

United States District Court,
D. Massachusetts.

IOVATE HEALTH SCIENCES, INC., Iovate T & P, Inc., MTOR U.S. Trademark Ltd., HHC U.S. Trademark Ltd., Leukic U.S. Trademark Ltd. and Multi Formulations Ltd,
Plaintiffs.

v.

ALLMAX NUTRITION, INC., Healthy Body Services, LLC and Healthy Body Services, Inc,
Defendant.

Civil Action No. 07-12334-NMG

July 10, 2009.

Background: Holder of patents and trademarks for nutritional supplements brought action against competitors alleging infringement. Court set forth to construe disputed claims.

Holdings: The District Court, Gorton, J., held that:

- (1) term, "increase," in claim of patent on method for increasing ability of muscles to retain creatine, was not meaningless, and thus was not in need of construction as matter of law, just because expert may have understood it to mean "statistically significant increase";
- (2) phrase, "increasing creatine retention," appearing in preambles of claims in patent on method for increasing ability of muscles to retain creatine, limited claimed invention;
- (3) phrase, "wherein A- represents the anion of citric, maleic, fumaric, or malic acid," in patent on class of creatine salts formed from reaction of creatine with citric, maleic, fumaric, or malic acid, meant isolated water soluble salt formed by the combination of creatine with one of the ionic (negatively charged) forms of citric, maleic, fumaric, or malic acid;
- (4) interpretation of patent claim by another judge in prior litigation was entitled to "reasoned deference" in subsequent litigation against other defendant regarding same patent;
- (5) phrases, "extract of green tea" and "green tea extract," in patents that claimed certain extract from green tea that aided weight loss, meant preparation of *Camellia sinensis* that had been processed to be concentrated in catechols;
- (6) applicant did not clearly disavow scope of "green tea extract" claim; and
- (7) phrase, "thermogenically effective amount" in patents that claimed certain extract from green tea that aided weight loss, meant amount that resulted in increase in total energy expenditure or fat burning.

Ordered accordingly.

5,719,119, 5,968,900, 5,973,199, 6,277,396, 6,814,986, 6,830,765. Construed.

Matthew S. Barrett, Brian C. Barry, Eric J. Marandett, Paul D. Popeo, Meghan L. Rhatigan, Daniel C. Winston, Choate, Hall & Stewart, Boston, MA, for Plaintiffs.

MEMORANDUM & ORDER

GORTON, District Judge.

In this patent infringement action the Court held a Markman hearing on June 29, 2009, at which counsel offered arguments in support of their proposed claim constructions of disputed terms. The following is the Court's ruling with respect to those terms.

I. Background

The plaintiffs, Iovate Health Sciences, Inc., Iovate T & P, Inc., MTOR U.S. Trademark Ltd., Leukic U.S. Trademark Ltd. and Multi Formulations Ltd. (collectively "Iovate") are in the business of marketing and selling health food and nutritional supplements (such as Anator-P70, Leukic, Hydroxycut and Hydroxycut Hardcore products) throughout the United States under the brand name "Muscle-Tech." In its second amended complaint filed on June 25, 2008, Iovate alleges that Allmax Nutrition, Inc., Healthy Body Services, LLC and Healthy Body Services, LLC (collectively "Allmax") sell products that are "confusingly similar" to Iovate's products and infringe on Iovate's patents and trademarks, including U.S. Patent Nos. 5,973,199 ("the '199 Patent"), 5,968,900 ("the '900 Patent"), 6,277,396 ("the '396 Patent"), 5,719,119 ("the '119 Patent"), 6,814,986 ("the '986 Patent") and 6,830,765 ("the '765 Patent"). FN1

FN1. The original complaint was filed on December 18, 2007, against Allmax and two individuals, Michael Kichuk and Ronald Torch, but the Court dismissed the claims against the individuals for lack of personal jurisdiction on April 23, 2008, 549 F.Supp.2d 127.

The parties dispute the construction of several terms in those patents. A brief synopsis of the patents-in-suit follows. FN2

FN2. None of the terms contained in the asserted claims of the '396 or '119 Patents requires the Court's construction and, thus, those patents are not discussed herein.

