 of the '596 patent recites:

---

a different construction on appeal. The dissent's primary criticism is that the "effective" limitation "is not disclosed in the plain language of the claims and is only present by virtue of the proposed claim construction." Dissent at 5. Respectfully, this is not factually accurate as nearly all of the claims of four of the patents at issue contain express limitations requiring effectiveness. *See* '865 patent 22:56–23:29 (all claims require the amount administered be "effective to increase beta-alanylhistidine dipeptide synthesis in the tissue"); '596 patent 14:66–15:6 (all claims require the amount administered be "effective to increase beta-alanylhistidine dipeptide synthesis in the tissue"); '084 patent 22:57–64, 23:1–24:3 (claims 13–14 and 16–18 require the claimed method "increase beta-alanylhistidine dipeptide synthesis in a tissue" and "the anaerobic working capacity of the tissue is increased"); '610 patent 22:24–23:5 (all claims require the supplement "increase[] beta-alanyl histidine levels in muscle tissue sufficient to delay the onset of fatigue in the human"). The dissent also suggests the "dietary supplement" limitation may not be a limitation because it only appears in the preamble of the claims. Dissent at 6. Again, that is not correct with regard to the claims at issue, many of which expressly include the dietary supplement limitation in the body. *See* '865 patent 22:56–23:29 (all claims); '610 patent 22:24–23:5 (all claims). In other claims, the "dietary supplement" language in the preamble provides a clear antecedent basis for language in the body of the claims. *See* '084 patent 22:25–38 (claims 1–4).

> 1. A method of regulating hydronium ion concentrations in a human tissue comprising:
>
> providing an amount of beta-alanine to blood or blood plasma *effective to increase beta-alanylhistidine dipeptide synthesis in the human tissue*; and
>
> exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the human tissue.

Claim 1 of the '865 patent recites:

> 1. A method of increasing anaerobic working capacity in a human subject, the method comprising:
>
> a) providing to the human subject an amount of an amino acid to blood or blood plasma *effective to increase beta-alanylhistidine dipeptide synthesis* in the tissue, wherein said amino acid is at least one of:
>
> > i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
> >
> > ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or
> >
> > iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; and
>
> b) exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the tissue,
>
> wherein the amino acid is provided through a *dietary supplement*.

Natural Alternatives' proposed construction of the "effective" limitations is to "elevates beta-alanine above natural

levels to cause an increase in the synthesis of beta-alanyl-histidine dipeptide in the tissue." J.A. 579–81. It defines "dietary supplement" as "an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance when administered to the human over a period of time." J.A. 581. It also defines "increasing anaerobic working capacity" as "increasing the amount of work performed by a muscle under lactate producing conditions." J.A. 580.

The district court held both claims are directed to natural laws. It held claim 1 of the '865 patent is directed to the natural law that "ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentration in human tissue and, thereby, increase the anaerobic working capacity in a human." J.A. 22. It held claim 1 of the '596 patent is directed to the natural law that "ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentration in human tissue and, thereby, aid in regulating hydronium ion concentration in the tissue." J.A. 21. We do not agree.

Administering certain quantities of beta-alanine to a human subject alters that subject's natural state. Specifically, homeostasis is overcome, and the subject's body will produce greater levels of creatine. *See* '596 patent 5:27–35. This, in turn, results in specific physiological benefits for athletes engaged in certain intensive exercise. *See* '596 patent 5:21–23. The claims not only embody this discovery, they require that an infringer actually administer the dosage form claimed in the manner claimed, altering the athlete's physiology to provide the described benefits. These are treatment claims and as such they are patent eligible.

As we explained in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1134–36 (Fed. Cir. 2018), claims that are directed to particular methods of treatment are patent eligible. The claims in *Vanda* involved a method of treating patients

with schizophrenia that first required performing a genetic test to determine if a patient was a CYPD2D6 performer. *Id.* at 1121. Based on the results of that test, a particular dose of iloperidone was selected and internally administered. *Id.* As a result, the risk of QTc prolongation, a dangerous side effect, was decreased. *Id.* at 1121 & n.2. We held that the claims were not directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation. *Id.* at 1134. While we acknowledged that the inventors had recognized the underlying relationships, we explained that those were not what was claimed. *Id.* at 1135. Instead, the claims were directed to a patent-eligible method of using iloperidone to treat schizophrenia, "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Id.* at 1136.

