United States District Court,
E.D. Texas, Lufkin Division.

IOVATE HEALTH SCIENCES, INC., University of Florida Research Foundation, Inc. and Flamma Spa,
Plaintiffs.
v.
BIO-ENGINEERED SUPPLEMENTS & NUTRITION, INC., d/b/a BSN Inc. and Medical Research Institute,
Defendants.

Civil Action No. 9:07-CV-46

June 5, 2008.

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MEMORANDUM OPINION AND ORDER CONSTRUING CLAIM TERMS OF UNITED STATES PATENT NOS. 5,973,199 ***and*** 6,100,287 (PART II)

RON CLARK**, District Judge.**

Plaintiffs Iovate Health Sciences, Inc. and University of Florida Research Foundation, Inc. FN1 filed suit against Defendants Bio-Engineered Supplements & Nutrition, Inc., d/b/a BSN Inc., and Medical Research Institute, claiming infringement of U.S. Patent Nos. 5,973,199 ("the '199 patent") and 6,100,287 ("the '287 patent"). In its Memorandum Opinion and Order of March 28, 2008, the court previously construed the disputed terms in the ' 199 patent. *See* Doc. # 137. Section I, "Claim Construction Standard of Review," and Section II, "Patent Background and Technology," of the March 28 Order are incorporated into this Order by reference. Having carefully considered the patents, the prosecution history, the parties' briefs, and the statements of the parties' counsel and experts, the court now construes the disputed terms in the ' 287 patent. FN2

FN1. A third Plaintiff, Flamma SpA was dismissed from the suit on October 4, 2007, after it sold all of its rights, title, and interest in the '199 patent to Iovate. *See* Doc. # 56.

FN2. To become familiar with the principles of biochemistry underlying both patents from the perspective

of one skilled in the art, and to help the court understand the technical basis for the conflicting opinions of the parties' experts, the court appointed a technical advisor, Dr. Richard Gomer [Docs. # 112, 114]. Dr. Gomer received his PhD in Biology at Caltech, followed by five years of postdoctoral training at the University of California, San Diego. He is a Professor in the Biochemistry & Cell Biology Department at Rice University in Houston, Texas, and has authored or co-authored over one hundred publications. For further information on his qualifications and experience, *see* http:// biochem.rice.edu/facultydetail new.cfm? riceid=920.

DISPUTED TERMS IN THE '287 PATENT

The first four disputed terms are found in claim 1 of the '287 patent, which reads as follows:

A method for **enhancing muscle performance or recovery from fatigue,** wherein said method comprises **administering** a composition comprising a **ketoacid** and an **amino acid** wherein said amino acid is cationic or dibasic FN3.

FN3. The parties agree that "wherein said amino acid is cationic or dibasic" means "the amino acid has a net positive charge or contains two basic groups." Tr. at p. 112, l. 23-p. 113, l. 8.

1. "Enhancing muscle performance or recovery from fatigue." '287 patent**, claim 1.**

At the hearing, all the parties agreed that "enhancing" means "increasing," Tr. at p. 113, ll. 9-23, and that "enhancing muscle performance," means "increasing the ability of muscle to maintain required or expected force or power output." Tr. at p. 115, l. 3-p. 117, l. 9.

For the remainder of the term, Iovate suggests that "enhancing ... recovery from fatigue" means "increasing resistance to exercise-induced fatigue. BSN argues that no construction is necessary, but in the event that the court does construe the term, B SN proposes "increasing athletic dynamic muscle strength and the ability to sustain muscle work by decreasing muscle absolute fatigue while retarding the rate of muscle fatigue or increasing recovery of dynamic muscle function from fatigue." For "recovery from fatigue," MRI suggests "expediting the complete return of an exerted muscle to a normal, unfatigued state after acute exhaustive anaerobic strength training exercise." The parties agreed at the hearing that in light of the construction of "enhancing muscle performance," the concept of resistance or endurance Iovate sought to include in the construction of "enhancing muscle recovery from fatigue," was redundant and need not be incorporated. Tr. at p. 126, l. 18-p. 127, l. 9.

