

2018-1295

**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.

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

BRIEF OF DEFENDANT-APPELLEE

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CERTIFICATE OF INTEREST

Counsel for Appellee Creative Compounds, LLC certifies that:

1. The full name of every party or amicus represented by us is:

Creative Compounds, LLC

2. The name of the real party in interest represented by us is:

Creative Compounds, LLC

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus represented by us:

Sterling International Enterprises LLC, a West Indies Limited Liability Corporation, is the sole member of Creative Compounds, LLC

4. The names of all law firms and the parties or associates that appeared for the party or amicus now represented by us in the trial court or agency or are expected to appear in this Court are:

OShea Law LLC: Kevin J. O'Shea

Nolte Law Firm: Nelson Nolte

Buche & Associates, P.C.: John K. Buche

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are:

Natural Alternatives Int'l, Inc. v. Hi-Tech Pharma., Inc. d/b/a ALR Indus., et al., Case No. 3:16-cv-02343-H-AGS, pending in the United States District Court for the Southern District of California

Date: June 22, 2018

/s/ Kevin J. O'Shea

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TABLE OF CONTENTS

	Page
CERTIFICATE OF INTEREST	i
TABLE OF AUTHORITIES	v
STATEMENT OF RELATED CASES	1
STATEMENT OF THE ISSUE	2
STATEMENT OF THE CASE	2
I. THE ASSERTED CLAIMS RECITE NATURALLY OCCURRING BETA-ALANINE AND CONVENTIONAL ELEMENTS SUCH AS A DIETARY SUPPLEMENT, AND SUPPLYING AND MIXING COMPONENTS	2
II. THE DISTRICT COURT RELIED ON THE CLAIM LANGUAGE AND THE PATENTS' DISCLOSURES TO FIND THE ASSERTED CLAIMS INVALID PURSUANT TO 35 U.S.C. § 101	4
A. The District Court Found Claim 1 Of The '084 Patent Invalid Pursuant To 35 U.S.C. § 101	7
B. The District Court Found Claim 6 Of The '376 Patent Invalid Pursuant To 35 U.S.C. § 101	9
C. The District Court Found Claim 1 Of The '596 Patent Invalid Pursuant To 35 U.S.C. § 101	10
D. The District Court Found Claim 1 Of The '865 Patent Invalid Pursuant To 35 U.S.C. § 101	11
E. The District Court Found Claim 1 Of The '610 Patent Invalid Pursuant To 35 U.S.C. § 101	12
SUMMARY OF THE ARGUMENT	14
ARGUMENT	15
I. STANDARD OF REVIEW	15

II. THE DISTRICT COURT ADOPTED NAI'S PROPOSED CLAIM CONSTRUCTION AND CORRECTLY HELD THE ASSERTED CLAIMS INVALID UNDER 35 U.S.C. § 101 FOR FAILING TO CLAIM PATENTABLE SUBJECT MATTER.....	15
III. THE ASSERTED CLAIMS SATISFY BOTH STEPS OF THE <i>ALICE</i> TEST AND ARE INVALID PURSUANT TO 35 U.S.C. § 101	18
A. The Asserted Claims Are Directed To Naturally Occurring Beta-Alanine	20
B. There Are No Elements In The Asserted Claims Sufficient To Transform The Claimed Naturally Occurring Phenomenon Into Patent Eligible Subject Matter	22
C. Creative Was Not Required To Submit Scientific Evidence Responding To NAI's Evidence Of The Inventors' Discovery Of A Mammal's Natural Response To Large Doses Of Beta-Alanine	24
D. The District Court Properly Analyzed The Elements Of The Asserted Claims Both Individually And Collectively And Correctly Concluded That The Asserted Claims Are Invalid Pursuant To 35 U.S.C. § 101	26
E. The '596 Patent Claims Do Not Recite Patent Eligible Subject Matter	31
F. The '376 Patent Claims Do Not Recite Patent Eligible Subject Matter	33
G. The '084 Patent Claims Do Not Recite Patent Eligible Subject Matter	35
H. The '865 Patent Claims Do Not Recite Patent Eligible Subject Matter	36
I. The '610 Patent Claims Do Not Recite Patent Eligible Subject Matter	40

IV. THE PTO GUIDANCE CITED BY NAI IS NEITHER BINDING NOR PERSUASIVE AND DOES NOT DESERVE <i>SKIDMORE</i> DEFERENCE IN THIS CONTEXT	42
V. THERE IS NO EXEMPTION IN THE PATENT LAWS FOR ANY INDUSTRY OR COMMERCIAL SECTOR.....	44
CONCLUSION.....	45

TABLE OF AUTHORITIES

Cases

<i>Affinity Labs of Texas, LLC v. DIRECTV, LLC</i> , 838 F.3d 1253 (Fed. Cir. 2016)	6, 24
<i>Alice Corp. Pty. v. CLS Bank Int'l</i> , 573 U.S. ---, 134 S. Ct. 2347 (2014).....	passim
<i>Apple, Inc. v. Ameranth, Inc.</i> , 842 F.3d 1229 (Fed. Cir. 2016)	5
<i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i> , 788 F.3d 1371 (Fed. Cir. 2015)	passim
<i>Association for Molecular Pathology v. Myriad Genetics, Inc.</i> , 569 U.S. 576 (2013).....	passim
<i>Bancorp Servs., L.L.C. v Sun Life Assurance Co. of Canada (U.S.)</i> , 687 F.3d 1266 (Fed. Cir. 2012)	17
<i>Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC</i> , 827 F.3d 1341 (Fed. Cir. 2016)	27, 31
<i>Baylor Cty. Hosp. Dist. v. Price</i> , 850 F.3d 251 (5th Cir. 2017)	46
<i>Cleveland Clinic Found. v. True Health Diagnostics LLC</i> , 859 F.3d 1352 (Fed. Cir. 2017)	passim
<i>Content Extraction & Transmission LLC v. Wells Fargo Bank</i> , 776 F.3d 1343 (Fed. Cir. 2014)	22
<i>Enfish, LLC v. Microsoft Corp.</i> , 822 F3d 1327 (Fed. Cir. 2016)	20, 21
<i>Fair Warning IP, LLC v. Iatric Sys., Inc.</i> , 839 F.3d 1089 (Fed. Cir. 2016)	7, 23
<i>Funk Bros. Seed Co. v. Kalo Inoculant Co.</i> , 333 U.S. 127 (1948).....	passim
<i>Genetic Techs. Ltd. v. Merial L.L.C.</i> , 818 F.3d 1369 (Fed. Cir. 2016)	passim
<i>In re Fisher</i> , 421 F.3d 1365 (Fed. Cir. 2005)	46

<i>In re Smith,</i> 815 F.3d 816 (Fed. Cir. 2016)	46
<i>Intellectual Ventures I LLC v. Erie Indem. Co.,</i> 850 F.3d 1315 (Fed. Cir. 2017)	16
<i>Intellectual Ventures I LLC v. Symantec Corp.,</i> 838 F.3d 1307 (Fed. Cir. 2016)	7, 25, 45
<i>Internet Patents Corp. v. Active Network, Inc.,</i> 790 F.3d 1343 (Fed. Cir. 2015)	22
<i>LeRoy v. Tatham,</i> 14 How. 156, 14 L.Ed. 367 (1852)	38
<i>Madey v. Duke Univ.,</i> 307 F.3d 1351 (Fed. Cir. 2002)	16
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.,</i> 565 U.S. 66 (2012).....	passim
<i>McRO, Inc. v. Bandai Namco Games Am. Inc.,</i> 837 F.3d 1299 (Fed. Cir. 2016)	22
<i>Newton v. Parker Drilling Mgmt. Servs., Ltd.,</i> 881 F.3d 1078 (9th Cir. 2018)	16
<i>Parker v. Flook,</i> 437 U.S. 584 (1978).....	23
<i>Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.,</i> 827 F.3d 1042 (Fed. Cir. 2016)	20, 44
<i>Recognicorp, LLC v. Nintendo Co.,</i> 855 F.3d 1322 (Fed. Cir. 2017)	23
<i>Secured Mail Solns. LLC v. Universal Wilde, Inc.,</i> 873 F.3d 905 (Fed. Cir. 2017)	21
<i>Skidmore v. Swift & Co.,</i> 323 U.S. 134 (1944).....	47, 48
<i>Smart Sys. Innovations, LLC v. Chicago Trans. Auth.,</i> 873 F.3d 1364 (Fed. Cir. 2017)	16
<i>Thales Visionix Inc. v. United States,</i> 850 F.3d 1343 (Fed. Cir. 2017)	21

Statutes

35 U.S.C. § 101	passim
35 U.S.C. § 102	30
35 U.S.C. § 103	28, 30

STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5(a), Appellee Creative Compounds, LLC (“Creative”) states that no other appeal in or from this civil action was previously before this or any other appellate court.

