UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

NATURAL ALTERNATIVES INTERNATIONAL, INC., Plaintiff, v. CREATIVE COMPOUNDS, LLC; et al., Defendants.	Case No.: 16-cv-02146-H-AGS **ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS** [Doc. No. 83.]
NATURAL ALTERNATIVES INTERNATIONAL, INC., Plaintiff, v. HI-TECH PHARMACEUTICALS, INC. doing business as ALR Industries, APS Nutrition, Innovative Laboratories, Formutech Nutrition, LG Sciences and Sports 1; and DOES 1-100, Defendants.	Case No.: 16-cv-02343-H-AGS **ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS** [Doc. No. 57.]

On July 10, 2017, Defendant Hi-Tech Pharmaceuticals, Inc. filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) in Case No. 16-cv-2343. (16-cv-2343-Doc. No. 57.) On July 19, 2017, Defendant Creative

Compounds, LLC filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) in related Case No. 16-cv-2146. (16-cv-2146-Doc. No. 83.) On August 14, 2017, Plaintiff Natural Alternatives International, Inc. filed its response in opposition to the two motions. (16-cv-2146-Doc. No. 85; 16-cv-2343-Doc. No. 59.) On August 21, 2017, the Defendants each filed a reply. (16-cv-2146-Doc. No. 86; 16-cv-2343-Doc. No. 60.)

The Court held a hearing on the matters on September 5, 2017. Scott A.M. Chambers, Kevin M. Bell, Richard J. Oparil, William J. McKeague, and Frederick W. Kosmo appeared for Plaintiff NAI. Kevin J. O'Shea appeared for Defendant Creative Compounds. Gregory L. Hillyer appeared for Defendant Hi-Tech. For the reasons below, the Court grants Defendants' motions for judgment on the pleadings.

Background

The following facts are taken from the allegations in Plaintiff's pleadings. Plaintiff NAI is a formulator, manufacturer, marketer, and supplier of nutritional supplements. (16-cv-2146-Doc. No. 48, FAC ¶ 14; 16-cv-2343-Doc. No. 21, FAC ¶ 8.) Plaintiff sells its branded CarnoSyn® beta-alanine product to customers throughout the United States and in other countries. (16-cv-2146-Doc. No. 48, FAC ¶ 1; 16-cv-2343-Doc. No. 21, FAC ¶ 1.) Plaintiff alleges that its CarnoSyn® product is covered by a robust portfolio of patent and trademark rights. (Id.)

Plaintiff NAI alleges that Defendant Creative Compounds is a global importer, supplier, and distributor of raw ingredients, including beta-alanine, to manufacturers of nutritional supplements. (16-cv-2146-Doc. No. 48-FAC ¶¶ 36-39.) Plaintiff alleges that Defendant Hi-Tech creates, manufactures, offers to sell, and sells dietary supplement products, including one or more products containing beta-alanine. (16-cv-2343-Doc. No. FAC ¶ 34.) Plaintiff NAI alleges that Defendants' activities infringe Plaintiff's patents. (16-cv-2146-Doc. No. 48, FAC ¶¶ 45-46, 127-31; 16-cv-2343-Doc. No. 21, FAC ¶¶ 56-193, 206-11.)

On August 24, 2016, Plaintiff NAI filed a complaint against Defendant Creative

Compounds. (16-cv-2146-Doc. No. 1.) Subsequently, Plaintiff filed a first amended complaint against Defendant Creative Compounds and others, alleging a single claim for patent infringement against Defendant Creative Compounds. (16-cv-2146-Doc. No. 48 ¶¶ 127-31.) In its claim for patent infringement against Defendant Creative Compounds, Plaintiff alleges infringement of U.S. Patent Nos. 5,965,596, 7,825,084, 7,504,376, 8,993,610, and 8,470,865. (Id. ¶¶ 20-47, 127-31.)

On September 16, 2016, Plaintiff NAI filed a complaint against Defendant Hi-Tech. (16-cv-2343-Doc. No. 1.) Subsequently, Plaintiff filed a first amended complaint against Defendant Hi-Tech, alleging claims for: (1) breach of contract; (2) patent infringement; and (3) violation of the Lanham Act § 32. (16-cv-2343-Doc. No. 21, FAC ¶¶ 197-217.) In its claim for patent infringement against Defendant Hi-Tech, Plaintiff alleges infringement of U.S. Patent Nos. 5,965,596, 7,825,084, RE45,947, 8,993,610, and 8,470,865. (Id. ¶¶ 10-29, 56-193, 206-11.)

By the present motions, Defendants Creative Compounds and Hi-Tech move for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) as to Plaintiff's claims for patent infringement against them. (16-cv-2146-Doc. No. 83-1; 16-cv-2343-Doc. No. 57-1.) Specifically, Defendants Creative Compound and Hi-Tech argue that the Court should dismiss Plaintiff's patent infringement claims because the patents-in-suit fail to claim patent-eligible subject matter and, thus, are invalid under 35 U.S.C. § 101.[1] (16-cv-2146-Doc. No. 83-1 at 6-14; 16-cv-2343-Doc. No. 57-1 at 6-14.)