Unlike the claims held ineligible in *Mayo*, which required only the observation of a natural law, the *Vanda* claims required a doctor to affirmatively administer a drug to alter a patient's condition from their natural state. *Id.* at 1135. In *Mayo*, the discovery underlying the claims was that when blood levels were above a certain level harmful effects were more likely and when they were below another level the drug's beneficial effects were lost. Nothing in the claim required any application of that discovery beyond the "steps that must be taken in order to apply the laws in question." *Mayo*, 566 U.S. at 82. The claims at issue in *Mayo* involved administering a prior art drug to a subject and determining the level of drug metabolite in that subject. *Id.* at 74–75. The claims further provided that particular levels of measured metabolite indicated a need to increase or decrease the amount of drug subsequently administered to the subject. *Id.* at 75. The claims did not, however, require any actual action be taken based on the measured level of metabolite. *Id.* at 75–76. The claim, therefore, "was not a treatment claim," because "it was 'not limited to instances in which the doctor actually decreases

(or increases) the dosage level.'" *Vanda*, 887 F.3d at 1136 (quoting *Mayo*, 566 U.S. at 76). This was expressly recognized in *Mayo*, which distinguished the *Mayo* claim from "a typical patent on a new drug or *a new way of using an existing drug*," because the *Mayo* claim did not "confine [its] reach to particular applications" of the natural laws relied upon. 566 U.S. at 87 (emphasis added). Such claims rely on the relationship between the administration of the drug and the physiological effects in the patient. The fact that the human body responds to the treatment through biochemical processes does not convert the claim into an ineligible one. As we explained in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1049 (Fed. Cir. 2016), the "natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability."

The Method Claims are directed to patent eligible new ways of using an existing product, beta-alanine, they are treatment claims. This falls clearly within the scope of § 101, which allows for patents on "any new and useful process," including "a new use of a known . . . composition of matter, or material." 35 U.S.C. §§ 100(b), 101. As the Supreme Court explained in *Mayo*, such patents on a new use of an existing drug are "typical." 566 U.S. at 87.

While the Method Claims have similarities to the claims found ineligible in *Mayo,* as they utilize an underlying natural law, this is not sufficient to establish that they are directed to that law. In *Mayo*, the Court held the claims did not do significantly more than simply describe the natural "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id.* at 77. The Method Claims similarly rely on the relationships between the administration of beta-alanine and beta-alanylhistidine dipeptide synthesis, but under Natural Alternatives' constructions, the Method Claims require specific steps be taken in order to bring about a change in a

subject, altering the subject's natural state. Unlike the claims in *Mayo*, the Method Claims at issue are treatment claims.

Like the claims in *Vanda*, the Method Claims contain specific elements that clearly establish they are doing more than simply reciting a natural law. Like the *Vanda* claims, which specify a patient population to be treated, the Method Claims specify particular results to be obtained by practicing the method. Claim 1 of the '596 patent is directed to a "method of regulating hydronium ion concentrations in a human tissue," and claim 1 of the '865 patent is directed to a "method of increasing anaerobic working capacity in a human subject." Similarly, both the *Vanda* claims and the Method Claims specify a compound to be administered to achieve the claimed result. Claim 1 of the '596 patent achieves the result through the administration of the specific compound beta-alanine, and claim 1 of the '865 patent requires use of one of the three specified forms of beta-alanine. The claims in *Vanda* further specified the dosages of the compound to be administered. The Method Claims likewise contain a dosage limitation by virtue of the "effective" limitation. As we looked to the specification in *Vanda* to determine the significance of the dosing ranges, 887 F.3d at 1135, here, the specification provides a method for calculating dosage based on a subject's weight, '596 patent 5:48–50. This goes far beyond merely stating a law of nature, and instead sets forth a particular method of treatment.