Iovate's construction does not address the concept of "recovery" found in this term. "Recovery" is first referred to in the '287 patent at col. 1, ll. 37-46. This section references the article by Baker *et al,* "Slow force recovery after long-duration exercise: metabolic and activation factors in muscle fatigue," *J. Appl. Physiol*. 74:2294-2300 (1993), which has been incorporated into the patent specification by reference.FN4 As discussed at the hearing, this reference defines "muscle fatigue" as "the decrease in muscle performance that occurs with various forms of exercise." Tr. at p. 114, ll. 2-17; *see also* Court's Ex. 5 [Doc. # 138].FN5

FN4. "Incorporation by reference provides a method for integrating material from various documents into a host document ... by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." Cook Biotech Inc. v. Acell, Inc., 460 F.3d

1365, 1376 (Fed.Cir.2006) (internal quotation omitted). In order to incorporate material by reference, "the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Id*. (internal quotation omitted). In making such a determination, "the standard of one skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." Zenon Envtl., Inc. v. United States Filter Corp., 506 F.3d 1370, 1384 (Fed.Cir.2007) (internal quotation and citation omitted). "Ambiguous terms within the patent can sometimes be interpreted in light of disclosures made in the material incorporated by reference." Neutrino Dev. Corp. v. Sonosite, Inc., 410 F.Supp.2d 529, 537 (S.D.Tex.2006). Here, the article was one specifically referenced by the patentees in connection with recovery from fatigue during acute and extended exercise. The definition of "muscle fatigue" given in this incorporated reference, therefore, is relevant to the court's interpretation of the "recovery" term in the context of the '287 patent.

FN5. The transcript of the Markman hearing contains the comments of the parties' counsel and experts, as well as their responses to questions from the court, concerning eleven "Court Exhibits" included in the record [Doc. # 138].

The Baker *et al*. article also includes Figure 2, which depicts recoveries of tectonic and twitch force. *See* Court's Ex. 6. Figure 2 shows that these forces do not return to 100% of the initial value during recovery. Nothing in the specification or prosecution history contradicts this, or in any way indicates that "recovery" is a complete return to a normal state. MRI's inclusion of "complete return of an exerted muscle to a normal, unfatigued state" in its definition is unduly limiting.

Similarly, neither the language of the claims and specification of the '287 patent, nor the Baker *et al*. definition of "muscle fatigue," limit fatigue to "fatigue after acute exhaustive anaerobic strength training exercise." This portion of MRI's proposed definition is excessively restrictive. Finally, some forms of exercise do not involve movement, so fatigue can be experienced in the absence of dynamic muscle function.FN6 BSN's proposed inclusion of the word "dynamic," is an unwarranted circumscription of the claim term. The court therefore construes this term as follows:

FN6. Some forms of exercise are static, rather than dynamic. A common example of this is holding a yoga pose. While the individual performing the pose is not actually moving, he or she is nonetheless performing exercise.

"Enhancing muscle performance" means "increasing the ability of muscle to maintain required or expected force or power output," and "enhancing recovery from fatigue" means "increasing muscle performance after muscle performance has been decreased by exercise."
2. "Administering/administered." '287 patent**, claims 1, 9, 10, and 12.**

Iovate suggests that this term does not need to be construed. If the court chooses to construe it, Iovate proposes "delivering into a body." BSN proposes "to manage or supervise the use of." MRI did not suggest a construction.

BSN argues that the term is repeatedly used in the specification to denote an individual managing the

administration of something to subjects. *See, e.g.,* col. 3, ll. 10-12; col. 4, ll. 17-20 and ll. 31-43; col. 7, ll. 55-57; col. 8, ll. 9-10; col. 12, ll. 55-57; col. 13, ll. 9-13; col. 14, ll. 9-13. However, BSN can point to no place in the specification that limits the meaning of the term to only that construction. In fact, BSN provides two dictionary definitions of the term "administer" as exhibits to its claim construction brief which include alternative definitions consistent with Iovate's suggestion: "to give remedially (~a dose of medicine)" and "to make application of; give: to administer medicine." *See Merriam-Webster Collegiate Dictionary* 15 (10th ed.2001) and *Webster's Encyclopedic Unabridged Dictionary of the English Language* 19 (1989), Exs. T and U, Def. BSN Cl. Const. Br. [Doc. # 101]. Neither of these two definitions appear to include the concept of managing or supervising, nor do they exclude the concept of giving something to a patient.