Discussion

I. Legal Standards

A. Standards for a Rule 12(c) Motion for Judgment on the Pleadings

In patent cases, a motion for judgment on the pleadings pursuant to Federal Rule of

[1] Defendant Creative Compounds specifically argues that the '084 patent, the '376 patent, the '596 patent, the '865 patent, and the '610 patent are invalid under § 101. (16-cv-2146-Doc. No. 83-1 at 6-14.) Defendant Hi-Tech specifically argues that the '084 patent, the '947 patent, the '596 patent, the '865 patent, and the '610 patent are invalid under § 101. (16-cv-2343-Doc. No. 57-1 at 6-14.)

Civil Procedure 12(c) is governed by the "the procedural law of the regional circuit." Amdocs (Israel) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288, 1293 (Fed. Cir. 2016). Under Federal Rule of Civil Procedure 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." "'Judgment on the pleadings is properly granted when[, accepting all factual allegations in the complaint as true,] there is no issue of material fact in dispute, and the moving party is entitled to judgment as a matter of law.'" Chavez v. United States, 683 F.3d 1102, 1108 (9th Cir. 2012). The Ninth Circuit has explained that the standard for deciding a Rule 12(c) motion "is 'functionally identical'" to the standard for deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Cafasso, U.S. ex rel. 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)); accord Chavez, 683 F.3d at 1108.

A complaint will survive a Rule 12(b)(6) motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Twombly, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id. (quoting Twombly, 550 U.S. at 557). Accordingly, dismissal for failure to state a claim is proper where the claim "lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1104 (9th Cir. 2008).

In reviewing a Rule 12(b)(6) motion to dismiss, a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the plaintiff. See Retail Prop. Trust v. United Bhd. of Carpenters & Joiners of Am., 768 F.3d 938, 945 (9th Cir. 2014). But, a court need not accept "legal conclusions" as true. Ashcroft

v. Iqbal, 556 U.S. 662, 678 (2009). Further, it is improper for a court to assume the plaintiff "can prove facts which it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983).

B. Standards for Patent Eligibility under § 101

Section 101 of the Patent Act defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has "'long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.'" Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013). "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).

"The Supreme Court has devised a two-stage framework to determine whether a claim falls outside the scope of section 101." Affinity Labs of Texas, LLC v. DIRECTV, LLC, 838 F.3d 1253, 1257 (Fed. Cir. 2016); see Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014). "The prescribed approach requires a court to determine (1) whether the claim is directed to a patent-ineligible concept, i.e., a law of nature, a natural phenomenon, or an abstract idea, and if so, (2) 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." Affinity Labs, 838 F.3d at 1257 (internal quotation marks omitted) (citing Alice, 134 S. Ct. at 2355).

The first step of the Alice 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." Id. at 1257. "The [second] step requires [courts] to look with more specificity at what the claim elements add, in order to determine 'whether they identify an "inventive concept" in the application of the ineligible subject matter' to which

the claim is directed. Id. at 1258. "This inventive concept must do more than simply recite 'well-understood, routine, conventional activity.'" FairWarning IP, LLC v. Iatric Sys., Inc., 839 F.3d 1089, 1093 (Fed. Cir. 2016). "The accused infringer bears the burden of proof on both steps." InsideSales.com, Inc. v. SalesLoft, Inc., No. 2:16CV859DAK, 2017 WL 2559932, at *2 (D. Utah June 13, 2017); see Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

The Federal Circuit 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]."[2] Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1373 (Fed. Cir. 2016); see, e.g., Amdocs, 841 F.3d at 1293 (reviewing eligibility under § 101 on an appeal from a grant of judgment on the pleadings under Rule 12(c)); see also 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."). Further, the Federal Circuit has explained that where there is "no claim construction dispute relevant to the eligibility issue," evaluation of a patent claim's subject matter eligibility under § 101 can proceed before claim construction.[3] Genetic Techs., 818

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[2] Plaintiff criticizes Defendants for failing to present any scientific evidence in support of their assertion that the patents-in-suit are invalid under § 101. (16-cv-2146-Doc. No. 85 at 1, 21; 16-cv-2343-Doc. No. 59 at 1, 21.) But there is no requirement that an accused infringer must submit extrinsic scientific evidence in order to attack the validity of a patent under § 101. Indeed, it is possible and proper for an accused infringer to attack the validity of a patent under § 101 through a Rule 12(b)(6) or a Rule 12(c) motion. See Genetic Techs., 818 F.3d at 1373; see, e.g., Amdocs, 841 F.3d at 1293.

In addition, Plaintiff cites to a district court decision holding that "[r]arely can a patent infringement suit be dismissed at the pleading stage for lack of patentable subject matter." Bristol-Myers Squibb Co. v. Merck & Co., No. CV 15-560-GMS, 2016 WL 1072841, at *1 (D. Del. Mar. 17, 2016). (16-cv-2146-Doc. No. 85 at 12; 16-cv-2343-Doc. No. 59 at 12.) The Court does not find Plaintiff's citation to this district court decision persuasive as it was issued prior to and is contrary to the Federal Circuit's decision in Genetic Techs.

[3] In its opposition, Plaintiff argues that there are claim construction disputes between the parties and provides several proposed claim constructions for terms in the patents-in-suit. (16-cv-2146-Doc. No. 85 at 7, 13-15, 21; 16-cv-2343-Doc. No. 59 at 7-8, 13-15, 21.) Plaintiff argues, therefore, that the Court should not resolve the § 101 eligibility issues in the cases until after claim construction. (16-cv-2146-

F.3d at 1373; see Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352, 1360 (Fed. Cir. 2017) ("[W]e have repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced."); see also Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.), 687 F.3d 1266, 1273 (Fed. Cir. 2012) ("[C]laim construction is not an inviolable prerequisite to a validity determination under § 101.").