Similarly, the fact that the active ingredient in the supplement is a molecule that occurs in nature and is consumed as part of the human diet also does not alter our analysis.[2] Creative Compounds argues that, if it were discovered that beta-alanine or another natural compound

---

[2] The U.S. Patent and Trademark Office has adopted

can be used to treat or cure Alzheimer's or some other disease, the method for doing so would not be patent eligible. Appellee Br. 28–29; Oral Arg. at 15:10–35. That is not the case before us. That flies in the face of the Patent Act, which expressly permits patenting a new use of an existing product. 35 U.S.C. §§ 100(b), 101. The Supreme Court has also rejected the idea that claims to methods making use of natural products are equivalent to claims to the natural products themselves. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013) (distinguishing between method claims for manipulating genes and claims to the genes); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims."). Moreover, while beta-alanine may exist in nature, Natural Alternatives has argued that the quantities being administered do not, and that the claimed consumption greatly exceeds natural levels. *See* J.A. 580–81 (providing a construction of the "effective" limitation in each of the Method Claims to mean

---

guidance on how examiners should determine whether a claim is eligible under § 101 and provided examples of eligible and ineligible claims. Under these guidelines, a claim to a practical application of a natural product to treat a particular disease is patent eligible. The parties dispute the persuasiveness of this document and the weight we should afford it under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The issue before us is a matter of law and the result is clear, thus this is not a case in which *Skidmore* deference would affect the outcome.

"elevates beta-alanine *above natural levels* to cause an increase in the synthesis of beta-alanylhistidine in the tissue" (emphasis added)).[3]

The Method Claims at issue are treatment claims. They cover using a natural product in unnatural quantities to alter a patient's natural state, to treat a patient with specific dosages outlined in the patents. We hold, therefore, that the Method Claims are not directed to ineligible subject matter.

Moreover, at step two, factual impediments exist to resolving the case at this stage. Claim 1 of the '865 patent requires "the amino acid is provided through a dietary supplement," with the dietary supplement limitation construed as "an addition to the human diet, which is not a natural or *conventional* food." J.A. 581 (emphasis added). Creative Compounds argues that the "inventors admitted in the '865 patent, and all of the patents-on-appeal, that placing a natural substance into a dietary supplement for administration to a human, in order to increase the function of tissues is a conventional, well-known activity." Appellee Br. 37 (citing '865 patent 1:41–44). The language it cites, however, does not stand for that proposition. Instead, the patent states "[n]atural food supplements are typically designed to compensate for reduced levels of nutrients in the modern human and animal diet. In particular, useful supplements increase the function of tissues when consumed." '865 patent 1:41–44. At most, this language shows that the prior art contained food supplements containing natural products, and typically those were used to compensate for reduced levels of nutrients. It does not establish that the dietary supplement in the claims, which

---

[3] Indeed, the record contains an expert declaration stating that "one 3.2 gram daily supplement of beta-alanine is the equivalent to eating at least 109 Big Macs per day." J.A. 914.

provides a dose well in excess of the normal levels of beta-alanine, would have been well-understood, routine, and conventional. While a fact-finder may ultimately determine that the dietary supplement limitation was well-understood, routine, and conventional, absent a clear statement to that effect in the specification, complaint, or other material properly before the court, when disputed such a determination may not be made on a motion for judgment on the pleadings.

Under Natural Alternatives' proposed claim constructions, the Method Claims are not directed to an exception to § 101 under the first step of the *Alice* test. Therefore, judgment on the pleadings was inappropriate.

II.

The district court also considered the patent eligibility of a number of claims to dietary supplements ("the Product Claims"). The parties and the district court treated claim 6 of the '376 patent and claim 1 of the '084 patent as representative of the claims in those patents. Claim 6 of the '376 patent depends on claims 1 and 5. In its opinion, the district court also held representative claim 34 of the '947 patent ineligible. Representative claim 34 of the '947 patent recites:

> 34. A human dietary supplement for increasing human muscle tissue strength comprising a mixture of creatine, a carbohydrate and free amino acid beta-alanine that is not part of a dipeptide, polypeptide or an oligopeptide, wherein the human dietary supplement does not contain a free amino acid L-histidine, wherein the free amino acid beta-alanine is in an amount that is from 0.4 g to 16.0 g per daily dose, wherein the amount increases the muscle tissue strength in the human, and wherein the human dietary supplement is formulated for one or more doses per day for at least 14 days.

