United States District Court,
N.D. California, San Jose Division.

UNITHER PHARMA, INC., et al,
Plaintiff(s).
v.
The DAILY WELLNESS COMPANY, et al,
Defendant(s).

Nos. C 02-05284 JW, C 03-5090 JW, C 03-5878 JW

Nov. 30, 2005.

Dina Grinshpun, Juanita R. Brooks, Fish & Richardson P.C., San Diego, CA, Karen I. Boyd, Palo Alto, CA, Limin Zheng, Fish & Richardson P.C., Redwood City, CA, for Plaintiffs.

Anup Tikku, Michael J. Bettinger, Rachel R. Davidson, Timothy Paar Walker, K&L Gates LLP, San Francisco, CA, for Defendants.

ORDER FOLLOWING CLAIM CONSTRUCTION HEARING

JAMES WARE**, District Judge.**

I. INTRODUCTION

This is a patent infringement lawsuit. The Plaintiffs are Unither Pharma, Inc., The Board of Trustees of the Leland Stanford Junior University, and New York Medical College (collectively, "Plaintiffs"). The Defendants are The Daily Wellness Company and Advanced Nutritional Biosystems, LLC (collectively, "Defendants"). Plaintiffs allege that Defendants are infringing United States Patents Nos. 5,217,997 ("the '997 Patent"), 5,428,070 ("the '070 Patent"), 5,891,459 ("the '459 Patent"), 6,117,872 ("the '872 Patent"), and 6,646,006 ("the '006 Patent"), which are assigned to Plaintiffs.

In a separate lawsuit (Case No. C03-05090 JW), the Plaintiffs allege that Herbalife International, Inc. is infringing the '006 Patent. In a third lawsuit (Case No. C03-05878 JW), Herbalife is suing Unither and is praying for a declaration that it does not infringe the '997 Patent, the '070 Patent, the '459 Patent, or the '872 Patent. FN1 The Court determined that the lawsuits are related and has ordered that they be reassigned to it.

The Court has subject matter jurisdiction over these lawsuits pursuant to 28 U.S.C. s. 1338(a), which grants federal district courts original and exclusive jurisdiction over civil actions for patent infringement.

Pursuant to the Patent Local Rules, the parties filed their respective claim construction briefs. On October 15, 2004, the Court conducted a claims construction hearing. This Order governs all three cases.

II. BACKGROUND

The five patents-in-suit relate to the use of amino acids to promote cardiovascular benefits. Specifically, the patents-in-suit relate to the use of an amino acid known as L-arginine to dilate blood vessels and thereby promote blood flow.

At a technology tutorial, the parties explained that blood vessels, which generally are tube-shaped, are comprised of two concentric layers. The inner layer, known as the endothelium, lines the inside of the blood vessels. The outer layer, known as vascular smooth muscle, gives blood vessels their structure and flexibility. When L-arginine is administered to the blood stream, endothelial cells absorb it. Once inside endothelial cells, L-arginine interacts with an enzyme known as Nitric Oxide Synthase (NOS). That interaction triggers a chemical reaction. L-arginine reacts with oxygen and calcium, both of which are present in the cell. At the end of the chemical reaction, L-arginine is converted into L-citrulline and a gas molecule called nitric oxide (NO). NO then diffuses through the endothelium and into the vascular smooth muscle, where it interacts with an enzyme known as guanylate cyclase. That interaction produces signaling molecules known as cyclic GMP (cGMP). cGMP, in turn, causes vascular smooth muscle to relax, dilating the blood vessel. Wider blood vessels promote blood flow and counteract clogging. The patents-in-suit all rest upon this basic science.

Pursuant to the Patent Local Rules of the Court, the Court conducted proceedings to construe words and phrases used in the claims of the patents.