Pursuant to Federal Circuit Rule 47.5(b), Creative identifies the following title and number of a case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court’s decision in the pending appeal: *Natural Alternatives Int’l, Inc. v. Hi-Tech Pharma., Inc. d/b/a ALR Indus., et al.*, Case No. 3:16-cv-02343-H-AGS, pending in the United States District Court for the Southern District of California

STATEMENT OF THE ISSUE

Whether granting Creative's Motion for Judgment on the Pleadings was correct where the asserted claims focus on a naturally occurring compound and include conventional, well-known elements.

STATEMENT OF THE CASE

I. THE ASSERTED CLAIMS RECITE NATURALLY OCCURRING BETA-ALANINE AND CONVENTIONAL ELEMENTS SUCH AS A DIETARY SUPPLEMENT, AND SUPPLYING AND MIXING COMPONENTS

Appellant Natural Alternatives International, Inc. ("NAI") alleged in its First Amended Complaint that Appellee Creative Compounds, LLC ("Creative") indirectly infringed claims in five related patents: U.S. Patent Nos. 7,825,084 ("the '084 patent"); 7,504,376 ("the '376 patent"); 5,965,596 ("the '596 patent"); 8,470,865 ("the '865 patent"); and 8,993,610 ("the '610 patent") (collectively, "the patents-on-appeal")¹. (Appx47.²) The patents-on-appeal are in the same family and share identical specifications in all relevant respects. (*Id.*)

¹ The parties and the District Court adopted the following representative claims for purposes of Creative's motion: claim 1 of the '084 patent; claim 1 of the '596 patent; claim 6 of the '376 patent; claim 1 of the '865 patent; and claim 1 of the '610 patent (collectively, "the asserted claims"). (Appx10 at n.4.)

² NAI argues for validity of its U.S. Patent No. RE45,947 ("the '947 patent") at several points in its opening brief. (*See, e.g.*, Appellant's Opening Brief ("Op. Br.") at 29-31, 38-39.) However, NAI did not assert the '947 patent against Creative (or any of the other defendants in the underlying lawsuit). (Appx27-52.) Therefore, Creative does not address the '947 patent here.

The patents-on-appeal disclose the inventors' alleged discovery of a mammal's natural response to high doses of beta-alanine. The patents do not disclose or claim any human action affecting that natural response, such as causing the response, increasing or decreasing the response, or accelerating or decelerating the response. Rather, the patents-on-appeal and NAI's evidence submitted in support of its opposition to Creative's motion show that the inventors discovered the natural effect that large doses of beta-alanine have always had.

According to the inventors' statements in the patents-on-appeal and during prosecution of the patents-on-appeal, beta-alanine occurs naturally in mammals' muscle tissues as a precursor to another naturally occurring compound, carnosine. (See, e.g., Appx657, '596 patent at 1:59-2:13; Op. Br. at 4.) Thus, ingesting beta-alanine will increase the level of carnosine in a mammal's tissues. (Appx659, '596 patent at 5:36-42.) The inventors describe in the patents-on-appeal their discovery that when a mammal ingests large amounts of beta-alanine, the mammal naturally produces large amounts of carnosine—*i.e.*, the mammal's natural response to large amounts of beta-alanine is not to maintain a homeostasis condition but, instead, to continue producing carnosine. (Appx659, '596 patent at 5:4-35; Appx690-691, '376 patent at 8:51-9:16; Appx725-726, '084 patent at 8:49-9:13; Appx760-761, '865 patent at 8:49-9:13; Appx795-796, '610 patent at 8:49-9:13; Appx1130, Declaration Under 37 CFR 1.132 of Inventor Dr. Roger Charles Harris ("Harris

Dec.”) at ¶¶ 7-8; Appx1132-1133, Harris Dec. at ¶¶ 14-18.) This discovery underlies the patents’ shared disclosure and all of the asserted claims.

The asserted claims focus on beta-alanine and dietary supplements containing beta-alanine. In addition to beta-alanine, the asserted claims recite well-known elements such as a “human dietary supplement,” (Appx697, ‘376 patent at claim 6; Appx732, ‘084 patent at claim 1; Appx802, ‘610 patent at claim 1), and related methods for making and using dietary supplements containing beta-alanine, (Appx663-664, ‘596 patent at claim 1; Appx802, ‘610 patent at claim 1).

II. THE DISTRICT COURT RELIED ON THE CLAIM LANGUAGE AND THE PATENTS’ DISCLOSURES TO FIND THE ASSERTED CLAIMS INVALID PURSUANT TO 35 U.S.C. § 101

After the initial pleadings were complete, Creative filed a Motion for Judgment on the Pleadings seeking to invalidate the patents-on-appeal pursuant to 35 U.S.C. § 101 for claiming ineligible subject matter. (Appx513-534.) Creative first argued that the District Court should adopt its earlier ruling in the related case *Natural Alternatives Int’l, Inc. v. Allmax Nutrition, Inc.*, No. 3:16-cv-01764-H-AGS (S.D. Cal.) (“Allmax”), that the ‘084 patent, the ‘596 patent, and the ‘376 patent are invalid pursuant to 35 U.S.C. § 101. (Appx524.) The District Court agreed and adopted its reasoning from *Allmax* into its order on Creative’s motion.

(Appx9-21.³) Creative then addressed the two remaining patents-on-appeal, the ‘865 patent and the ‘610 patent, arguing that those patents were also invalid for claiming ineligible subject matter. (Appx524-532.) The District Court agreed and held the remaining two patents-on-appeal invalid for claiming ineligible subject matter. (Appx21-26.)

The District Court considered each of the asserted claims independently, applying the two-part inquiry set forth in *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. ---, 134 S. Ct. 2347, 2355 (2014). (Appx10-26.) For each of the asserted claims, the District Court began its analysis with step one of the *Alice* inquiry, which “focuses on determining ‘whether the claim at issue is ‘directed to’ a judicial exception, such as an abstract idea.’” (Appx10-11 (quoting *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1241 (Fed. Cir. 2016)).) The District Court noted that “[t]his inquiry requires courts ‘to look at the ‘focus of the claimed advance over the prior art’ to determine if the claim’s ‘character as a whole’ is directed to excluded subject matter.” (Appx11 (quoting *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016)).)

³ The District Court addressed the ‘947 patent in its ruling, (see, e.g., Appx17-19), because NAI had asserted the ‘947 patent against Hi-Tech Pharmaceuticals, Inc. in a related case, and the District Court combined its ruling on Creative’s Motion for Judgment on the Pleadings with its ruling on Hi-Tech’s concurrent Motion for Judgment on the Pleadings filed in the separate case. (Appx3-5.)

The District Court concluded, based on the inventors' statements in the patents' shared specification, that beta-alanine is a naturally-occurring compound. (Appx11-12 & n.5 ('084 patent); Appx19-20 & n.11 ('376 patent); Appx20-21 & n.13 ('596 patent); Appx22 & n.14 ('865 patent); and Appx24 ('610 patent).) Accordingly, the District Court found that each of the asserted claims satisfies step one of the *Alice* inquiry because they are focused solely on beta-alanine. (*Id.*)

The District Court then analyzed each of the asserted claims independently to determine whether they also satisfy step two of the *Alice* inquiry, *i.e.*, whether, based on an examination of the elements of each claim individually and collectively, each claim "contain[s] an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application." (Appx13 (quoting *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017)).) The District Court applied this Court's guidance that "[t]he court 'must consider the elements of the claims both individually and as an ordered combination to determine whether additional elements transform the nature of the claims into a patent-eligible concept.'" (*Id.* (quoting *Cleveland Clinic*, 859 F.3d at 1361-62)) The District Court also understood that "the inventive concept contained in the claim 'must do more than simply recite 'well-understood, routine, conventional activity.'" (*Id.* (quoting *Fair Warning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016) and

citing *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1313 (Fed. Cir. 2016)).)

A. The District Court Found Claim 1 Of The ‘084 Patent Invalid Pursuant To 35 U.S.C. § 101

Claim 1 of the ‘084 patent recites “a human dietary supplement containing beta-alanine in a unit dosage of 0.4 to 16 grams.” (Appx11, Appx732.) The inventors acknowledged in the ‘084 patent that beta-alanine is a naturally occurring substance, and that beta-alanine is the focus of their alleged discovery. (Appx11 & n.5; Appx722, ‘084 patent at 2:21-26, 2:45-53.) Accordingly, the District Court found that claim 1 of the ‘084 patent is directed to excluded subject matter and satisfies the first step of the *Alice* inquiry. (Appx11-12.)