II. Analysis

Defendants Creative Compounds and Hi-Tech argue that Plaintiff's claims for patent infringement should be dismissed with prejudice because the patents-in-suit fail to claim patent-eligible subject matter and, thus, are invalid under 35 U.S.C. § 101. (16-cv-2146-Doc. No. 83-1 at 6-14; 16-cv-2343-Doc. No. 57-1 at 6-14.) In response, Plaintiff argues that the patents-in-suit are directed to patent-eligible subject matter. (16-cv-2146-Doc. No. 85 at 9-21; 16-cv-2343-Doc. No. 59 at 9-21.)

A. The '084 Patent, the '947 Patent, the '376 Patent, and the '596 Patent

In the related case Natural Alternatives International, Inc. v. Allmax Nutrition, Inc., No. 3:16-v-01764-H-AGS, this Court held that the '084 patent, the '947 patent, the '376 patent, and the '596 patent are all invalid under 35 U.S.C. § 101 for claiming ineligible subject matter, and the Court dismissed Plaintiff's claims for patent infringement in that case with prejudice. (16-cv-1764-Doc. No 64 at 10-21, 23.) In addition, the Court denied Plaintiff's motion for reconsideration of that order. (16-cv-1764-Doc. No. 73.)

Defendant Creative Compounds argues that in light of the Court's order in Case No 16-cv-1764, the Court should grant its motion and hold that the '084 patent, the '596 patent, and the '376 patent are invalid under § 101 in its case. (16-cv-2146-Doc. No. 83-1 at 6.)

Doc. No. 85 at 12; 16-cv-2343-Doc. No. 59 at 12.) Defendants argue that the patents-in-suit are invalid under § 101 even if the Court accepts Plaintiff's proposed claim constructions. (16-cv-2146-Doc. No. 86 at 3; 16-cv-2343-Doc. No. 60 at 3.) 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. See Genetic Techs., 818 F.3d at 1373.

Defendant Hi-Tech also argues that in light of the Court's order in Case No. 16-cv-1764, the Court should grant its motion and hold that the '084 patent, the '947 patent, and the '596 patent are invalid under § 101 in its case. (16-cv-2343-Doc. No. 57-1 at 6.) In response, Plaintiff NAI argues that these patents are valid and incorporates by reference its briefing from Case No. 16-cv-1764, specifically its opposition to the Defendants' Alice motions and its motion for reconsideration that it filed in that case. (16-cv-2146-Doc. No. 85 at 12-13; 16-cv-2343-Doc. No. 59 at 13.)

The Court holds that the '084 patent, the '947 patent, the '376 patent, and the '596 patent are all invalid under 35 U.S.C. § 101 for claiming ineligible subject matter, and the Court incorporates by reference the analysis set forth in its June 26, 2017 order and its August 28, 2017 order in Case No. 16-cv-1764. (16-cv-1764-Doc. Nos. 64, 73.) In addition, the Court sets forth that analysis below.

i. The '084 Patent

Claim 1 of the '084 patent[4] claims: "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." U.S. Patent No. 7,925,084 at 22:26-29 (filed Nov. 2, 2010). The Court begins its analysis of this claim with step one of the

[4] In analyzing the validity of patents-in-suit under § 101, Defendants primarily focus on certain claims and argue that a § 101 validity analysis can be performed based on representative claims. (16-cv-1764-Doc. No. 44-1 at 10-11; 16-cv-2146-Doc. No. 83-1 at 5-6; 16-cv-2343-Doc. No. 57-1 at 5-6.) In opposing Defendants' motions, Plaintiff does not contest this specific assertion by Defendants or Defendants' use of representative claims in their § 101 analysis, and Plaintiff's own § 101 analysis also utilizes representative claims. (See 16-cv-1764-Doc. No. 56 at 18-22; 16-cv-2146-Doc. No. 8 at 13-21; 16-cv-2343-Doc. No. 59 at 13-21) Accordingly, in evaluating the validity of these patents under § 101, the Court will focus on claim 1 of the '084 Patent, claim 1 of the '596 patent, claim 34 of the '947 patent, claim 6 of the '376 patent, claim 1 of the '865 patent, and claim 1 of the '610 patent as representative claims. Cf. Cleveland Clinic, 859 F.3d at 1360 ("Where, as here, the claims 'are substantially similar and linked to the same' law of nature, analyzing representative claims is proper."); Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (explaining that the district court "correctly determined that addressing each claim of the asserted patents was unnecessary" because "all the claims are 'substantially similar and linked to the same abstract idea'" and, thus, the district court properly used representative claims in its § 101 analysis).

Alice inquiry. "The step one inquiry focuses on determining 'whether the claim at issue is 'directed to' a judicial exception, such as an abstract idea.'" Apple, Inc. v. Ameranth, Inc., 842 F.3d 1229, 1241 (Fed. Cir. 2016). This 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." Affinity Labs, 838 F.3d at 1257.