1) The '900 Patent covers methods for increasing the ability of muscles to retain creatine, a naturally occurring compound that is involved in muscular contraction and the development of fatigue in vertebrate organisms such as humans. Increasing the amount of creatine within a muscle has been shown to affect muscular performance favorably by delaying the onset of fatigue. The invention claimed in the '900 Patent is that ingestion of creatine at roughly the same time as simple sugars enables muscles to retain more of the creatine than does the ingestion of creatine alone.

2) The '199 Patent covers a class of creatine salts formed from the reaction of creatine with citric, maleic, fumaric or malic acid. Creatine usually comes in the form of a powder that is mixed with water and ingested as a drink. Prior art forms of creatine did not dissolve well in water and, therefore, clung to the sides of a glass or settled at the bottom, making the supplement difficult to consume. In addition, when mixed with water, the prior art forms tended to convert rapidly to a compound called creatine monohydrate which has no nutritional value and is merely excreted from the body. The creatine salts claimed in the '199 Patent,

conversely, are purported to dissolve better in water and to be more stable than prior art forms of creatine.

3) The '765 Patent is a divisional application from the '986 Patent and the two share a common specification. They claim a certain extract from green tea that aids weight loss. One way to lose weight is to expend more energy than the energy supplied by food intake, thus causing the body to draw the energy it lacks through thermogenesis (i.e. burning of body fat). When the body faces such an energy deficit, however, it generally reacts to save energy and reduce thermogenesis, thus making a further reduction in food intake necessary in order to continue losing weight. The green tea extract described in the '986 and '765 Patents is sufficiently rich in catechols (a certain kind of organic compound) to stimulate thermogenesis, thus counteracting the body's natural reaction to an energy deficit.

II. Legal Analysis

A. Legal Standard

[1] In analyzing a patent infringement action, a Court must 1) determine the meaning and scope of the patent claims asserted to be infringed and 2) compare the properly construed claims to the infringing device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first step, known as claim construction, is an issue of law for the court to decide, whereas the second step is determined by the finder of fact. *Id.* at 979.

[2] [3] [4] The Court's responsibility is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. *Bell Atlantic Network Serv., Inc. v. Covad Comm. Group, Inc.*, 262 F.3d 1258, 1267 (Fed.Cir.2001). Where the ordinary meaning of a claim is not apparent, the Court can look to other sources available to the public, including: 1) intrinsic evidence (i.e., the words themselves, specification and prosecution history) and 2) extrinsic evidence (e.g., dictionaries, treatises and expert testimony). *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed.Cir.2005) (en banc) (citing *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed.Cir.2004)). Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence should be afforded the greatest weight in determining what a person of ordinary skill would have understood a claim to mean. *Id.* at 1324.

B. The '900 Patent

With respect to the '900 Patent, the parties contest terms appearing in Claim 1 which reads (with disputed terms underlined):

A method of increasing creatine retention in a human or animal body comprising causing an increase in blood plasma creatine concentration and causing a substantially simultaneous increase in blood plasma insulin concentration. FN3

FN3. Also at issue in this case are Claims 2, 5-10 and 12 which are dependent upon Claim 1.

In addition, the parties contest a term appearing in Claim 20 which reads:

A composition for use in a human or animal body, the composition comprising creatine or an active derivative thereof together with a carbohydrate or an active derivative thereof, wherein the composition

comprises the carbohydrate or its derivative in an amount by weight which is greater than an amount of the creatine or its derivative, and the amount of the creatine or its derivative and the amount of the carbohydrate or its derivative are effective to *increase creatine retention* in the body. FN4

FN4. Also at issue in this case are Claims 21 and 22 which are dependent upon Claim 20.

Finally, the parties also contest a term appearing in Claim 25 which reads:

A method of *increasing creatine retention* in a human or animal body comprising administering a composition comprising creatine or an active derivative thereof together with a carbohydrate or an active derivative thereof by at least one of ingestion and injection, wherein the composition comprises the carbohydrate or its derivative in an amount by weight which is greater than an amount of the creatine or its derivative. FN5

FN5. Also at issue in this case are Claims 26 and 29 which are dependent upon Claim 25.