Although Natural Alternatives argued that claim 34 is eligible as it is a treatment claim with a very specific dosing regimen contained within the claim itself, at oral argument Natural Alternatives acknowledged that this patent was not asserted against Creative Compounds. Oral Arg. 0:52–1:20. Though rendered ineligible in the same district court opinion as the other patents at issue in this appeal, the '947 patent was not asserted against Creative Compounds.[4] Claims not asserted in this litigation against this appellee, Creative Compounds, are not properly before this court in this appeal. This does not prejudice the patentee's ability to defend the eligibility of the '947 patent in future proceedings.

Turning to the Product Claims before us, claim 6 of the '376 patent depends on claims 1 and 5.

> 1. A composition, comprising:
>
> *glycine*; and
>
> > a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine, or
> >
> > b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide.
>
> 5. The composition of claim 1, wherein the composition is a dietary supplement or a sports drink.

---

[4] The '947 patent was asserted in a related litigation against Hi-Tech Pharmaceuticals, Inc. At the time of oral argument, that case was stayed. That case against that defendant is not part of the present appeal.

> 6. The composition of claim 5, wherein the *dietary supplement* or sports drink is a supplement for humans.

Claim 1 of the '084 patent recites:

> 1. A human *dietary supplement*, comprising a beta-alanine in a unit dosage of between about *0.4 grams to 16 grams*, wherein the supplement provides a unit dosage of beta-alanine.

Natural Alternatives proposed construing "dietary supplement" in the '376 patent and "human dietary supplement" in the '084 patent to mean "an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance and is manufactured to be used over a period of time." J.A. 572, 574.

The district court held that the Product Claims are directed to ineligible subject matter. It held claim 6 of the '376 patent is directed to the natural phenomena of beta-alanine and glycine and claim 1 of the '084 patent is directed to the natural phenomenon of beta-alanine. We do not agree.

Although beta-alanine is a natural product, the Product Claims are not directed to beta-alanine. A claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and "the potential for significant utility." *See Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). Just as the Method Claims are directed to specific methods of treatment that employ a natural law, the Product Claims are directed to specific treatment formulations that incorporate natural products, but they have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot.

In the Product Claims, beta-alanine and glycine are incorporated into particular dosage forms. Claim 6 of the '376 patent is directed to a "dietary supplement or sports

drink" that uses a combination of glycine and one of the specified forms of beta-alanine. Under Natural Alternatives' claim constructions, the quantity of beta-alanine must be sufficient to "effectively increase[] athletic performance," and the specification provides a method for determining such an amount. Similarly, the "dietary supplement" in claim 1 of the '084 patent uses the product beta-alanine at a dosage of "between about 0.4 grams to 16 grams" to "effectively increase[] athletic performance." In each case, the natural products have been isolated and then incorporated into a dosage form with particular characteristics. At this stage in the litigation, it has been sufficiently alleged that these characteristics provide significant utility, as the claimed dosage forms can be used to increase athletic performance in a way that naturally occurring beta-alanine cannot. Accordingly, neither claim is directed to ineligible subject matter.

Moreover, even though claim 6 contains a combination of glycine and beta-alanine, both of which are natural products, that is not necessarily sufficient to establish that the claimed combination is "directed to" ineligible subject matter. The Court's decision in *Funk Brothers* does not stand for the proposition that any combination of ineligible subject matter is itself ineligible. In *Funk Brothers*, the Court held that claims to a mixture of two naturally occurring bacteria were not patent eligible where each bacteria species in the claimed combination "ha[d] the same effect it always had," and the "combination of species produce[d] . . . no enlargement of the range of their utility." 333 U.S. at 131. The combination of the bacteria into the same package did "not improve in any way their natural function." *Id.* Here, as Creative Compounds' counsel acknowledged at oral argument, the record indicates that the claimed combination of glycine and beta-alanine could have synergistic effects allowing for outcomes that the individual components could not have. Oral Arg. 24:45–51, 28:00–29:30.