III. STANDARDS

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.' " Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (quoting Innova/Pure Water, Inc. v. Safari Water filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)). Claim construction is purely a matter of law, to be decided exclusively by the court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 387, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claims are construed from the perspective of a person of ordinary skill in the art at the time of the invention. Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed.Cir.1995). To determine the meaning of the claim terms, the court initially must look to intrinsic evidence-that is, the claims, the specification, and, if in evidence, the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The court must first look to the words of the claims themselves. *See* Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984) ("Words in a claim 'will be given their ordinary and accustomed meaning, unless it appears that the inventor used them differently"); *see also* Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1148 (Fed.Cir.2003) (noting that there is a "heavy presumption" in favor of a claim's ordinary meaning). These words are to be given their ordinary and customary meaning unless it is clear from the specification and prosecution history that the inventor used the term with a different meaning. *Id*. The claims should be interpreted consistently with the specification. *See* Renishaw PLC v. Marposs Societa per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998).

Where intrinsic evidence alone resolves any ambiguity in a disputed claim term, it is improper to rely on evidence which is external to the patent and file history. Vitronics, 90 F.3d at 1583. However, extrinsic evidence may be considered in the rare instances where the intrinsic evidence is insufficient to enable the court to construe disputed claim terms. Id. at 1585. Common sources of extrinsic evidence include expert testimony, inventor testimony, dictionaries, and technical treatises and articles. Id . at 1584.

IV. DISCUSSION

As an initial matter, the parties request that the Court first construe terms which pertain to more than one of the patents-in-suit. There are three such terms. First, the parties dispute whether two of the four method patents involved in this lawsuit require an intent as an element. Second, the parties dispute the proper construction of the term "amino acid," which appears in the claims of the '459 Patent, the '872 Patent, and the '006 Patent. Third, the parties dispute the proper construction of the term "sufficient amount" or "amount sufficient," which appears in the '997 Patent, the ' 070 Patent, and the '459 Patent.

A. "Intent" as an element of the '459 Patent, and the '872 Patents.

The parties agree that the methods claimed in the '997 Patent and the '070 Patent must be performed with an intent to achieve the claimed purposes. The parties, however, dispute whether the '459 Patent and the ' 872 Patent similarly require such an intent.

The '459 Patent claims:

1. A method of improving vascular NO activity FN2 of the vascular system of a human host by enhancing endothelial NO, said method comprising:

2. **A method of improving vascular NO activity of the vascular system of a human host** by enhancing endothelial NO, said method comprising: ...

3. **A method of improving vascular NO activity of the vascular system of a human host** by enhancing endothelial NO, said method comprising: ...

The '872 Patent claims:

1. A method for enhancing physical performance of a mammal prior to said physical performance, said method comprising: ...

* * *

7. **A method for enhancing human physical performance prior to said physical performance, said method comprising: ...**

* * *

12. **A method enhancing human physical performance prior to said physical performance, said method comprising: ...**

* * *

The Plaintiffs argue that these methods, like the methods claimed in the ' 997 Patent and the '070 Patent, must be performed with an intent to achieve their claimed purposes. The Defendants, on the other hand, argue that the methods claimed in the '459 Patent and the '872 Patent need not be performed with an intent to achieve their claimed purposes because neither patent explicitly recites a target population.

1. Intent Element in the '459 Patent

In the '459 Patent what is claimed is not simply a generic method comprising certain steps. Rather, "What is claimed is ... [a] method **of improving vascular NO activity of the vascular system of a human host by enhancing endothelial NO.**" '459 Patent at 26:38-41. Under the claim's plain meaning, then, the claimed method specifically is intended to "improve[e] vascular NO activity of a human host by enhancing endothelial NO." '459 Patent at 26:39-41. Thus, requiring that the claimed method be performed with that intent is consistent with the claim's plain meaning.

Furthermore, the '459 Patent's specification supports the finding of an intent requirement. The '459 Patent's specification is suffused with language which indicates that the '459 Patent's very purpose is to improve vascular function by enhancing endothelial NO. FN3 Reading the ' 459 Patent's method claims in light of its specification, it is clear that they must be performed with an intent to "improve[e] vascular NO activity of the vascular system of a human host by enhancing endothelial NO."