The District Court then examined the elements of claim 1 to determine whether the inventors had set forth any inventive concept sufficient to transform this natural phenomenon into patentable subject matter. (Appx13-14.) The District Court considered the elements of claim 1 of the ‘084 patent, individually and collectively, applying NAI’s asserted claim construction, as well as the ‘084 patent’s specification and additional evidence submitted by NAI. (Appx13-17.) Based on its analysis of this evidence, the District Court concluded that the mere act of placing a specific dosage of beta-alanine into a human dietary supplement, as recited in claim 1 of the ‘084 patent, “is insufficient to render the claims at issue patent eligible even accepting Plaintiff’s proposed construction for the term

‘human dietary supplement.’” (Appx13-14 & n.8.) Accordingly, the District Court found that “representative claim 1 of the ‘084 patent only discloses patent ineligible subject matter and, thus, is invalid under 35 U.S.C. § 101.” (Appx16-17.)

The District Court considered the U.S. Patent and Trademark Office’s (“PTO”) guidance regarding patentability published in 2014. (Appx17 n.9, Appx1167-1183.) The District Court noted that this guidance, unlike precedents from this Court and the Supreme Court, is not binding, and found it to be substantively unpersuasive. (*Id.*) In particular, the District Court noted that this Court had rejected the rationale that the PTO relied upon for finding patent eligibility in the examples that NAI emphasized in its briefing. (*Id. (citing Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1379 (Fed. Cir. 2015) and Cleveland Clinic, 859 F.3d at 1363).*⁴) The District Court also concluded that the PTO’s failure to even acknowledge the Supreme Court’s decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc., 565 U.S. 66 (2012)*, further undermined the value of the 2014 guidance. (*Id.*) Finally, the District Court determined that the PTO’s application of the “broadest reasonable interpretation” standard in the 2014 guidance, rather than the narrower standard applied by district

⁴ The PTO acknowledged in 2016 that this Court’s precedents issued after the 2014 guidance undermined the PTO’s rationale for patent eligibility relied on in the 2014 guidance document. (*Id.*)

courts, rendered the 2014 guidance document unpersuasive in the present context. (*Id.*)

B. The District Court Found Claim 6 Of The ‘376 Patent Invalid Pursuant To 35 U.S.C. § 101

The District Court found asserted claim 6 of the ‘376 patent invalid under 35 U.S.C. § 101 for similar reasons. (Appx19-20.) Claim 6 of the ‘376 patent claims a dietary supplement for humans containing a mixture of beta-alanine and glycine. (Appx19, Appx697.) The inventors recognized in the ‘376 patent’s specification that these are naturally occurring substances. (Appx19, Appx687, ‘376 patent at 2:15-20; Appx689, ‘376 patent at 6:8-11.) NAI also proposed a construction for “glycine” that recognizes this compound as a naturally occurring amino acid.⁵ (Appx573, Appx19 n.12.) Therefore, the District Court found that claim 6 satisfies the first step of the *Alice* inquiry because it “is directed to excluded subject matter, specifically beta-alanine, a natural phenomenon, and glycine, a natural phenomenon.” (Appx19-20.)

The District Court relied on the Supreme Court’s decision in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948) (holding that mixing different natural phenomena together to achieve a natural result is insufficient to

⁵ The District court acknowledged NAI’s argument that the term “glycine” includes glycine from non-natural sources but found this unpersuasive because NAI “failed to identify any meaningful difference between glycine derived from other sources and natural glycine.” (Appx19-20 n.12 (citations omitted).)

transform a discovery into patent eligible subject matter), to conclude that claim 6 of the ‘376 patent also meets the second step of the *Alice* inquiry. (Appx20.) Accordingly, the District Court held that claim 6 of the ‘376 patent is invalid under 35 U.S.C. § 101.

C. The District Court Found Claim 1 Of The ‘596 Patent Invalid Pursuant To 35 U.S.C. § 101

The District Court next analyzed asserted claim 1 of the ‘596 patent, which claims a method of regulating hydronium ion concentration in human body tissue by providing beta-alanine, thereby increasing the carnosine content in the tissue. (Appx20, Appx663-664.) The District Court initially determined that this claim is directed to a law of nature, *i.e.*, “that ingesting certain levels of beta-alanine, a natural substance, will increase carnosine concentration in human tissue and, thereby, aid in regulating the hydronium ion concentration in the tissue,” thereby satisfying the first step in the *Alice* inquiry. (Appx20-21.⁶) The District Court then determined that claim 1 of the ‘596 patent recites nothing more than applying this law of nature, which is insufficient to transform the alleged discovery into patent-eligible subject matter. (Appx21.) Accordingly, the District Court found asserted claim 1 of the ‘596 patent invalid under 35 U.S.C. § 101. (*Id.*)

⁶ The District Court recognized that “[t]his law of nature is disclosed in the specification of the ‘596 patent.” (Appx21 n.13; Appx658-659, ‘596 patent at 4:58-5:45.)

D. The District Court Found Claim 1 Of The ‘865 Patent Invalid Pursuant To 35 U.S.C. § 101

Like claim 1 of the ‘596 patent, asserted claim 1 of the ‘865 patent recites providing an amount of beta-alanine to a human via a dietary supplement to increase the carnosine concentration in the human’s tissue. (Appx21-22, Appx767-768.) Accordingly, like claim 1 of the ‘596 patent, the District Court found that claim 1 of the ‘865 patent is directed to a law of nature, *i.e.*, “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.” (Appx22.⁷) Thus, the District Court found that this claim satisfies the first step of the *Alice* inquiry. (*Id.*)

Further, like claim 1 of the ‘596 patent, the District Court found that asserted claim 1 of the ‘865 patent recites nothing more than application of this law of nature. (Appx22-23 (*citing Ariosa*, 788 F.3d at 1376).) The District Court considered whether specifying that beta-alanine is administered via a dietary supplement was sufficient to transform the claimed discovery into a patentable invention. (Appx23.) However, based on “the ‘865 patent disclosure that placing a natural substance into a dietary supplement to increase the function of tissues when consumed is conventional activity,” the District Court found that this

⁷ The District Court recognized that “[t]his law of nature is disclosed in the specification of the ‘865 patent.” (Appx22 n.14; Appx760-761, ‘865 patent at 8:27-9:27.)

conventional activity was insufficient to transform the inventors' alleged discovery into patentable subject matter. (*Id.*) Accordingly, the District Court found the second step of the *Alice* inquiry to be satisfied and asserted claim 1 of the '865 patent invalid under 35 U.S.C. § 101. (*Id.*)

E. The District Court Found Claim 1 Of The '610 Patent Invalid Pursuant To 35 U.S.C. § 101

Finally, the District Court determined that asserted claim 1 of the '610 patent, like the other asserted claims, is directed to beta-alanine, a naturally occurring substance, and "the natural law that ingesting certain levels of beta-alanine will increase the carnosine concentration in human tissue." (Appx24 & n.15, Appx802.) Unlike the other asserted claims, claim 1 of the '610 patent is directed to a method of manufacture. (Appx802.) The District Court found no meaningful distinction resulting from this difference: "The claimed advance over the prior art disclosed in the '610 patent is the discovery of the natural law that ingesting certain levels of beta-alanine, a natural phenomenon, will increase the carnosine concentration in human tissue and, thereby, increase the anaerobic working capacity in the human." (Appx25; *see also* Appx792, '610 patent at 1:32-36, 2:48-63; Appx795-796, '610 patent at 8:27-9:23.) Accordingly, the District Court found that claim 1 of the '610 patent satisfies the first step of the *Alice* inquiry. (Appx25.)

Turning to the second step of the *Alice* inquiry, the District Court recognized that the inventors admitted in the ‘610 patent’s specification “that placing a natural substance into a dietary supplement to increase the function of tissues when consumed is a conventional activity.” (Appx25; *see also* Appx792, ‘610 patent at 1:41-44.) The District Court also concluded that the generic claim elements “supplying the beta-alanine” and “mixing the beta-alanine” were insufficient, individually or collectively, to transform the law of nature into a patentable invention because “[u]tilizing conventional activity ‘specified at a high level of generality’ is insufficient to render claim 1 of the ‘610 patent eligible.” (Appx25-26 (citations omitted).) Therefore, like the other asserted claims, the District Court found that asserted claim 1 of the ‘610 patent satisfies both steps of the *Alice* inquiry and is invalid under 35 U.S.C. § 101. (Appx25-26.)