1. "Increase"

[5] Iovate asserts that the term "increase" should be construed to mean a "statistically significant increase." It offers expert testimony as proof that someone skilled in the art would understand the term in that way. In addition, it argues that Examples 1 and 2 in the patent specification used a standard measure of statistical significance when showing "increased" blood plasma insulin and muscle creatine concentrations.

Allmax, on the other hand, rejects any further construction of "increase" by the Court. It contends that Iovate is attempting to import an unnecessary limitation into a term that is already unambiguous. In support of its position, Allmax cites *Abbott Labs. v. Sandoz, Inc.*, 529 F.Supp.2d 893, 911 (N.D.Ill.2007), where the court refused to read a "statistically significant" requirement into the construction of the word "lower" because the ordinary and plain meaning of that word is simply "less than." The court explained that a word is not meaningless (and in need of construction as a matter of law) just because an expert may understand it to have a more "helpful" meaning.

Iovate responds that in *Abbott* one disputed claim included the term "statistically significant" whereas another did not and the court found it noteworthy in construing "lower" that the patentee could easily have added the "statistical significance" limitation if it had intended for that limitation to exist. Therefore, Iovate contends that *Abbott* is inapposite here where "statistically significant" does not appear at all in the patent-in-suit.

In further support of its position against the addition of a "statistical significance" limitation, Allmax also points out that Examples 3 and 4 in the '900 Patent do not use a standard measure of statistical significance. Iovate responds that those examples do not refer to an increase in creatine retention at all except tangentially by way of a reference to an increase in plasma insulin concentration that exhibited such a large increase as to be obviously statistically significant.

Iovate's further construction of "increase" is unwarranted. An "increase" and a "statistically significant increase" would have two different meanings (presumably even to a person skilled in the art). For example,

a 0.01% increase may not be statistically significant but is, nevertheless, an increase. Particularly because the term "statistical significance" is used in the specification to describe the kind of "increase" observed but is omitted from the disputed claims, "increase" will be read as just that and without the limitation of being "statistically significant."

2. "Increasing creatine retention" appearing in the preambles of Claims 1 and 25

[6] [7] The term "increasing creatine retention" appears in the preamble of Claims 1 and 25 of the '900 Patent. Both parties agree that a preamble does not limit an invention except when "it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir.2002). When a preamble fits the exception, it becomes a claim limitation which a patentee, in order to prove infringement, must show is contained within an accused device. *Id.* at 808, 812.

Iovate argues that the exception applies to "increasing creatine retention" because the essence of the invention in the '900 Patent is, in fact, the increased retention of creatine that occurs when it is ingested with simple sugars as compared to when it is ingested alone. In support of its argument, Iovate points out that that notion appears in the patent's title, the first sentence of its abstract and the opening and concluding sentences of the specification's general description. It also notes that statements made by the Patent and Trademark Office ("PTO") examiner and the applicant during the prosecution history of the '900 Patent indicate that "increasing creatine retention" is what distinguishes the '900 Patent from the prior art. Indeed, the examiner only allowed certain composition claims after the applicant added "increasing creatine retention" to them.

Allmax contends that "increasing creatine retention" is merely the effect of the claimed process (i.e. increasing the concentrations of creatine and insulin in blood plasma) and not a step in that process. Therefore, it disputes that "increasing creatine retention" is the essence of the invention in the '900 Patent or that the phrase should limit the invention pursuant to the exception. *See Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288-89 (Fed.Cir.2008) (noting that "the purpose of a claim preamble is to give context for what is being described in the body of the claim").

Allmax's response is unpersuasive. In fact, by contending that "increasing creatine retention" is the result of the claimed process and not a step in it, Allmax seems to support Iovate's argument. Moreover, Iovate contends that "increasing creatine retention" was "patentably significant" in that it was used to distinguish the claimed invention from the prior art while the patent application was pending before the PTO. Those factors indicate that the disputed term is limiting. *See Catalina*, 289 F.3d at 808-09. Accordingly, the Court will, as Iovate requests, construe the disputed term appearing in the preamble as limiting the claimed invention.