2. Intent Element in the '872 Patent

The language of the '872 Patent is equally straightforward and supports need for the method to be practiced with a particular intent. Here again, what is claimed is not simply a generic method comprising certain steps. Rather, "What is claimed is ... [a] method **for enhancing physical performance of a mammal" and "[a] method enhancing human physical performance....**" '872 Patent at 11:54-56, 12:45. Under the claims' plain meaning, then, the claimed methods specifically are intended to "enhance physical performance" of mammals and humans. '872 Patent at 26:55-56, 12:45. Thus, requiring that the claimed methods be performed with that intent is consistent with their plain meaning.

The '872 Patent's specification supports the finding of an intent requirement. The '872 Patent's specification is also suffused with language which indicates that the '872 Patent's very purpose is to enhance physical performance. FN4 Reading the ' 872 Patent's method claims in light of its specification, it is clear that they must be performed with an intent to "enhance physical performance."

To support their argument that no intent element is required, The Defendants cite *Jansen v. Rexall Sundown, Inc.,* 324 F.3d 1329 (Fed.Cir.2003). *Jansen* involved method claims for "treating or preventing macrocytic-megaloblastic anemia in humans ... which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof" and for "treating or preventing macrocyticmagaloblastic [sic] anemia in humans ... which comprises orally administering combined vitamin B12 and folic acid to a human in need thereof...." *Jansen,* 342 F.3d at 1330. The Federal Circuit construed this language to mean that the methods must be performed with the intent to achieve their indicated purposes. *Id.* at 1333 (holding that the claims are "a statement of the intentional purpose for which the method must be performed"). In The Daily Wellness Defendants' and Defendant Herbalife's words, *Jansen* considered whether a human taking the claimed formulation 'must know that he is *in need* of either treatment or prevention' of anemia. Because the claim recited a target population- '*a human in need* ' of 'treating or preventing' anemia-the Federal Circuit held that the claimed method must be performed with 'the *intentional purpose*' of treating or preventing anemia. (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 2:24-3:3); *see also* Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 2:16-17, 3:3-5. The Defendants also note that the *Jansen* court "was guided by the patentee's prosecution statements demonstrating that he had 'limited his claims to treatment or prevention' of anemia '*in those who **need** such treatment or prevention .*' " (Defendant Herbalife's Brief at 3:11-13. According to Defendants, since "[h]ere, there are no such statements [,]" Defendants attempt to distinguish *Jansen* and argue that the '459 Patent and

the '872 Patent do not require an intent element.

Defendants' argument suffers from two shortcomings. In *Jansen,* the court did not find the phrase "human in need thereof," itself dispositive. The *Jansen* court explicitly states:

We need not decide whether we would reach the same conclusion if either of the 'treating or preventing' phrase or the 'to a human in need thereof' phrase was not a part of the claim; together, however, they compel the claim construction arrived at by ... this court." *Jansen,* 342 F.3d at 1333.

Thus, simply because '459 Patent and the '872 Patent lack the "human in need thereof" language does not necessarily mean that they do not require an intent element.

Second, to the extent that The Daily Wellness Defendants' and Defendant Herbalife's argument rests upon *Jansen's* analysis of prosecution history, it is unpersuasive. The *Jansen* court stated that its analysis of prosecution history was merely secondary to its primary analysis of "the ordinary meaning of the claim language." *Jansen,* 342 F.3d at 1332; *see also id*. at 1333 ("Our conclusion as to the meaning of the claims is bolstered by an analysis of the prosecution history"). Thus, the language from *Jansen* regarding prosecution history, upon which The Defendants rely, is dicta. *Jansen* does not stand for the principle that a patent claim requires an intent element only when it explicitly recites a target population. However, to the extent that a finding of an intent element can be based on there being a target population, the '459 Patent and the '872 Patent recite specific (i.e., explicit or definite) target populations. The '459 Patent is targeted at "human hosts" and the '872 Patent is targeted at "mammals" and "humans." '459 Patent at 26:39-41; '872 Patent at 11:56, 12:45. These target populations may not be as narrow, but they arguably are specific target populations nonetheless.