Having found all of the asserted claims invalid under 35 U.S.C. § 101, the District Court granted Creative’s motion for judgment on the pleadings, (Appx26), and entered judgment in Creative’s favor. (Appx1-2.)

SUMMARY OF THE ARGUMENT

The asserted claims recite nothing more than the inventors' alleged discovery of a mammal's natural response to large amounts of the naturally occurring amino acid beta-alanine. The inventors admitted – correctly – in the patents' disclosures that beta-alanine occurs naturally and that they have done nothing to alter this amino acid or a mammal's natural response to it. Thus, the first step of the *Alice* inquiry is satisfied for each of the asserted claims.

The second step of the *Alice* inquiry is similarly satisfied in these circumstances, where the inventors have not disclosed or claimed any change in a mammal's natural response to ingesting naturally-occurring beta-alanine. Including well-known elements such as a “dietary supplement,” and “supplying” and “mixing” a compound, is not sufficient to transform the inventors' alleged discovery into a patentable invention. Thus, each of the asserted claims also satisfies the second step of the *Alice* inquiry.

The District Court correctly applied Supreme Court and Federal Circuit precedent to the facts of this case, including the language of the asserted claims as construed by NAI, the patents' shared disclosure, and the evidence submitted by NAI, and held the asserted claims invalid pursuant to 35 U.S.C. § 101. This Court should affirm.

ARGUMENT

I. STANDARD OF REVIEW

This Court “review[s] a district court’s judgment on the pleadings under the law of the regional circuit,” here the Ninth Circuit. *Smart Sys. Innovations, LLC v. Chicago Trans. Auth.*, 873 F.3d 1364, 1367 (Fed. Cir. 2017). The Ninth Circuit reviews *de novo* a grant of judgment on the pleadings pursuant to Rule 12(c). *See Newton v. Parker Drilling Mgmt. Servs., Ltd.*, 881 F.3d 1078, 1083 (9th Cir. 2018).

This Court “review[s] issues ‘unique to patent law,’ including patent eligibility under 35 U.S.C. § 101, consistent with [this] circuit’s precedent.” *Smart Sys.*, 873 F.3d at 1367 (*citing Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002)). “A district court’s determination of patent eligibility under § 101 is an issue of law that [this Court] review[s] *de novo*.” *Id.* (*citing Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1325 (Fed. Cir. 2017)).

II. THE DISTRICT COURT ADOPTED NAI’S PROPOSED CLAIM CONSTRUCTION AND CORRECTLY HELD THE ASSERTED CLAIMS INVALID UNDER 35 U.S.C. § 101 FOR FAILING TO CLAIM PATENTABLE SUBJECT MATTER

“[E]valuation of a patent claim’s subject matter eligibility under § 101 can proceed even before a formal claim construction. ‘[C]laim construction is not an inviolable prerequisite to a validity determination under § 101.’” *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1374 (Fed. Cir. 2016) (*quoting Bancorp Servs., L.L.C. v Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273

(Fed. Cir. 2012)). Nevertheless, the District Court expressly adopted NAI’s asserted claim construction for purposes of its Section 101 analysis:

Defendants argue that the patents-in-suit are invalid under § 101 even if the Court accepts Plaintiff’s proposed claim constructions.... Accordingly, in analyzing the validity of the patents-in-suit under 35 U.S.C. § 101, the Court will accept Plaintiff’s proposed claim constructions, and, therefore, there is no need to defer the subject matter eligibility determination of the patents-in-suit until after claim construction.

(Appx8-9 n.3 (internal record citation omitted) (*citing Genetic Techs.*, 818 F.3d at 1373); *see also* Appx13-14 & n.8, Appx19-20 n.12.)

The District Court considered, and rejected, NAI’s argument that its proposed constructions for the terms “human dietary supplement” and “dietary supplement” salvage the asserted claims. The District Court addressed this issue in the context of discussing the impact of the inventors’ acknowledgement in the patents-on-appeal “that placing a natural substance into a dietary supplement to increase the function of tissues is conventional activity.” (Appx13, Appx722, ‘084 patent at 1:37-44.⁸) This acknowledgement in the patents-on-appeal confirms that dietary supplements such as those recited in the asserted claims, and as construed

⁸ The District Court addressed this issue specifically in its ‘084 patent analysis. Nevertheless, this acknowledgement of the conventional nature of placing a natural substance into a dietary supplement to increase the function of tissues appears in each of the patents-on-appeal. (Appx657, ‘596 patent at 1:9-16; Appx687, ‘376 patent at 1:32-39; Appx757, ‘865 patent at 1:41-48; and Appx792, ‘610 patent at 1:41-48.) Thus, the District Court’s analysis is applicable to all of the asserted claims.

by NAI, are a well-known, conventional technique for administering a natural substance such as beta-alanine. NAI’s proposed claim constructions for “human dietary supplement” and “dietary supplement,” which the District Court expressly adopted, do not lead to a different result. (Appx14 n.8.)

The District Court held that “employing a dietary supplement to administer beta-alanine – a natural phenomenon – to achieve a high level of carnosine synthesis in a human – applying a natural law – is insufficient to render the claims at issue patent eligible even accepting [NAI’s] construction for the ‘human dietary supplement.’” (Appx13-14.) NAI mischaracterizes this holding as suggesting that the District Court ignored NAI’s proposed claim constructions. (Op. Br. at 20.) However, the District Court reached this holding after adopting NAI’s proposed claim constructions, including for the terms “dietary supplement” and “human dietary supplement.” (Appx8-9 n.3, Appx14 n.8.)

The District Court’s holding is tightly bound to the claim language and supported by the shared disclosure of the patents-on-appeal. For example, asserted claim 1 of the ‘084 patent recites, in full, “[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.” (Appx732.) This claim recites providing a unit dosage of beta-alanine via a human dietary supplement. The inventors admitted in the patents-on-appeal that

administering a dose of a natural substance via a dietary supplement is a conventional activity. (See, e.g., Appx722, ‘084 patent at 1:37-49; Appx13.) The claim also recites beta-alanine, which the inventors recognized is “present in the muscles of humans and other vertebrates,” i.e., it occurs naturally. (Appx722, ‘084 patent at 2:21-26; Appx11.) Thus, the District Court’s holding that “employing a dietary supplement to administer beta-alanine – a natural phenomenon – to achieve a high level of carnosine synthesis in a human – applying a natural law – is insufficient to render the claims at issue patent eligible even accepting [NAI’s] construction for the ‘human dietary supplement,’” (Appx13-14), is directly linked to the claim language. *Cf. Enfish, LLC v. Microsoft Corp.*, 822 F3d 1327, 1337 (Fed. Cir. 2016) (rejecting district court’s broad characterization of the asserted claim that was not linked to the claim language).

III. THE ASSERTED CLAIMS SATISFY BOTH STEPS OF THE *ALICE* TEST AND ARE INVALID PURSUANT TO 35 U.S.C. § 101

“Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (quoting *Mayo*, 566 U.S. at 70). “The concern underlying these judicial exclusions is that ‘patent law not inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity.’” *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting *Alice*, 134 S.Ct. at 2354). However, complete preemption is not required for a claim to be

invalid pursuant to Section 101, and “the absence of complete preemption does not demonstrate patent eligibility.” *Ariosa*, 788 F.3d at 1379; *see also Cleveland Clinic*, 859 F.3d at 1363.

“In *Alice*, the Supreme Court applied a two-step framework for analyzing whether claims are patent-eligible under section 101.” *Secured Mail Solns. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 909 (Fed. Cir. 2017). The first step requires the Court to “determine whether the claims at issue are ‘directed to’ a judicial exception, such as an abstract idea.” *Id.* (*citing Alice*, 134 S. Ct. at 2355). If not, the inquiry is done. *Id.* (*citing Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1346 (Fed. Cir. 2017), and *Enfish*, 822 F.3d at 1339). If the claims are directed to excluded subject matter, the Court “next consider[s] under step two whether the claims contain an ‘inventive concept’ sufficient to ‘transform the nature of the claim into a patent-eligible application.’” *Id.* (*quoting Alice*, 134 S.Ct. at 2355).