From a practical standpoint, the end product of BSN's management or supervision process is the introduction of some substance into a person's body. The court does not understand what process is being managed or supervised, if not one culminating in this result. The court will therefore construe this term as follows:

"Administering/administered" means "delivering into a body, or the management or supervision of the process whereby something is delivered into a body."

3. "Ketoacid." '287 patent**, claim 1.**

Iovate suggests "a compound that has a ketone and a carboxyl group." BSN proposes "a compound that has a ketone and a carboxyl group. A ketoacid is not a salt." MRI suggests "a ketoacid or a precursor to a ketoacid that when combined with glutamate forms a branched chain amino acid. A ketoacid is not a salt." At the hearing, the parties agreed that a ketoacid must have a ketone and a carboxyl group. Tr. at p. 134, ll. 8-15.

The major point of contention between the parties is BSN and MRI's proposed limitation that the ketoacid cannot be a salt. They argue that where the patentees wished to include the ketoacid's salt, they specifically do so, *see, e.g.,* col. 17, ll. 3-9, col. 7, ll. 45-49, and point to Pfizer, Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284, 1291 n. 6 (Fed.Cir.2006) (where claim 1 included pharmaceutically acceptable salts and claim 2 did not, the court stated that while "[t]heoretically, a claimed acid could be liberally construed to include the corresponding salts," the fact that the "pharmaceutically acceptable salts thereof" language was explicitly used in claim 1 but not in claim 2 precluded interpreting claim 2 to also include salts).

However, Iovate argues that a construction which does not include the salts of ketoacids would exclude GAKIC, a glycine and L-arginine calcium salt of alpha-ketoisocapronic acid disclosed in a preferred embodiment. The Federal Circuit has consistently held that a claim construction that excludes a preferred embodiment is "rarely, if ever, correct." Vitronics Corp. v. Conceptronic, 90 F.3d 1576, 1583 (Fed.Cir.1996). In addition, since dependent claims are presumed narrower in scope than the independent claims from which they depend, *see* AK Steel Corp. v. Sollac, 344 F.3d 1234, 1242 (Fed.Cir.2003), adopting BSN and MRI's interpretation would negate the claim language in claims 4 and 5 regarding the salts of alpha-ketoisocapronic acid. Reading the claims in conjunction with the specification compels the conclusion that "ketoacid" should not be limited to exclude salts where doing so would exclude a preferred embodiment and make claims 4 and 5 irreconcilable with claim 1.

MRI also argues that "ketoacid" should be construed as a "ketoacid or a precursor to a ketoacid that when combined with glutamate forms a branched chain amino acid." Including "ketoacid" twice within the

proposed construction does little to illuminate the dispute over this word or assist the jury. MRI argues that because the specification of the '287 patent envisions a composition comprising acids and salts of alpha-ketoisocaproic acid that are related to this compound other than those specifically named, col. 7, ll. 45-54, any acids and salts not related to alpha-ketoisocaproic acid are necessarily excluded. MRI then suggests that the common characteristic of alpha-ketoisocaproic acid and its relatives is the ability to form branched-chain amino acids ("BCAA") when combined with the amino acid glutamate.

What MRI is not able to do, however, is point to any line in the specification where ketoacids that do not react with glutamate to form BCAAs are excluded. MRI stakes its interpretation almost entirely on the paragraph beginning at col. 7, ll. 39; however, that paragraph repeatedly uses the word "may" rather than "shall" or "must" (i.e., "Other related acids and salts may be used. These other related acids and salts may be, for example...."). On the strength of the word "may," MRI seeks to arbitrarily exclude any ketoacids which do not form BCAAs upon reaction with glutamate even though it admits that there is no place in the specification which supports this interpretation. Tr. at p. 135, ll. 13-17. The court will define this term as follows:

"Ketoacid" means **"a compound that has a ketone and a carboxyl group."**

4. "Amino acid." '287 patent**, claim 1.**

Iovate suggests that amino acids are "a well-known, art recognized class of amine-containing organic acids which are found to occur naturally in living things." BSN proposes "a molecule which contains both an amine group (NH_2) and carboxyl group (COOH). An amino acid is not a salt." MRI suggests "an organic compound that contains at least one amino group and one carboxyl group."