B. "Amino Acid"

The parties dispute the construction of the term "amino acid," which appears in various claims of the '459 Patent, the '872 Patent, and the '006 Patent. For example:

5,891,459

What is claimed is:
1. A method of improving vascular NO activity of the vascular system of a human host by enhancing endothelial NO, said method comprising:

administering orally as a dietary supplement to said host in accordance with a predetermined regimen a prophylactic dose in an amount sufficient to enhance endogenous endothelial NO, L-arginine or L-arginine hydrochloride, as other than a natural food source and in the absence of other **amino acids** and polypeptides as other that dietary supplements, to enhance the level of endogenous NO in the vascular system.

* * *

6,117,872

What is claimed is:
1. A method for enhancing physical performance of a mammal prior to said physical performance, said method comprising:

administering to said mammal prior to said physical performance as the active ingredient an amino acid composition consisting of at least one **amino acid** selected the group consisting of arginine and lysine of at least about 60 mg/kg/day within 24 h of said physical performance.

* * *

6,646,006

What is claimed is:
1. A composition comprising L-arginine or a physiologically acceptable salt thereof in an amount sufficient to enhance nitric oxide production and grape skin extract, wherein said composition is in a form suitable for oral administration selected from the group consisting of a pill, tablet, powder, or capsule.

2. A composition as claimed in claim 1, further comprising at least one additional ingredient that enhances production of nitric oxide or that inhibits degradation of nitric oxide.

3. A composition comprising L-arginine or a physiologically acceptable salt thereof and at least one additional compound associated with production of nitric oxide other than L-arginine or a physiologically acceptable salt thereof, said composition excluding other **amino acids** which are not precursors of nitric oxide, wherein said composition is in a form suitable for oral administration selected from the group consisting of a pill, a powder, a liquid, and a capsule.

* * *

The Plaintiffs argue that the term "amino acid" refers only to 20 specific amino acids, which are found in proteins. The Defendants, on the other hand, argue that "amino acid" should "carry its plain and ordinary meaning.

As the Court stated in its description of the legal standard, Claim terms are ascribed their ordinary meaning unless the context, the specification, or the file history indicate a different meaning.

1. The plain meaning of the term "amino acid."

The term "amino acid' has an ordinary and accustomed meaning. It is a compound possessing an amino group and an acid group.

The claim language suggests that the term "amino acid" should be construed broadly and plainly. In two of the three patents in which the term "amino acid" appears (i.e., the '459 Patent and the '006 Patent), the term "amino acid" arises in the context of broad exclusionary language.

For example, Claim 1 of the '459 Patent claims:

A method of improving vascular NO activity ..., said method comprising [ ][a]dministering orally ... L-arginine ... *in the absence of* **other amino acids** and polypeptides.... '459 Patent at 26:39-49.

Similarly, Claims 3 and 5 of the '006 Patent claim:

A composition comprising L-arginine ..., said composition **excluding other amino acids which are not precursors of** nitric oxide**....** '006 Patent at 27:40-45, 27:52-61.

This exclusionary language is quite broad and plain. Such broad exclusionary language undermines the limitation in definition urged by The Plaintiffs.

2. The use of the term 'amino acid' in the specification of the respective patents.

The Court examines the specification of the respective patents to determine if there is a basis for construing the term to the narrower definition urged by the Uniter Plaintiffs.

The specification of each patent-in-suit uses the term "amino acid" but does not explicitly define it. The Plaintiffs contend that the Court should infer from the pharmaceutical, medical and dietary focus on proteins, which is the subject matter of the invention, that the reference to "amino acid" is only to the 20 amino acids used to form proteins. (*See* The Plaintiffs' Brief, Docket Item No. 130, at 7:18-20. However, as discussed below, while some references in the specification to amino acid are preceded by modifiers which narrow the term to a particular amino acid or group of amino acids, this narrowing language is not used in the claim, itself.