The first step of the *Alice* inquiry requires consideration of the claims in their entirety to determine whether they are directed to ineligible subject matter. *Id.* (*citing Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)). The Court “look[s] to whether the claims ‘focus on a specific means or method ... or are instead directed to a result or effect that itself is the abstract idea and merely invokes generic processes and machinery.’” *Id.* (*quoting*

McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299, 1314 (Fed. Cir. 2016) (ellipsis in original)).

In the second step of the *Alice* inquiry, the Court “consider[s] the elements of the claims to determine whether they transform the nature of the claim into a patent-eligible application of the abstract idea.” *Id.* at 911 (*citing Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1347 (Fed. Cir. 2014)). “This is the search for an inventive concept, which is something sufficient to ensure that the claim amounts to significantly more than the abstract idea itself.” *Id.* (*citing Content Extraction*, 776 F.3d at 1347). “To save a patent at step two, an inventive concept must be evident in the claims.” *Id.* (*quoting Recognicorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017)). Moreover, the “inventive concept must do more than simply recite ‘well-understood, routine, conventional activity.’” *Fair Warning*, 839 F.3d at 1093 (*quoting Mayo*, 565 U.S. at 79). Thus, “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.” *Mayo*, 565 U.S. at 79 (*quoting Parker v. Flook*, 437 U.S. 584, 590 (1978)).

A. The Asserted Claims Are Directed To Naturally Occurring Beta-Alanine

The asserted claims are directed to naturally occurring beta-alanine, which flows from the inventors’ alleged discovery disclosed in the patents-on-appeal, *i.e.*,

that when a mammal ingests large amounts of beta-alanine, the mammal's muscle tissue responds by producing large amounts of carnosine rather than maintaining a homeostasis condition. (Appx659, '596 patent at 5:4-35; Appx690-691, '376 patent at 8:51-9:16; Appx725-726, '084 patent at 8:49-9:13; Appx760-761, '865 patent at 8:49-9:13; Appx795-796, '610 patent at 8:49-9:13; Appx1130, Harris Dec. at ¶¶ 7-8; Appx1132-1133, Harris Dec. at ¶¶ 14-18.) The inventors do not claim to have invented any means for affecting the mammal's response to naturally occurring beta-alanine, such as causing the response, or accelerating or decelerating the response. Rather, they gave large amounts of beta-alanine to mammals and recorded the results. (*Id.*) Those results showed the mammals' natural response to ingesting large amounts of beta-alanine, and nothing more—*i.e.*, the beta-alanine had “the same effect it always had.” *Funk Bros.*, 333 U.S. at 131. The inventors merely recorded these naturally occurring effects. Thus, the asserted claims, all of which are directed to beta-alanine, and in some instances a combination of beta-alanine and another naturally-occurring compound, glycine, are directed to a natural phenomenon and satisfy the first *Alice* step.

NAI has not identified anything about the nature of the claims that would lead to a different conclusion. NAI's only argument is that asserted claims in the '084 and '376 patents include elements directed to dietary supplement

compositions. (Op. Br. at 24.⁹) But such an element-focused analysis is appropriate for the second step in the *Alice* inquiry, not the first. *Affinity Labs*, 838 F.3d at 1257 (noting that the second step of the *Alice* inquiry involves “whether the elements of the claim, considered both individually and as an ordered combination, add enough to transform the nature of the claim into a patent-eligible application.” (*citing Alice*, 134 S.Ct. at 2355)). Applying the proper analysis for the first step in the *Alice* inquiry, all of the asserted claims are directed to naturally-occurring beta-alanine, regardless of the implementation method. *Cf. Ariosa*, 788 F.3d at 1376 (finding that asserted claims directed to cffDNA, a naturally occurring phenomenon, satisfy the first step of the *Alice* inquiry).

B. There Are No Elements In The Asserted Claims Sufficient To Transform The Claimed Naturally Occurring Phenomenon Into Patent Eligible Subject Matter

The asserted claims include, in addition to beta-alanine and, in some instances, a combination of beta-alanine and another naturally-occurring compound, glycine, conventional elements such as a “dietary supplement,” a “human dietary supplement,” “providing” beta-alanine as part of a method, and “supplying” and “mixing” beta-alanine to make a dietary supplement. (Appx663-664, Appx697, Appx732, Appx767-768, Appx802.) These elements are not sufficient to transform the natural phenomenon claimed in the asserted claims into

⁹ NAI also refers to the ‘947 patent but, as noted above, NAI did not assert the ‘947 patent against Creative.

patent eligible subject matter. *See Intellectual Ventures I*, 838 F.3d at 1313 (“[S]imply appending conventional steps, specified at a high level of generality,’ which are ‘well known in the art’ and consist of ‘well-understood, routine, conventional activity’ previously engaged in by workers in the field, is not sufficient to supply the inventive concept.” (*quoting Alice*, 134 S.Ct. at 2355)).

NAI argues here and throughout its opening brief that the results recorded by the inventors after they administered large amounts of beta-alanine were allegedly “unexpected” and, therefore, the asserted claims are patentable under Section 101. NAI is wrong. The fact that the inventors, or even practitioners in the field, did not anticipate the natural result that the inventors discovered does not transform that result into something patentable. *See Myriad*, 569 U.S. at 591 (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”); *Ariosa*, 788 F.3d at 1379-80 (“While Drs. Lo and Wainscoat’s discovery regardingcffDNA may have been a significant contribution to the medical field, that alone does not make it patentable.”); *Genetic Techs.*, 818 F.3d at 1380 (“The method claims of *Mayo* and *Ariosa* were apparently also useful, and also invalid.”). NAI does not cite any case law to support its argument, likely because this argument would render the second step of the *Alice* inquiry, and indeed Section 101 itself, obsolete.

C. Creative Was Not Required To Submit Scientific Evidence Responding To NAI's Evidence Of The Inventors' Discovery Of A Mammal's Natural Response To Large Doses Of Beta-Alanine

There is no requirement for Creative to produce or submit extrinsic scientific evidence, whether in support of its Rule 12(c) motion or in response to evidence submitted by NAI. *See Cleveland Clinic*, 859 F.3d at 1360 (“[W]e have repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced.”); *Genetic Techs.*, 818 F.3d at 1373 (recognizing that “it is possible and proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion [or a Rule 12(c) motion].”); *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1347 (Fed. Cir. 2016) (“Courts may … dispose of patent infringement claims under § 101 whenever procedurally appropriate.”). Nevertheless, NAI criticizes Creative, as it did below, for not submitting scientific evidence in response to NAI’s submissions, and implies that the District Court was bound to accept NAI’s evidence. (Op. Br. at 26-27.) But NAI did not offer any evidence supporting any conclusion other than that the asserted claims are directed to ineligible subject matter. Rather, all of the evidence, as opposed to attorney argument, supports the District Court’s ruling. (*Id.* (citing the patents-on-appeal, the First Amended Complaint, and NAI’s briefs filed in the court below).) Therefore, Creative was not obligated to develop through discovery, or submit, scientific evidence.

The shared disclosure of the patents-on-appeal discloses that the inventors discovered mammals' natural response to large doses of beta-alanine. (Appx659, '596 patent at 5:4-35; Appx690-691, '376 patent at 8:51-9:16; Appx725-726, '084 patent at 8:49-9:13; Appx760-761, '865 patent at 8:49-9:13; Appx795-796, '610 patent at 8:49-9:13.) As discussed above, the asserted claims are directed solely to this natural phenomenon. And the asserted claims do not include any element sufficient to transform that natural phenomenon into patent eligible subject matter.

NAI cites declarations prepared during prosecution of the patents-in-suit and in support of NAI's oppositions to the various motions for judgment on the pleadings. (*See, e.g.*, Op. Br. at 27.) But these declarations confirm that the patents-on-appeal, and the asserted claims, disclose and recite only the inventors' discovery of how mammals naturally respond to large doses of beta-alanine. (*See, e.g.*, Appx1130-1134, Harris Dec. at ¶¶ 7-23.) In his declaration filed during prosecution of the reexamination of the '947 patent, one of the inventors, Dr. Harris, explained that administering a large amount of a naturally occurring compound to a human does not always lead to higher concentrations of the compound in the human; rather the human usually maintains a homeostasis condition with respect to the compound. (Appx1130, Harris Dec. at ¶ 7.) Dr. Harris went on in his declaration to explain that he and his co-inventor discovered that when a human consumes large doses of beta-alanine, his tissues will not

maintain a homeostasis condition but, instead, continue producing creatine. (Appx1130-1134, Harris Dec. at ¶¶ 8-23.)