3. "Increase creatine retention" appearing in the body of Claim 20

Iovate contends that the term "increase creatine retention" appearing in the body of Claim 20 means "increase creatine retention or storage *in muscle* as compared to the increase achieved by creatine alone" (emphasis added). It points out that the title and first sentence of the abstract of the '900 Patent refer to retention "in muscle."

Allmax responds that Iovate is improperly attempting to add an additional limitation to the claim even though the subject term has a readily understandable, plain meaning that does not require further

construction. Furthermore, it requests the Court to take note of the fact that Claim 20 reads "increase creatine retention *in the body*," a phrase that is repeated throughout the specification.

In reply, Iovate suggests that the '900 Patent refers to the increase in creatine retention in the muscle of the body and, in fact, uses the words "muscle" and "body" interchangeably, such as in the specification:

Creatine ... is known to be present in the muscles of vertebrates.... [It] is produced naturally by the body, but is also obtained from animal foods. Most bodily creatine is present in muscle, and it is believed that increasing the amount of creatine within muscle favorably affects muscular performance and the amount of work which can be done by the muscle. Accordingly, it is held desirable to be able to influence creatine retention in the body.

Allmax's argument is more persuasive. Because the meaning of the disputed term is readily apparent, there is no need for the Court to construe it further. In addition, as Allmax suggests, Iovate's construction does not seem to correlate with Claim 20 which expressly states "increase creatine retention in the body." Iovate's construction would, moreover, render Claim 20 nonsensical by having it read, in effect, "increase creatine retention or storage in muscle as compared to the increase achieved by creatine alone, in the body."

4. "Substantially simultaneous"

Iovate asserts that construing the term "substantially simultaneous" to mean, as it proposes, "sufficiently close in time to result in an increase in creatine retention" is consistent with the purpose of the invention, the teaching in the specification (which contains examples showing increases in creatine retention) and the manner in which one skilled in the art would interpret the term.

Allmax rejects Iovate's construction as an unnecessary limitation of a term which requires no construction because its plain meaning is clear. It also alleges that Iovate's construction is inappropriately tied to the ultimate effect of the claim (i.e. the increase in creatine retention) rather than to its actual use in the claims (i.e. as the necessary temporal relationship between two process steps). Allmax's arguments are persuasive.

5. "Causing an increase in blood plasma creatine concentration and causing a substantially simultaneous increase in blood plasma insulin concentration"

Iovate argues that "causing an increase in blood plasma creatine concentration and causing a substantially simultaneous increase in blood plasma insulin concentration" should be construed in accordance with the construction it proposes for the preceding disputed terms. That is, Iovate contends that the subject phrase should be construed to mean:

causing a statistically significant increase in blood plasma creatine concentration and causing a statistically significant increase in blood plasma insulin concentration sufficiently close in time to result in an increase in creatine retention.

Allmax asserts that, to the contrary, the term should be construed to mean "the effect resulting from the substantially simultaneous introduction of creatine and an agent operable to increase the blood plasma insulin concentration into the body." FN6 It argues that its construction is consistent with the specification which states:

FN6. Allmax asserted a different construction for the term in its opening brief but later revised it to make

certain that it did not limit the claim unintentionally (as Iovate contended that it did).

The plasma insulin concentration may be increased by infusion of insulin or an active derivative thereof and/or by the ingestion of an agent operable to cause an increase in the blood plasma insulin concentration.... Preferably the method comprises the simultaneous ingestion of creatine and an agent operable to cause an increase in the blood plasma insulin concentration substantially simultaneously with the arrival in the plasma of the creatine.