For example, the '459 Patent at 7:38-39 and the '006 Patent at 7:40-41, each lists "L-arginine, L-lysine, polypeptides comprising **these amino acids,** and the like" as precursors to NO.

The '459 Patent at 8:5-7 and the '006 Patent and 8:7-8, each states, "Naturally occurring sources [of the active ingredients] include protamine or other naturally occurring L-arginine or-lysine containing protein, which is high in one or both of the **indicated amino acids....**" The adjective "indicated" modifies the term "amino acids" so as to make "amino acids" refer specifically to the amino acids L-arginine and L-lysine.

The '872 Patent summarizes its invention as follows:

Physical capacity of individuals involved in muscular exertion is improved by administration of high levels of **basic amino acids** in addition to the diet normal for the individual. The **basic amino acids** are administered prior to the anticipated muscular exertion ... to cause vasodilation of vessels supplying exercising skeletal muscles and thereby enhance aerobic capacity. '872 Patent at 2:1-11.

The '872 Patent defines "basic amino acids" as L-arginine and L-lysine. *See* '872 Patent at 2:36-40.

The use of the adjective "these" or "indicated" or "basic" to modify the term "amino acids" makes these references to "amino acids" refer specifically to the amino acids L-arginine and L-lysine. However, these references do not support the conclusion that the term "amino acid" when used alone only refers to a limited group of amino acids.

3. The use of the term "amino acid" during prosecution of the patent.

Comments made during the prosecution of the '459 Patent shed light on the meaning of the term "amino acid." In remarks to the PTO dated May 6, 1997, the inventors summarized the invention as follows:

L-arginine and L-lysine are **conventional *amino acids*** which are normal parts of our diet and can be produced, as necessary by the host. Therefore, normally every individual has an ample supply of **these**

amino acids and in the event of a diminished level can naturally augment the amount of **the amino acid.** Despite the fact that **these two amino acids** are normally present in the diet and the body can regulate the amount of **these amino acids** which is present, nevertheless, Applicants have found that an amount of **the specific amino acids** in substantial excess of normal dietary amounts can have salutary effects in a number of situations, particularly situations where there is some vascular injury.

It is notable that the inventors' describe L-arginine and L-lysine as "conventional amino acids." Thus, "conventional" is used to modify the broader term "amino acids" to refer to the twenty specific amino acids found in proteins. This demonstrates that the inventors themselves knew of the broader, plainer meaning of "amino acid." Furthermore, it demonstrates that the inventors themselves knew how to modify the term "amino acid" so as to make it refer specifically to the twenty specific amino acids found in proteins.

Accordingly, the Court construes "**amino acid**" to mean a compound possessing an amino group and an acid group. Consequently, when, for example a claim of the '459 Patent excludes "other amino acids," it excludes all other amino acids. Similarly, when a claim of the '006 Patent excludes "other amino acids which are not precursors of nitric oxide," it excludes all other amino acids which are not precursors of nitric oxide.

C. "Sufficient Amount" or "Amount Sufficient"

The parties dispute the proper construction of the term "sufficient amount" or "amount sufficient," which appears in the '997 Patent, the '070 Patent, and the '459 Patent. The term appears in the respective patents as follows:

5,277,997

We claim:
1. A method for treating a high vascular resistance disorder in a mammal, said method comprising administering to a mammalian organism in need of such treatment **a sufficient amount** of L-arginine or pharmaceutically acceptable salt thereof to treat a high vascular resistance disorder.

5, 428,070

What is claimed is:
1. A method of inhibiting the development of atherosclerosis or restenosis in the vascular system of a human host susceptible to atherosclerosis or restenosis, said method comprising: administering to said host in accordance with a predetermined regimen a member of the group consisting of L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof for enhancement of NO production by NO synthase in **an amount sufficient** to enhance the level of endogenous NO in the vascular system.