Given that this is the pleading stage, we would have to accept this statement as true even if it were just an allegation in the pleadings. Instead, what we have goes far beyond that, including a statement in an article attached to an expert report explaining that "one of insulin's effects is to increase amino acid (such as beta-alanine) into our cells," J.A. 1063, a statement in the specification that "[i]t may be that glycine enhances insulin sensitivity," '376 patent at 6:3–5, and an expert declaration explaining that direct supplementation of a different amino acid had no effect unless "co-supplemented with glucose or other compounds increasing the concentration of insulin in circulation," J.A. 1132. All of these suggest that when combined the beta-alanine and glycine have effects that are greater than the sum of the parts. At a minimum, there are sufficient factual allegations to render judgment on the pleadings inappropriate. Accordingly, given the factual allegations, these claims would still survive a motion for judgment on the pleadings at the first step of the *Alice* test.

Finally, even if the Product Claims were directed to ineligible subject matter, judgment on the pleadings would still be inappropriate under step two. Like claim 1 of the '865 patent, the Product Claims contain a dietary supplement limitation, with the same proposed construction. *See* J.A. 572, 574. As we explained with regard to the Method Claims, the specification does not contain language supporting the idea that this limitation was well-understood, routine, and conventional. The language in the specification does not support this proposition, and patentee's claim construction contradicts Creative Compounds' position, so such a determination may not be made on a motion for judgment on the pleadings.

III.

The parties and the district court have treated claim 1 of the '610 patent as representative of the claims in that patent ("the Manufacturing Claims"). It recites:

> 1. Use of beta-alanine in manufacturing a human dietary supplement for oral consumption;
>
> supplying the beta-alanine, which is not part of a dipeptide, polypeptide or oligopeptide, as a single ingredient in a manufacturing step of the human *dietary supplement* or
>
> mixing the beta-alanine, which is not part of a dipeptide, polypeptide or oligopeptide, in combination with at least one other ingredient for the manufacture of the human *dietary supplement*,
>
> whereby the manufactured human dietary supplement is for oral consumption of the human dietary supplement in doses over a period of time increases beta-alanyl histidine levels in muscle tissue sufficient to delay the onset of fatigue in the human.

Natural Alternatives proposed construing "[u]se of beta-alanine in manufacturing a human dietary supplement" to mean "making an addition to the human diet using beta-alanine, which is not a natural or conventional food, to be administered over a period of time and that effectively increases athletic performance." J.A. 574. It proposed construing "supplying the beta-alanine, which is not part of a dipeptide, polypeptide or oligopeptide, as a single ingredient in a manufacturing step of the human dietary supplement" to mean "providing the free amino acid beta-alanine, an ester of beta-alanine or an amide of beta-alanine in a step of making an addition to the human diet using beta-alanine as the only active ingredient, which is not a natural or conventional food, which effectively increases athletic performance when administered to a human over a period of time." J.A. 575. It proposed construing "mixing the beta-alanine, which is not part of a dipeptide, polypeptide or oligopeptide, in combination with at least one other ingredient for the manufacture of the human dietary supplement" to mean "making an addition to the human diet,

which is not a natural or conventional food, and which effectively increases athletic performance when administered to a human over a period of time, using the free amino acid beta-alanine, an ester of beta-alanine or an amide of beta-alanine and at least one other ingredient." J.A. 575.

The district court held claim 1 of the '610 patent is directed to "the natural phenomenon beta alanine and the natural law that ingesting certain levels of beta-alanine will increase the carnosine concentration in human tissue." J.A. 24. We do not agree. The Manufacturing Claims are not directed to the natural law or product of nature, but instead are an application of the law and new use of that product. Claim 1 of the '610 patent is even further removed from the natural law and product of nature at issue in the Method Claims and Product Claims, respectively. It is directed to the manufacture of a human dietary supplement with certain characteristics. The supplement is not a product of nature and the use of the supplement to achieve a given result is not directed to a law of nature. We do not see, therefore, how a claim to the manufacture of a non-natural supplement would be directed to the law of nature or natural product.

CONCLUSION

The claims at issue are not directed to ineligible subject matter under step one of the *Alice* test. We live in the natural world, and all inventions are constrained by the laws of nature. As the Supreme Court has warned, we must be careful not to overly abstract claims when performing the *Alice* analysis. For the foregoing reasons, we reverse the district court's decision that the claims are directed to ineligible subject matter, and we remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED

United States Court of Appeals for the Federal Circuit

NATURAL ALTERNATIVES INTERNATIONAL, INC.,
Plaintiff-Appellant

v.