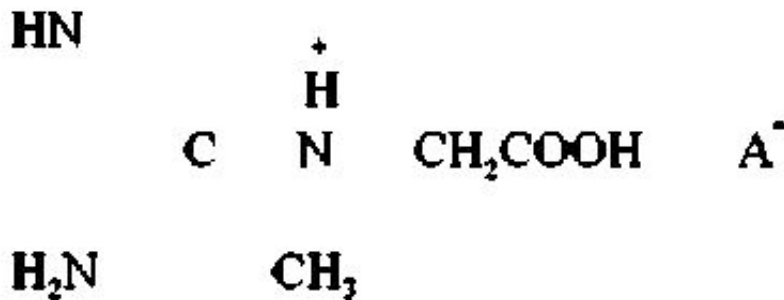
Iovate contests Allmax's construction for seeming to cover essentially any "effect," thus effectively reading the express requirement of an "increase in blood plasma insulin concentration" out of the claim. Allmax disagrees with that analysis because the "agent[s] operable to increase the blood plasma insulin concentration" apparently have the inherent effect of increasing blood plasma insulin concentration upon being introduced into the body.

It is unclear 1) why the word "causing" should be construed as "effect" as Allmax proposes and 2) why the disputed term needs further construction by the Court when its plain meaning appears to be readily understandable. Accordingly, the Court will adopt neither proposed construction and will construe the term no further.

C. The '199 Patent

[8] With respect to the '199 Patent, the parties contest the terms appearing in Claim 1:

An isolated hydrosoluble salt of creatine of the formula:



wherein A- represents the anion of citric, maleic, fumaric, or malic acid.

An anion generically refers to an ion that has a single or multiple negative charges. The number of negative charges an anion contains determines the number of molecules having a single positive charge (such as creatine) with which it can react. Thus, for example, an anion of citric acid containing two negative charges can react with two molecules of creatine (forming di-creatine citrate). The parties dispute whether "anion" has such a broad definition when it appears in Claim 1 of the '199 patent.

Allmax asserts that the disputed term means "wherein A- represents the anion (i.e., charged particle with a single negative charge) of citric, maleic, fumaric or malic acid." In support thereof, Allmax suggests that the

specification for the '199 Patent depicts the anions of the invention with a single "-" and discloses only anions having a single negative charge. It claims that "A" followed by one "-" (as opposed to multiple "-" or "n-" where "n" represents any number of negative charges) would be understood by persons of skill in the art to refer to an anion with a single negative charge, particularly where the claim recites that "A- represents the anion."

Furthermore, Allmax points to the prosecution history during which the applicant for the '199 Patent referred to "the four compounds claimed herein-salts of creatine with citric, maleic, fumaric, and malic acids." Allmax submits that those four compounds are ones formed by combining creatine and each of the named acids in their ionic form possessing a single negative charge: "creatine citrate", "creatine maleate", "creatine fumarate" and "creatine malate." If the applicant meant to include acids in a form possessing more than a single negative charge (argues Allmax), he would have referred to more than four compounds (those listed in the preceding sentence as well as di- and tri-creatine citrate, di-creatine maleate, di-creatine fumarate and di-creatine malate).FN7

FN7. Citric acid can carry up to three negative charges (and thus can combine with up to three creatine molecules) whereas the other three acids can carry only up to two such charges (and thus can combine with one or two creatine molecules).

In addition, Allmax cites to solubility data contained in Table I of the '199 Patent which appears to relate only to salts containing a single negative charge. Finally, it notes that none of the patents citing the '199 Patent as a reference describe it as disclosing anything other than mon creatine salts, thus allegedly indicating how people skilled in the art view the scope of the '199 Patent.

By contrast, Iovate asserts that the term "anion" should not be limited to particles with a single negative charge. It submits that nowhere in the '199 Patent do the inventors state an intention to limit their invention to mon creatine salts. It rejects Allmax's assertion that one skilled in the art would interpret "A-" as referring to an anion with only one negative charge.

Iovate also rejects Allmax's reliance on the applicant's statement concerning "the four compounds" by explaining that that reference was meant merely to distinguish prior art forms which did not disclose any creatine salts whatsoever and, thus, does not clearly limit the claim scope. Moreover, Iovate argues that Table I is not intended to be limiting, *see Phillips*, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"), and that the way in which other patents cite the '199 Patent carries no weight, *see Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 809 (Fed.Cir.2007) (finding that the usage of a disputed term in other patents merits little consideration).