Thus, according to NAI's scientific evidence, the inventors discovered that providing large doses of beta-alanine caused "the same effect it always had," *Funk Bros.*, 333 U.S. at 131, and the inventors recorded that natural effect. This evidence supports Creative's position, and the District Court's ruling, that the asserted claims are directed to the natural phenomenon beta-alanine. There was neither any requirement, nor any need, for Creative to develop scientific evidence through discovery, or to submit evidence responding to NAI's submissions.

D. The District Court Properly Analyzed The Elements Of The Asserted Claims Both Individually And Collectively And Correctly Concluded That The Asserted Claims Are Invalid Pursuant To 35 U.S.C. § 101

The District Court properly applied the second step of the *Alice* inquiry by analyzing the asserted claims on a claim-by-claim basis, "consider[ing] the elements of the claims both individually and as an ordered combination to determine whether additional elements transform the nature of the claims into a patent-eligible concept." (Appx13 (quoting *Cleveland Clinic*, 859 F.3d at 1361-62).) For example, the District Court described the combination of the elements of claim 1 of the '084 patent as describing "placing a specific dosage of beta-alanine into a human dietary supplement." (Appx13.) This is consistent with the text of the claim:

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.

(Appx732.¹⁰) The District Court then addressed the individual elements of the claim in view of the inventors' admission in the '084 patent's disclosure that "placing a natural substance into a dietary supplement to increase the function of tissues is conventional activity." (Appx13, Appx722, '084 patent at 1:37-44.) Based on its analysis, the District Court correctly held that the claim elements are insufficient to transform the natural phenomenon to which the claim is directed into patentable subject matter:

Because placing a natural substance into a human dietary supplement to increase the function of tissues when consumed is a conventional activity, employing a dietary supplement to administer beta-alanine – a natural phenomenon – to achieve a high level of carnosine synthesis in a human – applying a natural law – is insufficient to render the claims at issue patent eligible even accepting Plaintiff's proposed construction for the term "human dietary supplement."

(Appx13-14 (footnote and trailing citations omitted).) Thus, the District Court properly applied the second step of the *Alice* inquiry by considering both the claim's individual elements and the claim as a whole, *i.e.*, as an ordered

¹⁰ NAI argues that the District Court's analysis of the '947 patent under the second step of the *Alice* inquiry was erroneous. (Op. Br. at 28-35.) The '947 patent is not at issue in this appeal. Nevertheless, Creative addresses the issues raised in this section of NAI's Opening Brief in the event that the Court determines that these issues may be relevant to the patents-on-appeal.

combination, and did not merely conduct an obviousness-type analysis. (Appx13-17.¹¹)

NAI argues that an obviousness analysis under 35 U.S.C. § 103 should not supplant a Section 101 analysis. (Op. Br. at 32 (*citing Bascom*, 827 F.3d at 1345 [sic, 1350]).) In *Bascom*, the court stated the unexceptional proposition that “[t]he inventive concept inquiry requires more than recognizing that each claim element, by itself, was known in the art.” *Id.* at 1350. The District Court’s analysis went well beyond an element-by-element analysis focused on prior art such as would be appropriate in a Section 103 determination. The District Court considered whether the elements of the claim, individually and collectively, were sufficient to transform the natural phenomenon into patentable subject matter. This is what the Supreme Court requires with the second step of the *Alice* inquiry. Thus, the District Court’s analysis was proper and its conclusion correct.

NAI argues that under the District Court’s analysis, “even if an inventor discovered that massive amounts of beta-alanine or some other natural product cured Alzheimer’s or some other disease, the invention would still not be eligible for patent protection.” (Op. Br. at 32.) While such a discovery would be

¹¹ The District Court similarly applied the second step of the *Alice* inquiry to the remaining patents-on-appeal, focusing on both the individual elements and the claims as a whole, and correctly held each of the asserted claims invalid under Section 101. (Appx19-20 (‘376 patent), Appx20-21 (‘596 patent), Appx21-23 (‘865 patent), Appx24-26 (‘610 patent).)

extraordinarily important and useful, NAI is correct that it would not be patentable—unless there was something that transformed naturally-occurring beta-alanine (or some other natural product) into patent eligible subject matter. *See Myriad*, 569 U.S. at 591 (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”); *Ariosa*, 788 F.3d at 1379-80 (“While Drs. Lo and Wainscoat’s discovery regarding cffDNA may have been a significant contribution to the medical field, that alone does not make it patentable.”); *Genetic Techs.*, 818 F.3d at 1380 (“[Plaintiff’s] attempts to distinguish this case on the ground that the method of claim 1 is useful have no basis in case law or logic. Claim 1 stands rejected under § 101 as ineligible for claiming unpatentable subject matter, not for lack of utility. The method claims of *Mayo* and *Ariosa* were apparently also useful, and also invalid.”).

NAI makes a second “slippery slope” argument, namely that the District Court’s holding leads inexorably to the conclusion that “the use of chemicals to treat diseases is not eligible for patent protection because the body will always have a natural reaction to whatever is administered to it.” (Op. Br. at 33.) This incredulous argument relies on a distorted characterization of this case and the District Court’s ruling. The District Court did not invalidate the asserted claims because they recite a body’s reaction to a chemical. Rather, the asserted claims are invalid because the inventors discovered the natural response of mammals when

dosed with large amounts of beta-alanine. If the inventors had created a non-natural composition and/or caused a non-natural response in mammals, this would likely be a different case. But they did not create a non-natural composition or cause any non-natural response. They recorded and claimed the mammals' natural response to ingesting large amounts of beta-alanine—*i.e.*, the beta-alanine had “the same effect it always had.” *Funk Bros.*, 333 U.S. at 131.

NAI also argues that the District Court erred by ruling the patents-on-appeal invalid in the context of a motion for judgment on the pleadings, without requiring the parties to undertake fact and expert discovery, and without “a proper analysis under §§ 102 and 103.” (Op. Br. at 32.) However, as the District Court noted, this Court “has expressly recognized that ‘it is possible and proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion [or a Rule 12(c) motion].’” (Appx8 (added text in original) (*quoting Genetic Techs.*, 818 F.3d at 1373).) Moreover, there is no basis, and NAI cites none, for the argument that the District Court must undertake an analysis under 35 U.S.C. § 102 and/or 35 U.S.C. § 103 in lieu of, prior to, or concurrently with a Section 101 analysis. The District Court conducted a proper analysis of the Section 101 issues pursuant to this Court’s and the Supreme Court’s guidance, and correctly held the asserted claims invalid under 35 U.S.C. § 101.

NAI finally argues that “carnosine can be increased to *unnatural* levels from massive administrations of an amino acid with no physiological buffering capacity itself is simply not a lateral law but is an invention eligible for patent protection.” (Op. Br. at 35 (emphasis added).) NAI is wrong. The level to which carnosine is increased in a mammal’s body after ingesting large amounts of beta-alanine *is a natural phenomenon*, *i.e.*, the inventors did not create any “unnatural” response in mammals. They discovered mammals’ natural response to administration of large doses of beta-alanine, and noted that this natural response is different than a mammal’s response to large doses of other substances. (Appx1130-1133, Harris Dec. at ¶¶ 7-18.)

There is nothing “unnatural” disclosed or claimed in the patents-on-appeal. Accordingly, the District Court correctly held the patents invalid pursuant to Section 101, and this Court should affirm.

E. The ‘596 Patent Claims Do Not Recite Patent Eligible Subject Matter

Asserted claim 1 of the ‘596 patent “claims a method of regulating hydronium ion concentrations in human tissue by provid[ing] the amino acid beta-alanine to human tissue via blood or blood plasma[,] thereby increasing the carnosine content in the tissue.” (Appx20, Appx663-664.) NAI adopts this characterization in its Opening Brief to define the subject matter to which this claim is directed. (Op. Br. at 35.) Thus, claim 1 of the ‘596 patent is directed to

the discovery that ingesting certain levels of beta-alanine, a natural substance, increases carnosine concentration in human tissue, a natural response, thereby aiding in hydronium ion concentration. The inventors admitted in the ‘596 patent’s specification that this is a law of nature. (Appx657, ‘596 patent at 2:10-13; Appx658-659, ‘596 patent at 4:58-5:45.) Therefore, claim 1 of the ‘596 patent satisfies the first step of the *Alice* inquiry. *Cf. Ariosa*, 788 F.d at 1376 (“The method therefore begins and ends with a natural phenomenon.”).