5,891,459

What is claimed is:
1. A method of improving vascular NO activity of the vascular system of a human host by enhancing endothelial NO, said method comprising: administering orally as a dietary supplement to said host in accordance with a predetermined regimen a prophylactic dose in **an amount sufficient** to enhance endogenous endothelial NO, L-arginine or L-arginine hydrochloride, as other than a natural food source and in the absence of other amino acids and polypeptides as other that dietary supplements, to enhance the level

of endogenous NO in the vascular system.

The Plaintiffs argue that the term "sufficient amount" or "amount sufficient" means "the typical amount administered for the specific purpose of the administration." (The Plaintiffs' Brief, Docket Item No. 130, at 10:20.) The Defendants argue that the term "sufficient amount" or "amount sufficient" is a highly precise, yet moving, target. In their words, "the amount that is 'sufficient' will vary from individual to individual" as "every person is different[.]" (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 7:14-15.)

The Abstract of the '997 Patent states that the amount of L-arginine that should be administered is "**typically ...** in the range of about 1 mg to 1500 mg per day." The Detailed Description of the Preferred Embodiments of the '997 Patent contains similar language: "The **typical** effective amount of L-arginine ... would be in the range of about 1 mg to about 1500 mg per day, **more preferably,** about 10 mg to about 400 mg." '997 Patent at 6:15-19.

The Summary of the Invention, which tracks the claim language itself, states that:

[T]he present invention ... provides a method for treating hypertension [, or vasospasm, or angina pectoris, or cerebral ischemia, or preeclampsia, or bronchial asthma] in a mammalian organism by administering to a mammalian organism in need of such treatment **a sufficient amount** of Larginine or pharmaceutically acceptable salt thereof to treat hypertension[, or vasospasm, or angina pectoris, or cerebral ischemia, or preeclampsia, or bronchial asthma]. '997 Patent at 3:54-4:20.

The target population is simply "mammalian organisms"-not "any given individual mammalian organism." The relative breadth of the target population suggests that the patent is to be read broadly.

The written description portion of the patent specification does state that the "sufficient amount" of L-arginine will vary somewhat, according to which subset of "mammalian organisms" is being targeted. However, the specification generalizes that amount. For example, the Detailed Description of Specific Embodiments states:

Pediatric compositions would **typically** contain proportionally less of the active ingredient." '997 Patent at 6:26-28.

This language makes it clear that the term is used to signify that the amount is varied based on what is known to be effective in a broad grouping of mammals as opposed to the particularized needs of a particular mammal. By stating that pediatric compositions will "typically" contain less of the active ingredient, the specification confirms that the '997 Patent is aimed at mammalian organisms generally and the typical amount of the active ingredient necessary to treat their high vascular resistance disorders.

As with the '997 Patent, the specification of '070 Patent FN5 and the ' 459 Patent similarly suggests that "amount sufficient" refers to a typically sufficient amount.

Words such as "desirably," "generally," "usually," and "about" suggests that the '070 Patent is aimed at human hosts generally and the **typical** amount of L-arginine necessary to inhibit the development of atherosclerosis or restenosis.

In each of the three patents the term "sufficient amount" or "amount sufficient" refers to a specifically claimed purpose. Under the '997 Patent, L-arginine must administered in a "sufficient amount" to "treat a high vascular resistance disorder ." '997 Patent at 11:25-30. Under the '070 Patent, L-arginine must be administered in an "amount sufficient" to "enhance the level of endogenous NO in the vascular system." '070 Patent at 12:6-16. Under the '459 Patent, L-arginine must be administered in an "amount sufficient" to "enhance endogenous endothelial NO." '459 Patent at 26:39-49. Under the highly individualized construction urged by The Defendants, it would be impossible in any given situation to know ex ante what the "sufficient amount" of the dosage will actually be. Because of various factors in a human patient-s personal make-up, the patient could require considerably more L-arginine than a typical human patient in order to, for example, treat a high vascular resistance order. Under the Defendants' proposed construction, if that patient ingests L-arginine in an amount typically sufficient to achieve those purposes, and with the intent to achieve those purposes, the patient would not infringe the patents. In fact, even if, after learning that the typically sufficient amount of L-arginine is insufficient in the patients specific case, the patient then gradually increases dosage with the intent to achieve the claimed purpose, the patient still may not infringe the patents. Under the construction urged by the Defendants, the patient would only infringe the patent when the dosage reaches that level which is sufficient to achieve the claimed purposes in that patients individualized case. Such a construction would lead to a subjective indefinite result.