In place of Allmax's construction, Iovate requests that the Court adopt the construction of Claim 1 reached by Judge Ron Clark of the United States District Court for the Eastern District of Texas in another suit brought by Iovate (to which Allmax was not a party). There, Judge Clark construed Claim 1 to mean:

an isolated ... water soluble salt formed by the combination of creatine with one of the ionic (negatively charged) forms of citric, maleic, fumaric or malic acid.

859162, at (E.D.Tex. Mar. 28, 2008). He further established that "ionic (negatively charged) forms" refers to "the fact that some acids, like citric acid, can have different forms with one, two, or three negative charges per molecule, depending on solution conditions." *Id.*

Iovate argues that Judge Clark correctly recognized that the specification for the '199 Patent itself states that "A- represents the anion of a mono, bi-or tri-carboxylic acid" (where a bi-carboxylic acid carries two negative charges and a tri-carboxylic acid has three). Thus, Iovate propounds that the specification expressly contemplates reactions between creatine and anions carrying more than one negative charge.

In response, Allmax reminds the Court that the construction adopted in the Eastern District of Texas is not binding here. *See Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 540 F.Supp.2d 1233, 1242 (M.D.Fla.2008) (noting that even where another district court has construed a patent's terms, "the Court has an independent obligation to determine the meaning of the claims, and to render its own independent claim construction").

[9] Judge Clark's interpretation is, however, entitled to "reasoned deference." *See id.* (citation omitted). Although some of the evidence offered by Allmax suggests that the inventor of the '199 Patent specifically contemplated monocarboxylic acids, it does not, conversely, suggest that the inventor also specifically contemplated excluding bi- and tri-carboxylic acids. Moreover, the claim specifically uses a generic term, "anion," and does not limit that term to only those particles carrying one negative charge. Accordingly, the Court will adopt Judge Clark's interpretation as Iovate requests.

D. The '765 and '986 Patents

[10] With respect to the '765 Patent, the parties contest terms appearing in Claim 1 which reads:

A method for treating obesity in a patient in need of said treatment comprising orally administering to said patient an *extract of green tea* comprising from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine, said catechols and caffeine being present in said extract in a *thermogenically effective amount*, the ratio of the concentration of catechols to the concentration of caffeine in the *extract of green tea* being between 2 and 10.

The disputed term "extract of green tea" and the similarly disputed term "green tea extract" also appear in Claims 2, 5, 6, 9 and 10 of the '765 Patent and Claims 1, 2, 5 and 6 of the '986 Patent.

1. "Extract of green tea" and "green tea extract"

Green tea is produced from a plant species known as *Camellia sinensis* of which one variety is *Camellia sinensis assamica* (hereinafter referred to as "*assamica*"). Iovate proposes that the terms "extract of green tea" and "green tea extract" should be construed to mean "a preparation of *Camellia sinensis* which has been processed to be concentrated in catechols." Allmax proposes a narrower definition: "a concentrated preparation obtained from the leaves or buds of *Assamica* type *Camellia sinensis*."

[11] In support of its proposed construction, Allmax relies on two particular elements from the prosecution history of the '765 and '986 Patents. First, it notes that inventor Max Rombi ("Rombi") submitted a disclosure to the PTO examiner stating that "only [*assamica*] produced the synergistic thermogenic proportions of caffeine and catecholamines according to the present invention." Next, Allmax notes that apparently the examiner allowed the issuance of the patent only after Rombi pointed out that his disclosure

taught an extraction that utilized two leaves and the bud of the green tea.