The parties agreed at the hearing that an amino acid is an organic compound, and that it can be a salt. Tr. at p. 152, l. 13-p. 153, l. 20; p. 165, ll. 8-20. Iovate further agreed that an amino acid contains an amine or amino group and a carboxyl group. Tr. at p. 166, l. 18-p. 167, l. 12. The parties thus do not dispute that an amino acid contains an amine functional group (-NH_2) and a carboxyl functional group (-COOH).

The first point of contention between the parties with respect to this term is Iovate's inclusion of a "well-known, art recognized class" in its definition. Iovate's technical expert, Dr. Gokel, stated in his declaration submitted with Iovate's Reply Brief that

A person of ordinary skill in the art would understand the plain meaning of the term "amino acid' in the context of the '287 patent to be the well-known, art-recognized class of amine containing organic acids ... The amino acids have the general formula:

H_2N-CHR-COOH

in which the R group is typically referred to as the "sidechain ." The hydrogens on the amino group may be replaced by carbons in some of the naturally-occurring amino acids (e.g., proline, creatine, etc.).
Decl. of Dr. Gokel, Ex. 1, Iovate Reply Br. at para. 26 [Doc. # 113]. While perhaps technically correct, Dr. Gokel's definition is not likely to be particularly helpful to a jury. For example, as Dr. Gokel himself notes, the general structure he recites would have to be qualified to include those amino acids which, like proline, replace one of the hydrogens on the-NH_2 amino group with carbon.
Perhaps recognizing this difficulty, Iovate suggests instead that the construction include the description

"well-known, art-recognized class." However, this vague term does little to assist a jury either, as those without advanced biology or chemistry degrees would be hard-pressed to identify which amino acids are within this undefined, albeit "well-recognized," class. To those who are not persons of skill in the art, Iovate's proposed construction would itself need to be further construed.

The second point of contention is Iovate's proposed limitation that the amino acids be those which are naturally occurring. Claim 1 requires only that the amino acids in question be cationic (positively charged) or dibasic (having two basic groups). Despite several references in the specification to those amino acids being found in living organisms, *see* col. 8, ll. 11-20, 21-53, there is no suggestion that the patentees intended to limit the amino acids covered by the claims in this manner. The court therefore construes this term as follows:

"Amino acid" means **"an organic molecule that contains an amine or amino group and a carboxyl group."**

5. "Low calorie beverage." '287 patent**, claim 10.**

Claim 10 reads as follows: "The method, according to claim 1, wherein said composition is administered as a **low calorie beverage ."**

Iovate suggests that a "low calorie beverage is one that has its calories controlled through the use of a low calorie sweetener, non-nutritive sweetener, or artificial sweetener." BSN proposes "the beverage that the composition is mixed in is a low calorie beverage (that has 40 or fewer calories per serving, or if the serving size is 30 grams or less, 40 calories per 50 grams of the beverage) prior to the composition being added." MRI suggests "a beverage that has 40 or fewer calories per serving, or if the serving size is 30 grams or less, 40 calories per 50 grams of the beverage."

Iovate acknowledges that the specification of the '287 patent does not provide a definition for this term. Iovate is able to offer nothing more to support its own construction than a suggestion that the patent mentions a low calorie cranberry juice which contains saccharin. *See* col. 10, 11. 56-60. Iovate's construction would exclude, for example, the scenario in which the base of the beverage is water if no sweetener were added to the drink, on nothing more than the fact that in the examples provided by the patentees, the particular drink used happened to include a sweetener.

On the other hand, BSN and MRI both argue that a low calorie beverage has been defined by the FDA to mean a food with 40 or fewer calories per serving or, if the serving size is 30 grams or less, 40 calories per 50 grams of the beverage. 21 C.F.R. s. 101.60. While Iovate is correct that the specification itself does not make reference to FDA standards, it does not attempt to provide an alternative to this uniform, government-approved definition of "low-calorie beverage," which would be common knowledge among those of skill in the art. Iovate offers no viable alternative.