The Court construes the term "**sufficient amount**" or "**amount sufficient**" to mean an amount typically administered to a subset of mammalian organisms for the purpose of the administration.

D. Disputed Terms in the '997 Patent**.**

1. "Treating"

Claim 1 of the '997 Patent claims:

"[a] method for **treating** a high vascular resistance disorder in a mammal, said method comprising administering ... a sufficient amount of L-arginine ... to **treat** a high vascular resistance disorder." '997 Patent at 11:25-30.

The parties dispute the proper construction of the term "treating." The parties agree that "treating" encompasses the provision of care and management of the one being treated to combat or ameliorate disease, disorder, or injury. The dispute is whether "treating" also encompasses prevention. The Plaintiffs argue that it does. The Defendants argue that it does not.

The '997 Patent's Abstract tracks the claim language closely and summarizes the invention as: "[a] method for **treating** a high vascular resistance disorder in a mammal...."

Also disclosed is a method for preventing or treating bronchial asthma in a mammal by administering:

... L-arginine to **prevent or treat** bronchial asthma."

This shows that the inventors distinguished between "preventing" and "treating." To one skilled in the relevant art, the term "treating" encompasses some notions of prevention, however. As The Plaintiffs note, *Mosby's Medical, Nursing, and Allied Health Dictionary* defines "treatment" as "the care and management of a patient to combat, ameliorate, or prevent a disease, disorder, or injury." Those skilled in the relevant art, would understand that the medical conditions which are the subject matter of the patent can develop

gradually over time. Once it is recognized that a person has or is at substantial risk of developing a particular disease, disorder or injury, any medical care given to the patient is "treatment," irrespective of whether it is being given to combat, ameliorate or prevent that particular disease. The key difference between "treatment" and purely preventative measures is recognition of the need for treatment for a particular disease, disorder or injury. Care given to ensure overall good health, unconnected to a particular disease, disorder or injury is not "treatment." of a disease, disorder or injury.

Accordingly, the Court defines "**treating**" as providing care or management to a mammal because the mammal is suffering or is believed to be suffering from a disease, disorder or injury. "Treating" also includes providing care or management to a mammal because, at the time treatment is being given, it is believed that without treatment that particular mammal will develop or has a significant risk of developing a particular disease, disorder, or injury and the care or management is being given to impede or prevent development of that particular disease, disorder or injury. Care or management given to ensure overall good health, unconnected to a particular disease, disorder or injury is not "treatment."

2. "A Mammalian Organism in Need of Such Treatment"

Claim 1 of the '997 Patent claims:

"[a] method for treating a high vascular resistance disorder in a mammal, said method comprising administering to **a mammalian organism in need of such treatment** a sufficient amount of L-arginine ... to treat a high vascular resistance disorder." '997 Patent at 11:25-30.

The parties dispute the proper construction of the term "a mammalian organism in need of such treatment." "Such treatment" indisputably refers to treatment of "a high vascular resistance disorder."

The dispute over this term is twofold. First, the parties dispute whether the term can include the human population in general. Second, they dispute whether "a mammalian organism in need of such treatment" must actually be medically diagnosed to have a high vascular resistance disorder. The Plaintiffs argue that the term can encompass the human population in general and that an actual medical diagnosis is not required.

The Defendants argue that the term does not encompass the human population in general and that an actual medical diagnosis is required (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 10:17-18 ("[T]he term requires that a mammal ... be diagnosed as having a high vascular resistance disorder")).