Iovate responds that prosecution history cannot be used to limit claim scope unless the applicant (and not the examiner) "took a position before the PTO that would lead a competitor to believe the applicant had disavowed" claim scope. *See* *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed.Cir.2002); *see also* *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed.Cir.2005). Iovate suggests that the applicant for the '986 and '765 Patents at all times maintained a position that "green tea" covers all varieties of *Camellia sinensis*. Indeed, even when the examiner initially rejected his claim because the term was not limited to *assamica* or any other specific variety of *Camellia sinensis*, the applicant continued to argue that "green tea" was a generic term covering all varieties of *Camellia sinensis* and that the claim "should not be limited to a particular tea variety."

Moreover, Iovate asserts that Rombi's disclosure with respect to *assamica* was made specifically to contradict the examiner's assertion that the pending claim lacked novelty because any green tea extract using an 80% ethanol extraction would contain the claimed concentrations of catechols. Thus, Rombi sought to demonstrate that, although some varieties of green tea such as *assamica* produce the claimed extract, others do not.

In light of the evidence offered by Iovate, the applicant's effort to distinguish his invention from prior art did not "clearly disavow []" the scope of the claim and, accordingly, the Court will adopt the construction proposed by Iovate rather than Allmax's more narrow construction based purely on the prosecution history. *See* *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1327 (Fed.Cir.2003).

2. "Thermogenically effective amount"

[12] The parties apparently agree that the term "thermogenically effective amount" requires construction by the Court because it does not have a well understood, plain meaning. They disagree, however, about how it should be construed.

Iovate contends that the term means "an amount which results in a statistically significant increase in total energy expenditure or fat burning." It contends that the '765 Patent states that "thermogenesis" corresponds to "the energy expended by the body to maintain a constant temperature" and that the body burns fat when the energy it expends is greater than the energy supplied by food intake. It also argues that the "statistically significant" limitation is necessary to comport with the understanding of a person skilled in the art as described above for the term "increase" and as evidenced by the fact that the specification for the '765 Patent describes an amount that produced no statistically significant increase in thermogenesis by stating that it "does not increase thermogenesis."

By contrast, Allmax argues that the disputed term means "at least 125 mg ECGC and at least 50 mg caffeine." That proposed construction is based purely on the specification for the '986 and '765 Patents which provides only one example of the effect the invention's compounds have in humans, and 125 mg of catechols and 50 mg of caffeine were used in that example (and were determined to achieve thermogenesis).

Iovate rejects Allmax's construction as importing an improper limitation into the claim. It asserts that the quantities referenced in the specification were only one (and not the only) example of the invention. Indeed, the Federal Circuit Court of Appeals has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."

Phillips, 415 F.3d at 1323. Therefore, there appears to be no reason to construe the disputed term as narrowly as Allmax requests. Furthermore, Iovate's construction is reasonable with the exception of the "statistically significant" limitation (for the reasons explained above with respect to the '900 Patent). Thus, the Court will interpret "thermogenically effective amount" to mean "an amount which results in an increase in total energy expenditure or fat burning."

ORDER

For the reasons set forth in the preceding Memorandum, the Court hereby construes the disputed claims as follows:

The '900 Patent

1. *increase* and *increasing* requires no construction;
2. *increasing creatine retention* appearing in the claim preamble is construed to limit the invention;
3. *increasing creatine retention* appearing in the claim body requires no construction;
4. *substantially simultaneous* requires no construction; and
5. *causing an increase in blood plasma creatine concentration and causing a substantially simultaneous increase in blood plasma insulin concentration* requires no construction.

The '199 Patent

6. *wherein A- represents the anion of citric, maleic, fumaric, or malic acid* means wherein A- represents the ionic (negatively charged) forms of citric acid, maleic acid, fumaric acid, or malic acid, and "ionic (negatively charged) forms" refers to the fact that some acids, like citric acid, can have different forms with one, two or three negative charges per molecule, depending on the solution conditions.

The '986 and '765 Patents

7. *extract of green tea* and *green tea extract* mean a preparation of *Camellia sinensis* which has been processed to be concentrated in catechols; and
8. *thermogenically effective amount* means an amount which results in an increase in total energy expenditure or fat burning.

So ordered.

D.Mass., 2009.

Iovate Health Sciences, Inc. v. Allmax Nutrition, Inc.

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