Here, claim 1 of the '084 patent claims a human dietary supplement containing beta-alanine in a unit dosage of 0.4 to 16 grams. Beta-alanine is the only ingredient of the supplement referenced in the language of claim 1. See '084 Patent at 22:26-29. Thus, beta-alanine is the focus of the claim.[5] In its specification, the '084 patent explains that beta-alanine is an amino acid, id. at 3:3-6, and is "present in the muscles of humans and other vertebrates." Id. at 2:21-26; see id. at 8:49-53 ("These precursors[, beta-alanine and L-histidine], can be generated within the body or are made available via the diet."). (See also 16-cv-1764-Doc. No. 11, FAC ¶ 12; Doc. No. 56 at 16.) Thus, the '084 patent acknowledges that beta-alanine is a natural occurring phenomenon.[6] Accordingly, claim 1 of '084 patent is directed to excluded subject matter – specifically beta-alanine, a natural

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[5] That beta-alanine is the focus of the claimed invention is also supported by language in the '084 Patent's specification. In describing the invention, the specification explains:

> The invention provides methods of increasing anaerobic working capacity in a tissue, comprising the following steps: (a) providing a beta-alanylhistidine dipeptide and a glycine, an insulin, an insulin mimic, or an insulin-action modifier; and (b) administering the beta-alanine and at least one of the glycine, insulin mimic, or insulin-action modifier to the tissue in an amount effective to increase beta-alanylhistidine dipeptide synthesis in the tissue, thereby increasing the anaerobic working capacity in the tissue.

'084 Patent at 2:45-53. Here, the specification describes the invention as being directed to providing and administering beta-alanine along with another substance in order to increase the anaerobic working capacity in tissue.

[6] In light of this, the Court does not find persuasive Plaintiff's reliance on Rutgers v. Qiagen N.V., No. 15CV7187PGSLHG, 2016 WL 828101 (D.N.J. Feb. 29, 2016). (16-cv-1764-Doc. No. 56 at 17.) In that case, the district court found it at least plausible that the claimed invention "uses artificial conditions that do not occur in nature." Rutgers, 2016 WL 828101, at *3. In contrast, here, the specification of the '084 patent provides that beta-alanine occurs naturally within the human body.

phenomenon – thereby satisfying step one of the Alice inquiry. See, e.g., Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376 (Fed. Cir. 2015), cert. denied, 136 S. Ct. 2511 (2016) (finding step one of the Alice inquiry satisfied where the claims were directed to cffDNA, a naturally occurring phenomenon).

Plaintiff argues that a human dietary supplement containing beta-alanine is not a natural phenomenon, and, therefore, the claim is directed to patent-eligible subject matter. (16-cv-1764-Doc. No. 56 at 17-18, 19-20, 21-22.) But in making this argument, Plaintiff misconstrues the step one analysis for determining subject matter eligibility under § 101. Step one of the § 101 inquiry does not simply look to whether the overall claimed invention is itself a natural phenomenon. Rather, step one of the inquiry requires a court to look at what the claim is specifically directed to and whether what it is directed to is a natural phenomenon, law of nature, or abstract idea. See Affinity Labs, 838 F.3d at 1257. For example, a computer is a physical machine and is not itself an abstract idea. Nevertheless, in Alice, the Supreme Court found that the claims at issue were directed to an abstract idea – specifically, "the concept of intermediated settlement" – even though all of the claims were implemented using a computer. See 134 S. Ct. at 2352-53, 2355; see also id. at 2358 ("The fact that a computer 'necessarily exist[s] in the physical, rather than purely conceptual, realm,' is beside the point."). Similarly, here, claim 1 is directed to the natural phenomenon beta-alanine even though the claim is implemented using a "human dietary supplement."[7] Because claim 1 is directed to a natural phenomenon, the Court will now

[7] Plaintiff also argues that when beta-alanine is isolated from the dipeptide, carnosine, beta-alanine has different properties than carnosine. (16-cv-1764-Doc. No. 56 at 22-23.) But even assuming Plaintiff is correct and this is true, this fact does not alter the Court's § 101 analysis. In Myriad, the Supreme Court rejected the argument that the claims at issue were "saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2118 (2013); see In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 760 (Fed. Cir. 2014). Similarly, here, the Court rejects Plaintiff's contention that isolating beta-alanine from carnosine is sufficient to render the claims subject matter eligible and not directed to a natural phenomenon. Further, the Court notes that the specification explains that beta-alanine itself, not just carnosine, "can be generated within the body." '084 Patent at 8:49-53.

turn to step two of the Alice inquiry.

In step two, the reviewing court "examine[s] the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application." Cleveland Clinic, 859 F.3d at 1361. The 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. at 1361-62. Further, the inventive concept contained in the claim "must do more than simply recite 'well-understood, routine, conventional activity.'" FairWarning IP, 839 F.3d at 1093; see Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1313 (Fed. Cir. 2016) ("'[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 activit[ies]' previously engaged in by workers in the field, is not sufficient to supply the inventive concept.").

Here, the inventive concept described in claim 1 of the '084 patent is placing a specific dosage of beta-alanine into a human dietary supplement. See '084 Patent at 22:26-29. The '084 patent acknowledges that placing a natural substance into a dietary supplement to increase the function of tissues is conventional activity. The background section of the specification of the '084 patent provides:

> Natural 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. It can be particularly important to supplement the diets of particular classes of animals whose normal diet may be deficient in nutrients available only from meat and animal products . . . .

Id. at 1:37-44. 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."[8] See, e.g., Ariosa, 788 F.3d at 1377 (holding that utilizing routine and conventional methods for amplifying and detecting cffDNA, a natural phenomenon, was insufficient to render the claims at issue patent eligible); Alice, 134 S. Ct. at 2357-58 (holding that the introduction of a general-purpose computer to implement an abstract idea was insufficient to render the claims at issue patent eligible); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 78-82 (2012) (finding the well understood, 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). Accordingly, representative claim 1 of the '084 patent is directed to patent-ineligible subject matter, and, thus, is invalid under 35 U.S.C. § 101.