Claim 1 of the ‘596 patent also satisfies the second step of the *Alice* inquiry. The elements of claim 1 of the ‘596 patent, both individually and as an “ordered combination,” are insufficient to transform the claimed law of nature into a patent-eligible application. The claim elements—“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—merely state the law of nature and add the direction “apply it.” That is not sufficient to transform the patent ineligible law of nature into a patent eligible application. *See Ariosa*, 788 F.3d at 1377 (“*Mayo* made clear that transformation into a patent-eligible application requires ‘more than simply stat[ing] the law of nature while adding the words ‘apply it.’’’); *Mayo*, 566 U.S. at 77 (“If a law of nature is not patentable, then neither is a process reciting a law of nature.”).

NAI does not identify any element, or elements, in claim 1 of the ‘596 that when considered individually or as an ordered combination would transform the claimed law of nature into a patentable application. (Op. Br. at 36-37.) Instead, NAI relies on its oft-repeated argument that a mammal’s natural response to large doses of beta-alanine was not “conventional, routine, or well-understood.” (Op. Br. at 37.) That is likely true of every patent found invalid pursuant to Section 101 for claiming a law of nature, and it is not sufficient alone to satisfy the Section 101 inquiry. *See Myriad*, 569 U.S. at 591 (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”). To hold otherwise would eviscerate Section 101 and ignore this Court’s and the Supreme Court’s precedents. Therefore, the District Court was correct to invalidate claim 1 of the ‘596 patent for failing to claim patentable subject matter, and this Court should affirm.

F. The ‘376 Patent Claims Do Not Recite Patent Eligible Subject Matter

Asserted claim 6 of the ‘376 patent depends from claims 1 and 5 and recites a dietary supplement or sports drink for humans that contains a mixture of beta-alanine and glycine, both of which are natural substances. (Appx697, Appx689, ‘376 patent at 6:1-11; Appx690, ‘376 patent at 8:51-55.) Thus, claim 6 of the ‘376 patent satisfies step one of the *Alice* inquiry. NAI does not offer any meaningful argument against this conclusion. (Op. Br. at 37.)

Regarding the second step in the *Alice* inquiry, NAI merely repeats its argument that its proposed claim construction salvages claim 6. (Op. Br. at 37.) As discussed above, the District Court applied NAI's proposed claim construction and correctly found claim 6 of the '376 patent, and the other asserted claims, invalid under Section 101. (See, e.g., Argument Section II, *supra*.)

The District Court relied on the Supreme Court's ruling in *Funk Bros.* to conclude that claim 6 of the '376 patent satisfies the second step of the *Alice* inquiry. (Appx20.) In *Funk Bros.*, the claims at issue were directed to a combination of specific bacteria strains that unexpectedly did not inhibit one another's activity when they were combined. *Funk Bros.*, 333 U.S. at 129-30. The Supreme Court noted that the inventor did not "create [the] state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. These qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature." *Id.* at 130 (citing *LeRoy v. Tatham*, 14 How. 156, 14 L.Ed. 367 (1852)).

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.

Id. Although the claimed idea was advantageous and may have been “an important commercial advance,” the claimed combination “serve[s] only the ends nature originally provided and act[s] quite independently of any effort of the patentee.” *Id.* at 131-32. Therefore, the claims at issue in *Funk* were invalid for failing to claim patentable subject matter. *Id.* at 132.

Similar to the combination of bacteria strains in *Funk Bros.*, NAI’s combination of two naturally occurring substances, beta-alanine and glycine, “serve[s] only the ends nature originally provided and act[s] quite independently of any effort of the patentee.” Thus, the elements in claim 6 of the ‘376 patent, considered individually or collectively, are not sufficient to transform the claimed natural phenomenon into patentable subject matter. The District Court correctly found claim 6 of the ‘376 patent invalid under Section 101, and this Court should affirm.

G. The ‘084 Patent Claims Do Not Recite Patent Eligible Subject Matter

NAI gives the ‘084 patent only short shrift in its Opening Brief, offering no meaningful arguments in support of the patent. (Op. Br. at 39-40.) Nevertheless, it is clear that the District Court was correct in finding claim 1 of the ‘084 patent invalid pursuant to 35 U.S.C. § 101. (Appx10-17.)

Claim 1 of the ‘084 patent recites “a human dietary supplement containing beta-alanine in a unit dosage of 0.4 to 16 grams.” (Appx732.) The inventors

acknowledged in the ‘084 patent that beta-alanine is a naturally occurring substance, and that beta-alanine is the focus of their alleged discovery. (Appx722, ‘084 patent at 2:21-26, 2:45-53.) Accordingly, the District Court correctly found that claim 1 of the ‘084 patent is directed to excluded subject matter and satisfies the first step of the *Alice* inquiry. (Appx11-12.)

Furthermore, the elements of claim 1 of the ‘084 patent are not sufficient, considered both individually and collectively, to transform the claimed natural phenomenon into patentable subject matter. To the contrary, the inventors’ conventional act of placing a dosage of beta-alanine into a human dietary supplement, as recited in claim 1 of the ‘084 patent, “is insufficient to render the claims at issue patent eligible even accepting Plaintiff’s proposed construction for the term ‘human dietary supplement.’” (Appx13-14 & n.8.) Accordingly, the District Court correctly found that “representative claim 1 of the ‘084 patent only discloses patent ineligible subject matter and, thus, is invalid under 35 U.S.C. § 101.” (Appx16-17.) This Court should affirm that ruling.

H. The ‘865 Patent Claims Do Not Recite Patent Eligible Subject Matter

Similar to claim 1 of the 596 patent, *supra*, claim 1 of the ‘865 patent claims a method of increasing the anaerobic working capacity of a human by providing the human with beta-alanine via a dietary supplement effective to increase the carnosine concentration in the human’s tissue. (Appx767-768.) Thus, like claim 1

of the ‘596 patent, this claim is directed to a law of nature, namely that ingesting certain levels of beta-alanine, a natural substance, increases carnosine concentration in human tissue, which is a natural response unaffected by any effort of the inventors. *See Ariosa*, 788 F.3d at 1376 (“The method therefore begins and ends with a natural phenomenon.”). Therefore, claim 1 of the ‘865 patent satisfies step one of the *Alice* inquiry.

Claim 1 of the ‘865 patent also satisfies the second step of the *Alice* inquiry because the claim elements, whether considered individually or collectively, add nothing more than the direction to “apply it” to the claimed law of nature. *See Ariosa*, 788 F.3d at 1377 (“*Mayo* made clear that transformation into a patent-eligible application requires ‘more than simply stat[ing] the law of nature while adding the words ‘apply it.’’’); *Mayo*, 566 U.S. at 77 (“If a law of nature is not patentable, then neither is a process reciting a law of nature.”). The claim element “dietary supplement,” as construed by NAI, does not salvage claim 1 of the ‘865 patent. 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. (Appx757, ‘865 patent at 1:41-44.) Such well-known, conventional activity is not sufficient to transform the claimed law of nature into patent eligible subject matter. *See Alice*, 134 S.Ct. at 2357-58 (holding that the introduction of a

general purpose computer to implement an unpatentable abstract idea was insufficient to salvage the claims at issue); *Ariosa*, 788 F.3d at 1377 (holding that performance of routine, conventional methods for amplification and detection of cfDNA, a natural phenomenon, was insufficient to render the claims at issue patent eligible). Therefore, claim 1 of the ‘865 patent also satisfies the second step of the *Alice* inquiry, and this claim—like the other asserted claims—is invalid under Section 101.

As discussed above, the District Court adopted NAI’s proposed claim construction, including its proposed construction of the limitation “effective to increase beta-alanylhistidine dipeptide synthesis in the tissue,” and found claim 1 of the ‘865 patent invalid under Section 101. (Op. Br. at 40; Appx8-9 n.3, Appx14-17 & n.8, Appx21-23 & n.14.) The inventors were clear throughout the patents-on-appeal that when a mammal ingests certain levels of beta-alanine, a naturally occurring substance, the mammal’s anaerobic working capacity naturally increase. (Appx760-761, ‘865 patent at 8:27-9:27.) In a declaration filed during prosecution of the reexamination of the ‘947 patent, Dr. Harris, one of the inventors, explained that administering a large amount of a naturally occurring compound to a human does not always lead to higher concentrations of the compound in the human’s tissues; rather the tissue usually maintains a homeostasis condition with respect to the compound. (Appx1130, Harris Dec. at ¶ 7.)

However, Dr. Harris and his co-inventor discovered that when a human consumes large doses of beta-alanine, the human's tissues do not maintain a homeostasis condition but, instead, continue producing creatine. (Appx1130-1134, Harris Dec. at ¶¶ 8-23.) That is, the human's tissues continue to do what they have always done when faced with large amounts of beta alanine, without Dr. Harris or his co-inventor having exerted any effort to cause, or affect, this result. *Funk Bros.*, 333 U.S. at 131.