CREATIVE COMPOUNDS, LLC,
Defendant-Appellee

DOES 1-100, CORE SUPPLEMENT TECHNOLOGIES, INC., HONEY BADGER, LLC, MYOPHARMA, INC.,
Defendants

2018-1295

Appeal from the United States District Court for the Southern District of California in No. 3:16-cv-02146-H-AGS, Judge Marilyn L. Huff.

REYNA, *Circuit Judge*, concurring-in-part, dissenting-in-part.

The majority reverses the district court's grant of Creative Compounds' motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), which alleged that the asserted patents claim patent ineligible subject matter under 35 U.S.C. § 101, and remands the case for further proceedings. I dissent from my colleagues' broad

stroke of eligibility, primarily because I conclude that the majority's § 101 analysis relies on an erroneous claim construction. I concur, however, in the result reached by the majority to remand for further proceedings, which I expect permits the district court to revisit the § 101 question under a proper claim construction.[1]

DISCUSSION

In construing claims, we give words the ordinary and customary meaning that the term would have to a person of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). In some cases, the ordinary meaning "may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. This is such a case. For example, applying ordinary and customary meaning to the terms of claim 1 of the '084 patent, I would conclude as a matter of law that the claim is ineligible under § 101.

Claim 1 of the '084 patent recites:

> 1. A human dietary supplement, comprising a beta-alanine in a unit dosage of between about 0.4 grams to 16 grams, wherein the supplement provides a unit dosage of beta-alanine.

---

[1] *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362–63 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it. Because we determine that the district court is in the best position to determine the proper construction of this claim term in the first instance, we remand for further proceedings consistent with this opinion.").

'084 patent col. 22 ll. 26–29. Claim 1 is directed to what is undisputedly a naturally occurring substance, beta-alanine. *See id.*; Appellant Br. 4. This natural substance is applied by wholly conventional and natural means, adding it to a human's diet. Claim 1 discloses nothing else. In particular, the claim discloses no basis to argue that the claimed beta-alanine is transformed into something other than beta-alanine. Claim 1, therefore, recites patent ineligible subject matter.

The majority concludes that claim 1 is patent eligible. My main concern with its analysis is that it relies on a claim construction that improperly imports limitations into the claims and is contradicted by the written description. This may be an unavoidable result given the lack of claim construction in this case.

Natural Alternatives argued that the district court should construe the claims before resolving the motion for judgment on the pleadings. Creative Compounds asserted that, for purposes of the motion, the claims were ineligible both under its proposed construction and Natural Alternatives' proposed construction.

The district court did not construe the claims, nor did it conclusively adopt either party's proposed claim construction. Instead, the court determined that, for purposes of the motion, it would review the claims under Natural Alternatives' proposed claim construction, an approach that, in the district court's view, would obviate the need to defer deciding the motion until after it conducted claim construction.[2]

---

[2] The majority points out that neither party argued for a different construction on appeal. But I believe that is only a reflection of the procedural posture of this case. This appeal concerns the district court's grant of a Rule 12(c) motion, where the court adopted Natural Alternatives'

On appeal, Natural Alternatives argues that the district court ignored its proposed claim construction. Appellant Br. 19–20. Natural Alternatives asserts that we should adopt its proposed construction and "remand the case back to the District Court to engage in the proper procedure directed by *Markman*." Appellant Br. 2.

As to claim 1 of the '084 patent, Natural Alternatives proposed the following claim construction to the district court:

> (1) "*human dietary supplement*" be construed as "an addition to the human diet, ingested as a pill, capsule, powder or liquid, which is not a natural or conventional food, meat or food flavoring or extract, or pharmaceutical product which effectively increases the function of a tissue when administered to the human over a period of time" J.A. 14 n.8.
>
> (2) "*dietary supplement*" be construed as "an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance and is manufactured to be used over a period of time." J.A. 14 n.8.

Creative Compounds proposed that "dietary supplement" be construed as:

> "An ingredient such as a vitamin, mineral, herb, amino acid, concentrate, or extract intended for ingestion, which adds further nutritional value to the diet by increasing tissue function." J.A. 586.

---

proposed construction to evaluate patent eligibility in plaintiff's favor. Because of that, the appeal was premised under Natural Alternatives' construction. On remand, however, I do not read the majority's decision as one that precludes claim construction.