BSN seeks to add the additional limitation that the beverage is low-calorie before the claimed composition is added. However, claim 10 states that the "composition is administered as a low-calorie beverage," not that the beverage itself must be low-calorie and, when the claimed composition is added, no longer needs to be so. The court will therefore define this term as follows:

A **"low calorie beverage"** is **"a beverage that has 40 or fewer calories per serving, or if the serving**

size is 30 grams or less, 40 calories per 50 grams of the beverage."

6. "Capsules." '287 patent**, claim 12.**

Claim 12 reads as follows: "The method, according to claim 1, wherein said composition is administered orally by **capsules."** Iovate suggests ordinary meaning. BSN proposes that "capsules" has an "ordinary meaning that would exclude tablets." MRI does not suggest a construction.

BSN's position is not grounded upon the specification or prosecution history. Rather, BSN argues only that a person of ordinary skill would understand that "capsule" excludes "tablet" and that Iovate admitted as much in its amended infringement contentions (Nitrix, one of BSN's allegedly infringing products, is sold in tablet form and "the tablets of Nitrix perform substantially the same function of the claimed capsules, in substantially the same way as the claimed capsules, with substantially the same result."). Iovate's Second Amended Disclosure of Asserted Claims and Infringement Contentions, Def. BSN Cl. Const. Br., Ex. N, at p. 20 [Doc. # 101]. However, this is an infringement argument which is inappropriate at the claim construction phase. The parties agreed at the hearing that any argument over whether a tablet is equivalent to a capsule under a doctrine of equivalents infringement theory is best left for resolution on summary judgment or trial. Tr. at p. 187, l. 25-p. 191, l. 8.

As noted *supra,* the parties agree that "capsule" should have its ordinary meaning. "Capsule" is commonly understood to be a soluble shell or container, usually made of gelatin, which encloses a dose of medication, vitamins, or other nutritional preparation that is taken orally. *See, e.g., The American Heritage Dictionary* 133 (4th ed.2001) ("a small soluble container, usually of gelatin, that encloses a dose of oral medicine or vitamins."); *Merriam-Webster's Collegiate Dictionary* 169 (10th ed.2002) ("a shell usually of gelatin for packaging something [as a drug or vitamin]" or "a usual medicinal or nutritional preparation for oral use consisting of the shell and its contents."); *Webster's 3rd New International Dictionary* 333 (2002) ("a gelatin shell enclosing medicine."); *McGraw-Hill Dictionary of Scientific & Technical Terms* 325 (6th ed.2003) ("a soluble shell in which drugs are enclosed for oral administration."). The court therefore defines this term as follows:

"Capsule" means **"a soluble shell or container, usually made of gelatin, which encloses a dose of medication, vitamins, or other nutritional preparation that is taken orally."**

7. "Conjugated." '287 patent**, claim 8.**

Claim 8 reads as follows: "The method, according to claim 1, wherein said amino acid and said ketone are **conjugated."** The parties agreed at the hearing that "conjugated" means "chemically paired or coupled." Tr. at p. 164, ll. 20-25.

8. "Total work output." '287 patent**, claim 15.**

Claim 15 reads as follows: "The method, according to claim 1, wherein said method increases the **total work output."** The parties agreed at the hearing that **"total work output"** means "the total amount of energy transferred or exerted by a force over a given period of time as measured in joules." Tr. at p. 191, ll. 9-21.

9. "Dynamic performance." '287 patent**, claims 16, 17.**

An exemplar use of this term is found in claim 16, which reads as follows: "The method, according to claim 1, wherein said method improves **dynamic performance** during concentric contraction." The parties agreed that "dynamic performance during concentric contraction is muscle force or work during concentric contraction." Tr. at p. 192, ll. 8-21.

CONCLUSION

The jury shall be instructed in accordance with the court's interpretation of the disputed claim terms in the '287 patent.

So **ORDERED.**

E.D.Tex.,2008.
Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.