Plaintiff argues that the inventive concept of the patents-in-suit is to "unnaturally over-supplement the normal/natural level of beta-alanine in the diet of an individual over time to force an override [in] the homeostatic nature of the individual's muscle tissue to achieve an unnatural high level of carnosine synthesis." (16-cv-1764-Doc. No. 67-1 at 14; accord 16-cv-2146-Doc. No. 85 at 1-2; 16-cv-2343-Doc. No. 59 at 1.) Further, Plaintiff has provided the Court with evidence and proposed claim constructions in support of its proposed inventive concept. (16-cv-1764-Doc. No. 67-1 at 4-6, 9-12, 17-18; 16-cv-2146-Doc. No. 85 at 2, 5, 14-18; 16-cv-2343-Doc. No. 59 at 2, 5-6, 14-18.) But even assuming Plaintiff is correct, this inventive concept would still be insufficient to render the patents-in-suit subject matter eligible under § 101. This inventive concept as described by Plaintiff

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[8] Plaintiff proposes that the term "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." (16-cv-1764-Doc. No. 56 at 20-21; Doc. No. 67-1 at 17.) Plaintiff also proposes that the term "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." (16-cv-2146-Doc. No. 85 at 5; 16-cv-2343-Doc. No. 59 at 5.) Even if a "human dietary supplement/dietary supplement" is itself not a natural or conventional food, that fact does not alter the specification's disclosure that placing a natural substance into a human dietary supplement to increase the function of tissues when consumed is conventional activity.

still only describes a natural law: the relationship between beta-alanine in an individual's diet with the carnosine synthesis that occurs in the individual's tissue. Plaintiff contends that if the patents are directed to achieving an unnaturally high level of carnosine synthesis, then the patents are not directed to a natural law and are subject matter eligible. (16-cv-1764-Doc. No. 67-1 at 14-15.) Plaintiff is wrong. Even if the patents-in-suit relate to achieving an unnaturally high level of carnosine synthesis, the relationship between beta-alanine supplements in one's diet and the achievement of an unnaturally high level of carnosine synthesis is still a natural process that exists in principle apart from any human action and, thus, is a natural law.

The Supreme Court's decision in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012) is instructive on this point. In Mayo, the Supreme Court found the patents at issue invalid under § 101 because they merely set forth laws of nature. See id. at 78-82. The Supreme Court explained: "Prometheus' patents set forth laws of nature—namely, 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. Similarly, here, Plaintiff's proposed inventive concept merely sets forth a law of nature—the relationship between a diet containing beta-alanine supplements and the level of carnosine synthesis in the individual's tissue. In Mayo, the Supreme Court further explained:

> While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

Id. Similarly, here, while it takes some human action (the incorporation of a beta-alanine supplement into one's diet) to trigger the high level of carnosine synthesis in a particular person, "the relation itself exists in principle apart from any human action." Id. The relation is a consequence of the ways in which the body reacts to the beta-alanine

supplements an "entirely natural process[]. And so a patent that simply describes that relation sets forth a natural law." Id. Thus, Plaintiff's own description of the inventive concept of the patents-in-suit is insufficient to render the claims at issue subject matter eligible under § 101.

Plaintiff further argues that the patents-in-suit disclose a new and useful method of increasing the amount of carnosine in muscles. (16-cv-1764-Doc. No. 56 at 16.) But even assuming this is true, this also is insufficient to render the claims at issue patent eligible. The Supreme Court has explained that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Myriad, 133 S. Ct. at 2117; see 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 in 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.").

Finally, Plaintiff argues that the claimed invention of providing beta-alanine in effective amounts to a human does not preempt the natural law of regulating hydronium ion concentration in human tissue. (16-cv-1764-Doc. No. 56 at 18-19, 21-22.) But the Federal Circuit has explained that "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." Ariosa, 788 F.3d at 1379. "Where a patent's claims are deemed only to disclose patent ineligible subject matter under the Mayo[/Alice] framework, . . . preemption concerns are fully addressed and made moot." Id.; accord Cleveland Clinic, 859 F.3d at 1363. Thus, any potential preemption concerns are fully addressed through the Court's analysis of the patents-in-suit under the two-step Alice framework. See id. Under that framework, representative claim 1 of the '084 patent only discloses patent ineligible subject matter and,

thus, is invalid under § 101.[9]

ii. The ’947 Patent

Claim 34 of the ’947 patent claims:

> 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,

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[9] Plaintiff also argues that the Court should consider and apply certain PTO guidance regarding claim construction and subject matter eligibility. (16-cv-1764-Doc. No. 67-1 at 18-21; Doc. No. 71 at 9-10.) The Court notes that "[PTO] Guidance 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))); see Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002). The Court has reviewed the cited guidance, and the Court does not find it persuasive.