I find that Natural Alternatives' construction of "human dietary supplement" and "dietary supplement" improperly imports limitations into the claims, incorporates a definition that is contrary to the plain meaning of the terms, and is flawed because it is contradicted by the written description.

For example, the construction imports the limitation that beta-alanine "effectively increases the function of a tissue when administered to the human over a period of time."[3] This limitation is not disclosed in the plain language of the claims and is only present by virtue of the proposed claim construction.[4]

---

[3] Likewise, for claim 6 of the '376 patent, the added limitation is that it "effectively increases athletic performance when administered to the human over a period of time."

[4] The majority states that it is not accurate to criticize the claims on the basis that the "effective" limitation does not appear in the plain language of the claims. I disagree. First, while some of the asserted claims use the word "effective," not all do. Claim 1 of the '084 patent is independent and does not include any reference to effectiveness. The majority's citations to other claims within the '084 patent do not detract from my basic point that "dietary supplement" or "human dietary supplement" do not, alone, import an effectiveness component as the proposed construction requires. Likewise, none of the asserted claims of the '376 patent include any reference to effectiveness. Second, if "dietary supplement," as a term, included an effectiveness component, this would undermine the necessity for claim 1 of the '865 patent to use the term "effective." In other words, the fact that some claims use "effective" to reflect that limitation undercuts a construction that such limitation exists within the definition of "dietary supplement" or "human dietary supplement." Lastly,

Natural Alternatives' proposed construction are also contradicted by the written description. For example, the proposed construction of "human dietary supplement" limits the claim in the '084 patent to dietary supplements that are: (1) ingested in pill, capsule, powder, or liquid form; (2) not meat or food flavoring or extract, or a pharmaceutical product; (3) effective to increase the function of tissues over time; and (4) not natural or conventional food. Appellant Br. 20; J.A. 14 n.8. Yet the specification notes that "[t]he compositions of the invention can be used for the preparation of a dietary supplement (including, e.g., drinks, gels, foods) or pharmaceutical compositions for humans or animals." '084 patent col. 5 ll. 13–16. On the one hand, the construction excludes pharmaceutical products and foods, while on the other hand, the specification expressly includes foods within the definition of "dietary supplement" and expands the scope of the invention to include "pharmaceutical compositions" for humans or animals.

Interestingly, the District of Delaware, in evaluating a related patent, declined to construe "dietary supplement," holding that the term was not a limitation. *Natural Alternatives Int'l Inc. v. Vital Pharm. Inc.*, No. 1:09-CV-00626, Dkt. No. 125 at 2 (D. Del. May 31, 2011) ("*Delaware Order*"). The court noted that "dietary supplement" appeared only in the preamble of the claims and that the specifications did not demonstrate that the term was a necessary aspect of the invention.[5] *Id.*

---

even for the claims that use "effective," that limitation still depends on Natural Alternatives' proposed claim construction of "effective" as "elevat[ing] beta-alanine *above natural levels* to cause an increase in the synthesis of beta-alanyl-histidine dipeptide in the tissue." J.A. 579–81 (emphasis added).

[5] The majority contends that, through this citation, I am incorrectly suggesting that "dietary supplement" may

Natural Alternatives' construction also defines "human dietary supplement" to "effectively increase[]" the function of a tissue over time.[6] J.A. 14 n.8. This definition is

---

not be a limitation. To be clear, that is what the District of Delaware held, and I raise that holding to underscore the complexities about the proposed construction, particularly because one of the patents at issue in the Delaware case (U.S. Patent. No. 6,426,361) had similar claims as those here. For example, claims 1 and 5 of the '361 patent recite:

> 1. A composition comprising a mixture of a creatine and a composition comprising an amino acid or an active derivative thereof selected from the group consisting of a beta-alanine, an ester of a beta-alanine and an amide of a beta-alanine.
>
> . . . .
>
> 5. A dietary supplement comprising a mixture of a creatine and a composition comprising an amino acid or an active derivative thereof selected from the group consisting of a beta-alanine, an ester of a beta-alanine and an amide of a beta-alanine.