Thus, even adopting NAI's proposed constructions, the elements in claim 1 of the '865 patent, individually or collectively, do nothing to cause an unnatural effect. Rather, as the inventors admitted throughout the patents-on-appeal, these elements recite conventional, well-known activities.

NAI argues that "increases in carnosine do not occur naturally because it is dependent on both the amount of beta-alanine as well as the period of time spent maintaining excessive amounts of beta-alanine." (Op. Br. at 42.) This is a non sequitur. The fact that there is a direct link between carnosine concentration levels, on the one hand, and the amount of beta-alanine administered and the amount of time over which the administration takes place, on the other hand, confirms that this is a natural phenomenon. *See Mayo*, 566 U.S. at 78-82 (finding that well-known, routine and conventional steps of administering a drug and then reconsidering the dosage in light of a natural law insufficient to render the claims

at issue patent eligible). The inventors added nothing patentable to the natural law that increasing the amounts of beta-alanine administered to a mammal leads to increased carnosine concentration rather than homeostasis. *See Funk Bros.*, 333 U.S. at 131-32 (holding that although a claimed discovery was advantageous and may have been “an important commercial advance,” it is not patentable when it “serve[s] only the ends nature originally provided and act[s] quite independently of any effort of the patentee.”).

Claim 1 of the ‘865 patent is invalid for failing to claim patentable subject matter. This Court should affirm the District Court’s ruling.

I. The ‘610 Patent Claims Do Not Recite Patent Eligible Subject Matter

Claim 1 of the ‘610 patent recites the use of beta-alanine to manufacture a dietary supplement that is to be used for increasing carnosine concentrations in human tissue. (Appx802.) Thus, like the other asserted claims, claim 1 of the ‘610 patent is directed to the natural phenomenon of beta-alanine and the natural law that ingesting beta-alanine will increase carnosine concentrations. (Appx792, ‘610 patent at 2:24-30, 2:42-44; Appx795-796, ‘610 patent at 8:27-9:23.) Therefore, claim 1 of the ‘610 patent satisfies the first step of the *Alice* inquiry.

Turning to step two of the *Alice* inquiry, “[i]f a law of nature is not patentable, then neither is a process reciting a law of nature.” *Mayo*, 566 U.S. at 77. Here, the elements of claim 1 of the ‘610 patent recite conventional, well-

known steps such as “supplying” and “mixing” beta-alanine. (Appx802); *cf. Rapid Litig.*, 827 F.3d at 1048. In *Rapid Litig.*, the claims at issue recited “a new and useful method of preserving hepatocyte cells.... Through the recited steps the patented invention achieves a better way of preserving hepatocytes.” *Id.* The elements of claim 1 of the ‘610 patent provide no such new and useful process affecting beta-alanine. Instead, these elements merely recite conventional manufacturing steps of supplying beta-alanine and mixing it with at least one other ingredient. NAI does not identify anything new or unique about these routine manufacturing steps. (Op. Br. at 48.)

NAI argues that the result of the routine manufacturing steps—a dietary supplement with beta-alanine to increase beta-alanylhistidine levels in muscle tissue—is sufficiently transformative to salvage this claim. (Op. Br. at 48.) However, as noted above, administering large doses to achieve increased levels of beta-analylhistidines, and by extension carnosine, represents a natural phenomenon requiring no input or effort from the inventors. Such admittedly conventional activity, (Appx792, ‘610 patent at 1:41-44), is not sufficient to transform this natural phenomenon into patentable subject matter. *See Intellectual Ventures I*, 838 F.3d at 1313 (“[S]imply appending conventional steps, specified at a high level of generality,’ which are ‘well known in the art’ and consist of ‘well-understood, routine, conventional activity’ previously engaged in by workers in the

field, is not sufficient to supply the inventive concept.” (*quoting Alice*, 134 S.Ct. at 2355)); *Ariosa*, 788 F.3d at 1377; *Mayo*, 566 U.S. at 78-82.

The District Court correctly held claim 1 of the ‘610 patent, and all of the asserted claims, invalid for failing to claim patentable subject matter. This Court should affirm that ruling in its entirety.

IV. THE PTO GUIDANCE CITED BY NAI IS NEITHER BINDING NOR PERSUASIVE AND DOES NOT DESERVE *SKIDMORE* DEFERENCE IN THIS CONTEXT

The PTO issued guidance on December 16, 2014 for its Examiners to consider in connection with the patentability of “nature-based products.” (Appx1167-1183.) This guidance document provides “illustrative” examples based specifically on the fact patterns in the document. (Appx1167.) The PTO warned that “[o]ther fact patterns may have different eligibility outcomes.” (*Id.*)

This guidance document is “not binding on this Court.” *In re Smith*, 815 F.3d 816, 819 (Fed. Cir. 2016) (*quoting In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005)). Apparently recognizing this, NAI argues that the Court should grant the document *Skidmore* deference. (Op. Br. at 49-50); *see Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 251, 261 (5th Cir. 2017) (recognizing that the extent of deference afforded to an agency’s interpretation of a statute pursuant to *Skidmore* “depends on ‘the thoroughness evident in [the agency’s] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all

those factors which give it power to persuade, if lacking power to control.”” (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

NAI argues that claim examples 7 and 8 in the guidance, which the PTO characterizes as patent eligible, require a finding that its asserted claims are not invalid. (Op. Br. at 50-51; Appx1168-1169.) This argument ignores that, as the PTO explained in the guidance document, “[t]hese claims are analyzed for eligibility in accordance with their broadest reasonable interpretation,” which the PTO applies but the courts do not. (Appx1169.) Moreover, the PTO specifically relied on the non-preemptive nature of example claims 7 and 8: “Although claims 7-8 recite nature-based products (amazonic acid), a full eligibility analysis of these claims is **not needed** because the claims clearly do not seek to tie up all practical uses of the nature-based products.” (*Id.* (emphasis added)) As the District Court noted in connection with its analysis of this guidance document, this Court rejected the absence of preemption rationale after the PTO published its guidance document. *See Ariosa*, 788 F.3d at 1379; *Cleveland Clinic*, 859 F.3d at 1363; (Appx17 n.9.) Indeed, the PTO acknowledged in a later guidance that “while a preemptive claim may be ineligible, the absence of complete preemption does not demonstrate that a claim is ineligible.” *See* May 2016 Subject Matter Eligibility Update at 7 (May 4, 2016), <https://www.uspto.gov/sites/default/files/documents/>

ieg-may-2016-memo.pdf (last visited on June 20, 2018). It also bears noting that the 2014 guidance document includes no references to the Supreme Court’s *Mayo* decision, much less an explanation of how the two example claims cited by NAI could be patent eligible in view of *Myriad* and *Mayo*. (Appx17 n.9; Appx1167-1183.)

The PTO’s guidance document is not persuasive in the present context because it relies on the “broadest reasonable interpretation” standard that is not applicable here, and also because it lacks any analysis of the most relevant Supreme Court precedent. Furthermore, subsequent guidance issued by the PTO two years later contravenes the specific analysis that NAI relies upon to argue for validity of the asserted claims. This Court has never granted *Skidmore* deference to the PTO’s guidance document and there is no reason to start doing so now.

V. THERE IS NO EXEMPTION IN THE PATENT LAWS FOR ANY INDUSTRY OR COMMERCIAL SECTOR

The patent laws, including 35 U.S.C. § 101, do not exempt any industry, and precedent from the Supreme Court and this Court apply equally across all commercial sectors and industries without favor. This includes the dietary supplement industry, of which Creative is an active part, and the “natural products chemistry” industry. (Op. Br. at 54.)

The District Court offered no leeway to NAI because of its inclusion in the dietary supplement industry, and did not ignore the law because of the nature of the

asserted claims. If NAI or the amici want the law changed, they need to appeal to Congress, not the District Court or this Court.

The District Court faithfully applied the law, including guidance from the Supreme Court and this Court developed through years of precedent. This Court should do the same and affirm the District Court's ruling.

CONCLUSION

For the foregoing reasons, Creative respectfully requests that the Court affirm the District Court's grant of judgment on the pleadings.

June 22, 2018

Respectfully submitted,

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**United States Court of Appeals
for the Federal Circuit**

Natural Alternatives Intl. v. Creative Compounds, LLC, 2018-1295

CERTIFICATE OF SERVICE

I, Julian Hadiz, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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June 22, 2108

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