With respect to the guidance regarding subject matter eligibility, Plaintiff cites to two claim examples set forth in the PTO's December 16, 2014 "Nature-Based Products" guidance. (16-cv-1764-Doc. No. 67-1 at 19-20.) The two examples claim methods of administering amazonic acid, a natural substance, to a human to treat cancer. See Nature-Based Products 3 (Dec. 16, 2014), https://www.uspto.gov/sites/default/files/documents/mdc_examples_nature-based_products.pdf. The PTO guidance states that the two claims are subject matter eligible under § 101, but in explaining why this is so, the guidance states: "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.) This absence of preemption rationale for finding a claim subject matter eligible under § 101 has subsequently been rejected by the Federal Circuit in Ariosa and in Cleveland Clinic. See Ariosa, 788 F.3d at 1379; Cleveland Clinic, 859 F.3d at 1363. Indeed, in its most recent guidance on subject matter eligibility, the PTO has acknowledged that "while a preemptive claim may be ineligible, the absence of complete preemption does not demonstrate that a claim is eligible." May 2016 Subject Matter Eligibility Update 7 (May 4, 2016), https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf. Further, the Nature-Based Products guidance contains no explanation of why the two claims are eligible under Myriad in light of Mayo. Indeed, the guidance does not contain any reference at all to the Supreme Court's decision in Mayo. Accordingly, the Court does not find the two examples set forth in the PTO guidance persuasive. Supreme Court and Federal Circuit precedent, not PTO guidance, is binding on this Court. As explained above, under Supreme Court precedent – in particular Mayo and Myriad – and Federal Circuit precedent – in particular Ariosa and Cleveland Clinic – claim 1 of the ’084 patent is invalid under § 101.

Further, the PTO guidance regarding claim construction is not persuasive because the PTO "is required to use a different standard for construing claims than that used by district courts." In re Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1369 (Fed. Cir. 2004). The PTO utilizes the "broadest reasonable interpretation" standard. See id. at 1364; Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2142 (2016). As Plaintiff itself acknowledges, this standard is different from and broader than the claim construction standard utilized by district courts. (See 16-cv-1764-Doc. No. 56 at 23 ("the BRI is a broader standard than that utilized by the courts").) See Am. Acad. of Sci. Tech Ctr., 367 F.3d at 1369.

> 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.

U.S. Patent No. RE45,947 at 16:1-11 (filed Mar. 29, 2016). The Court begins its analysis of this claim with step one of the Alice inquiry. Claim 34 claims a human dietary supplement containing a mixture of beta-alanine, creatine, and a carbohydrate.[10] Beta-alanine is a naturally occurring phenomenon. See '947 Patent at 2:9-15, 5:21-25. In addition, the specification of the '947 patent discloses that creatine is also a naturally occurring phenomenon. See id. at 1:50-55 ("Creatine . . . is found in large amounts in skeletal muscle and other 'excitable' tissues (e.g., smooth muscle, cardiac muscle, or spermatozoa) . . . ."). Further, a carbohydrate is also a naturally occurring phenomenon. See id. at 3:33-34, 5:61-63, 6:57-58. Thus, claim 34 is directed to excluded subject matter, specifically the natural phenomena of beta-alanine, creatine, and carbohydrates. See, e.g., Ariosa, 788 F.3d at 1376. Accordingly, step one of the Alice inquiry is satisfied, and the Court will turn to step two.

In Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130-31 (1948), the Supreme Court held that mixing different natural phenomena together – specifically, in that case different bacterial species – is insufficient to render an invention patent eligible even though it was not previously known that the substances could be mixed together, and that the combination provided certain advantages. Thus, in the present case, mixing beta-alanine, a natural phenomenon, with a carbohydrate and creatine, two other natural phenomena, and placing that mixture in a human dietary supplement to increase the function of tissues, a conventional activity, is insufficient to render claim 34 patent eligible. See id. Accordingly representative claim 34 of '947 patent is directed to patent-ineligible

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[10] The Court notes that claim 34 of the '947 patent is similar to claim 1 of '084 patent, except that claim 34 of the '947 also includes creatine and a carbohydrate in the dietary supplement. Accordingly, the Court's analysis as to the eligibility of claim 1 of the '084 patent also applies to its analysis of claim 34 of the '947 patent.

subject matter, and, thus, is invalid under 35 U.S.C. § 101.

iii. The '376 Patent

Claim 6 of the '376 Patent is dependent from Claim 5 which is dependent from Claim 1. Those three claims provide:

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

U.S. Patent No. 7,504,376 at 22:27-47 (filed Mar. 17, 2009). The Court begins its analysis of this claim with step one of the Alice inquiry. Claim 6 of the '376 patent claims a human dietary supplement containing a mixture of beta-alanine and glycine.[11] Beta-alanine is a naturally occurring phenomenon. See '376 Patent at 2:15-20, 8:51-55. In addition, the specification of the '376 patent discloses that glycine is also a naturally occurring phenomenon.[12] See id. at 1:56-61, 6:1-5. Thus, claim 6 is directed to excluded subject

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[11] The Court notes that claim 6 of the '376 patent is similar to claim 34 of the '947 patent except that the dietary supplement claimed in claim 6 of the '376 patent contains a mixture of beta-alanine and glycine, rather than beta-alanine, creatine, and a carbohydrate. Accordingly, the Court's analysis as to the eligibility of claim 1 of the '084 patent and claim 34 of the '947 patent also applies to its analysis of claim 6 of the '376 patent.