'361 patent col. 15 ll. 17–21, 30–34. In concluding that "dietary supplement" was not a limitation, the court pointed out that "the specification simply notes that the claimed 'composition *can be* a dietary supplement.'" *Delaware Order* at 2 (citing '361 patent col. 3 l. 41 (emphasis in original)). The claims implicated in this case are similar to those in the *Delaware Order*, and the written descriptions likewise include this permissive—yet non-restrictive—language. *E.g.*, '569 patent col. 3 l. 32; '376 patent col. 6 l. 48; '084 patent col. 6 l. 52; '865 patent col. 6 l. 53; '610 patent col. 6 l. 54.

[6] For the '376 patent the construction defines "dietary supplement" to effectively increase athletic performance. J.A. 14 n.8.

contrary to the plain meaning of the term: "a product taken orally that contains one or more ingredients which are intended to supplement one's diet and are not considered food."[7] Nor is this a case where the patentee has acted as its own lexicographer. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). To do so, "a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Nowhere does the patentee set forth such a definition.[8]

This court is hesitant to construe claims for the first time on appeal. *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1368 (Fed. Cir. 2012). This tendency reflects a concern to avoid conflating de novo review with

---

[7] *Dietary supplement*, Merriam-Webster Unabridged, http://unabridged.merriam-webster.com/unabridged/dietarysupplement; *see also Phillips*, 415 F.3d at 1314 (general purpose dictionaries are helpful when construction involves widely accepted meaning of commonly understood words); *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334–35 (Fed. Cir. 2000) ("Without evidence in the patent specification of an express intent to impart an innovative meaning to a claim term, the term takes on its ordinary meaning. For such ordinary meaning, we turn to the dictionary definition of the term." (internal citations omitted)).

[8] Notably, the definitions of "dietary supplement" set out by the Food and Drug Administration, J.A. 590, and the Dietary Supplement Health and Education Act, 21 U.S.C. § 321(ff), also do not reflect a functional/effectiveness component within the meaning of the term. That is, these definitions do not support a finding that the effective increase of athletic performance or tissue function is embedded within the meaning of "dietary supplement."

an independent analysis in the first instance. *See Wavetronix LLC v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1355 (Fed. Cir. 2009) (noting this court's review of claim construction without deference is not an independent analysis in the first instance (citing *Nazomi Commc'ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1371 (Fed. Cir. 2005))). Construing claims on appeal, however, is proper under limited circumstances, particularly when the record is sufficiently developed to enable construction. *See e.g., Meyer*, 690 F.3d at 1369; *Wavetronix*, 573 F.3d at 1355. I do not see such a record in this case. Apparently, the majority agrees because it too did not construe the claims, but rather choose to rely on the construction proposed by Natural Alternatives.

If anything, this appeal was pre-ordained to result in a remand. The district court decided the Rule 12(c) motion at the pleading stage while acknowledging that it could defer its decision until after it conducted claim construction. On appeal, Natural Alternatives argues that the district court erred when it decided not to conduct claim construction before deciding the motion. The majority remands to the district court for further proceedings, which I take to mean could include a formal claim construction and a potential revisit of the § 101 issue.

I would remand because I believe the district court and the majority relied on an erroneous claim construction. So, the question is whether anything meaningful has been achieved in these circumstances. This case, and the general development of the law concerning § 101 analysis at the pleading stage, causes me to ask whether the time has come for this court to reconsider whether a Rule 12(c) motion based on § 101 should be decided before claim construction. *See Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012) ("[I]t will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full

understanding of the basic character of the claimed subject matter."); *see e.g., Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, 66 F. Supp. 3d 829, 835 (E.D. Tex. 2014) (Bryson, J.) ("[T]he Court has waited until after the claim construction hearing in this case to rule on the [Rule 12(c) motion] in order to ensure that there are no issues of claim construction that would affect the Court's legal analysis of the patentability issue."); *Presqriber, LLC v. AO Capital Partners LLC*, No. 6:14-CV-440, 2015 WL 11578559, at *6 (E.D. Tex. Mar. 31, 2015) (denying Rule 12(b)(6) motion without prejudice to conduct claim construction and obtain a full understanding of the claimed invention relevant to a § 101 analysis).

CONCLUSION

On the basis set forth above, I concur-in-part and dissent-in-part.