[12] Plaintiff argues that the term "glycine" in claim 6 should be construed to include glycine from other sources, i.e., non-natural sources. (16-cv-1764-Doc. No. 56 at 20 (citing '376 Patent at 6:8-11).) But even assuming Plaintiff is correct, and the term "glycine" in claim 6 encompasses both non-natural and natural glycine, that would still mean that natural glycine, a naturally occurring phenomenon, would

matter, specifically beta-alanine, a natural phenomenon, and glycine, a natural phenomenon. See, e.g., Ariosa, 788 F.3d at 1376. Accordingly, step one of the Alice inquiry is satisfied, and the Court will turn to step two.

Under the Supreme Court's decision in Funk Bros., mixing beta-alanine, a natural phenomenon, with glycine, a natural phenomenon, and placing that mixture in a human dietary supplement to increase the function of tissues, a conventional activity, is insufficient to render claim 6 patent eligible. See Funk Bros., 333 U.S. at 130-31. Accordingly representative claim 6 of '376 patent is directed to patent-ineligible subject matter, and, thus, is invalid under 35 U.S.C. § 101.

iv. The '596 Patent

Claim 1 of the '596 patent claims:

> 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.

U.S. Patent No. 5,965,596 at 14:66-15:6 (filed Oct. 12, 1999). The Court begins its analysis of this claim with step one of the Alice inquiry. Claim 1 of the '596 patent claims a method of regulating hydronium ion concentrations in human tissue by provided the amino acid beta-alanine to human tissue via blood or blood plasma thereby increasing the carnosine content in the tissue. See id. (Doc. No. 56 at 18.) The Court agrees with Defendants that

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be included with the scope of claim 6. Further, as Defendants correctly note, Plaintiff has failed to identify any meaningful difference between glycine derived from other sources and natural glycine. (16-cv-1764-Doc. No. 59 at 9.) In In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 760 (Fed. Cir. 2014), the Federal Circuit held that claims directed to DNA primers were ineligible under § 101 even though the primers "are synthetically replicated" because the primers "are structurally identical to the ends of DNA strands found in nature." Thus, without Plaintiff identifying some meaningful difference between natural glycine and synthetic glycine, the fact that the claimed glycine might be derived from other sources is insufficient to render claim 6 patent eligible.

this claim is directed to a law of nature, specifically the principle 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.[13] See Mayo, 566 U.S. at 77 (finding that the claims at issue were directed to laws of nature); Genetic Techs., 818 F.3d at 1374-76; see also Ariosa, 788 F.3d 1at 1376 ("The method therefore begins and ends with a natural phenomenon."). Accordingly, because claim 1 of the '596 patent is directed to a law of nature, the Court will now turn to step two of the Alice inquiry.

Turning to step two of the Alice inquiry, the elements contained in claim 1 of '596 patent do not disclose an inventive concept sufficient to transform the claimed law of nature into a patent-eligible application. The Court agrees with Defendants that the language in claim 1 does nothing more than simply state the law of nature and add the words apply it to human tissue. Specifically, the language in claim 1 simply acknowledges the natural law that providing beta-alanine to human tissue will increase the carnosine concentration in the tissue and aid in regulating hydronium ion concentration, and then merely instructs to do so. This is insufficient to render the claim patent-eligible. 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."). In sum, representative claim 1 of the '596 patent is directed to patent-ineligible subject matter, and, thus, is invalid under 35 U.S.C. § 101.

B. The '865 Patent

Claim 1 of the '865 patent claims:

> 1. A method of increasing anaerobic working capacity in a human subject, the method comprising:

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[13] This law of nature is disclosed in the specification of the '596 patent. See '596 Patent at 2:10-13, 4:58-5:45.

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.

U.S. Patent No. 8,470,865 at 22:56-23:5 (filed Jun. 25, 2013). The Court begins its analysis of this claim with step one of the Alice inquiry. Claim 1 of the '865 patent is similar to Claim 1 of the '596 patent. Claim 1 of the '865 patent claims a method of increasing the anaerobic working capacity in a human by providing the human with an amount of beta-alanine via a dietary supplement effective to increase the carnosine concentration in the human's tissue. See id. Thus, this claim is directed to a law of nature, specifically the principle 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.[14] See Mayo, 566 U.S. at 77 (finding that claims at issue were directed to laws of nature); Genetic Techs., 818 F.3d at 1374-76; see also Ariosa, 788 F.3d 1at 1376 ("The method therefore begins and ends with a natural phenomenon."). Accordingly, because claim 1 of the '865 patent is directed to a law of nature, the Court will now turn to step two of the Alice inquiry.

Turning to step two of the Alice inquiry, the elements contained in claim 1 of '865

[14] This law of nature is disclosed in the specification of the '865 patent. See '865 Patent at 2:42-44; 8:27-9:27.

patent do not disclose an inventive concept sufficient to transform the claimed law of nature into a patent-eligible application. The language in claim 1 of does nothing more than simply state the relevant law of nature and add the words apply it to human tissue. Specifically, the language in claim 1 simply acknowledges the natural law that providing a certain amount of beta-alanine to human tissue will increase the concentration in the tissue and, thereby, increase the anaerobic working capacity in the human, and then merely instructs to do so by administering the beta-alanine. This is insufficient to render the claim patent-eligible. 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 language does specify that the beta-alanine is administered via a "dietary supplement." '865 Patent at 23:4-5. But the specification of the '865 patent discloses that placing a natural substance into a dietary supplement to increase the function of tissues when consumed is conventional activity. See id. at 1:9-12. Thus, the language in claim 1 of the '865 patent requiring that the beta-alanine be administered via a dietary supplement is insufficient to render the claims at issue patent eligible even accepting Plaintiff's proposed construction for the term "dietary supplement." See, e.g., Ariosa, 788 F.3d at 1377 (holding that utilizing routine and conventional methods for amplifying and detecting cffDNA, a natural phenomenon, was insufficient to render the claims at issue patent eligible); Alice, 134 S. Ct. at 2357-58 (holding that the introduction of a general-purpose computer to implement an abstract idea was insufficient to render the claims at issue patent eligible); Mayo, 566 U.S. at 78-82 (finding the well understood, 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). In sum, representative claim 1 of the '865 patent is directed to patent-ineligible subject matter, and, thus, is invalid under 35 U.S.C. § 101.

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C. The ’610 Patent

Claim 1 of the ’610 patent claims:

> 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.

U.S. Patent No. 8,993,610, at 22:24-37 (filed Mar. 31, 2015). The Court begins its analysis of this claim with step one of the Alice inquiry. Claim 1 of the ’610 patent claims using beta-alanine in the manufacturing of a dietary supplement, where the dietary supplement is to be used for increasing carnosine concentration in human tissue. See id. Claim 1 of the ’610 patent, like the other claims at issue, 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.[15] See Mayo, 566 U.S. at 77 (finding that claims at issue were directed to laws of nature); Genetic Techs., 818 F.3d at 1374-76; Ariosa, 788 F.3d at 1376 (“The method therefore begins and ends with a natural phenomenon.”).

Plaintiff argues that claim 1 of the ’610 patent is directed to a method of manufacture and not a natural phenomenon and, therefore, is subject matter eligible. (16-cv-2146-Doc.

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[15] The specification of the ’610 patent acknowledges that beta-alanine is a natural phenomenon. See ’610 Patent at 2:24-30, 3:6-9, 8:49-53. The specification of the ’610 patent also discloses the law of nature that ingesting certain levels of beta-alanine will increase the carnosine concentration in human tissue. See id. at 2:42-44, 8:27-9:23.

No. 85 at 19-20; 16-cv-2343-Doc. No. 59 at 19-20.) The Court disagrees. Although the claim is drafted as a method of manufacturing a dietary supplement, the focus of the claim language and what it is specifically directed to is the natural phenomenon beta-alanine and the natural law that ingesting certain levels of beta-alanine will increase the carnosine concentration in human tissue. Step one of the Alice 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." Affinity Labs, 838 F.3d at 1257. 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. See '610 patent at 1:32-36, 2:48-63, 8:27-9:23. The '610 patent does not focus any claimed advancements related to the manufacture of dietary supplements. Thus, under the Alice step one inquiry, claim 1 of the '610 patent is directed to excluded subject matter, a natural law and a natural phenomenon. See Affinity Labs, 838 F.3d at 1257. Accordingly, because claim 1 of the '610 patent is directed to a natural phenomenon and a law of nature, the Court will now turn to step two of the Alice inquiry.

Turning to step two of the Alice inquiry, the elements contained in claim 1 of '610 patent do not disclose an inventive concept sufficient to transform the claimed law of nature/natural phenomenon into a patent-eligible application. The elements of claim 1 of the '610 patent describe using beta-alanine in the manufacturing of a dietary supplement, where the dietary supplement is to be used for increasing carnosine concentration in human tissue. See '610 Patent at 22:24-37. The specification of the '610 patent discloses that placing a natural substance into a dietary supplement to increase the function of tissues when consumed is conventional activity. See id. at 1:41-44. Further, the specific manufacturing steps disclosed in claim 1 of the '610 patent merely require: (1) "supplying the beta-alanine;" or (2) "mixing the beta-alanine" with some undisclosed "other ingredient." Id. Utilizing conventional activity "'specified at a high level of generality'" is insufficient to render claim 1 of the '610 patent eligible. Intellectual Ventures I, 838

F.3d at 1313; see Ariosa, 788 F.3d at 1377 (holding that utilizing routine and conventional methods for amplifying and detecting cffDNA, a natural phenomenon, was insufficient to render the claims at issue patent eligible); Mayo, 566 U.S. at 78-82 (finding the well understood, 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). In sum, representative claim 1 of the '610 patent is directed to patent-ineligible subject matter, and, thus, is invalid under 35 U.S.C. § 101.

D. 35 U.S.C. § 101 Conclusion

In sum, the '084 patent, the '947 patent, the '376 patent, the '596 patent, the '865 patent, and the '610 patent claim ineligible subject matter and, thus, are invalid under 35 U.S.C. § 101.[16] Accordingly, the Court grants Defendants' motions for judgment on the pleadings, and the Court dismisses Plaintiff's claims for patent infringement with prejudice.

Conclusion

For the reasons above, the Court grants Defendants' Rule 12(c) motions for judgment on the pleadings. Accordingly, the Court dismisses Plaintiff's claims for patent infringement with prejudice. The cases will proceed on Plaintiff's remaining claims.

IT IS SO ORDERED.

DATED: September 5, 2017

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT

[16] Plaintiff argues that if the Court invalidates the patents-in-suit on § 101 grounds, it would represent a tectonic shift in the law. (16-cv-1764-Doc. No. 67-1 at 21-22; 16-cv-2146-Doc. No. 85 at 3; 16-cv-2343-Doc. No. 59 at 3.) The Court disagrees. The Court's § 101 analysis simply follows Supreme Court and Federal Circuit precedent regarding subject matter eligibility under 35 U.S.C. § 101.