The term "a mammalian organism in need of such treatment" cannot encompass the human (or mammalian) population in general. If it did, then the words "in need of such treatment" would be rendered meaningless. *See Kahrl, supra,* s. 4.03[E] [4] ("A claim should not be construed to leave words without meaning or influence upon the scope of the claim"). Claim 1 does not claim a method of administering Larginine "to a mammalian organism" generally. The only mammalian organisms covered are those "in need of such treatment."

Furthermore, the term "a mammalian organism in need of such treatment" does not require that the mammalian organism's need for such treatment necessarily must be recognized via medical diagnosis. Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (Fed.Cir.2003), is instructive here. In *Jansen,* the Federal

Circuit confronted claim language analogous to the claim language here. The claim language in *Jansen* read: "[a] method of treating or preventing macrocytic-megaloblastic anemia in humans ... which comprises administering ... a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid" and "[a] method of treating or preventing macrocytic-magaloblastic [sic] anemia in humans ... which comprises orally administering combined vitamin B12 and folic acid *to a human in need thereof* in sufficient amounts ... of at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid within one day." Jansen, 342 F.3d at 1330. In construing the italicized language, the Federal Circuit concluded that "the word 'thereof' ... should be construed to refer to the treatment or prevention of macrocytic-megaloblastic anemia" and, more importantly, that "that 'need' must be recognized and appreciated...." *Id*. at 1334.

The Defendants stretch *Jansen* beyond its holding. They contend: "Without a [medical] diagnosis, [a mammalian organism's] need would neither be 'recognized' nor 'appreciated.' Thus, a [medical] diagnosis is required." (*See* Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 10:24-25.) *Jansen* says nothing about a diagnosis or a medical diagnosis. All *Jansen* says is that the " 'need' must be *recognized* and appreciated," Jansen, 342 F.3d at 1334 (emphasis added), and it concludes that the "patent claims ... mean that the combination of folic acid and vitamin B12 must be administered to a human with a *recognized need* to treat or prevent macrocytic-megaloblastic anemia[,]" *id*. (emphasis added).

Accordingly, the Court construes the term **"a mammalian organism in need of such treatment**" to mean a mammalian organism suffering from a high vascular disorder or having a significant risk of suffering from a high vascular resistance disorder.

E. Disputed Terms in the '070 Patent**.**

The '070 Patent is titled "Treatment of Vascular Degenerative Diseases by Modulation of Endogenous Nitric Oxide Production of Activity." The parties dispute the proper construction of two terms that only appear in the '070 Patent.

1. "A Human Host Susceptible to Atherosclerosis **or** Restenosis**"**

Claim 1 of the '070 Patent claims:

"[a] method of inhibiting the development of atherosclerosis or restenosis in the vascular system of **a human host susceptible to** atherosclerosis **or** restenosis**....**" '070 Patent at 12:6-8.

The parties dispute whether the term "a human host susceptible to atherosclerosis or restenosis" encompasses the human population in general. The Plaintiffs argue that it does. The Defendants argue that it does not.

The term "a human host susceptible to atherosclerosis or restenosis" cannot encompass the human population in general. If it did, then the words "susceptible to atherosclerosis or restenosis" would be rendered meaningless. *See Kahrl, supra,* s. 4.03[E][4] ("A claim should not be construed to leave words without meaning or influence upon the scope of the claim"). The only humans that are covered by Claim 1 are humans "susceptible to atherosclerosis or restenosis." This cannot mean the entire human population generally.

Furthermore, the Court construes "susceptible to" to mean "at a significant risk of." The purpose of the '070

Patent is to "treat" atherosclerosis and restenosis. As previously defined, "treatment" encompasses providing care or management to a mammal because without treatment the mammal will develop or is has a "significant risk of developing" a disease.

The Court's construction of "susceptible to" is not affected by the use of the general term "prophylactically" in the written description of the '070 patent:

"The administration of L-arginine may be administered prophylactically, so as to inhibit atherogenesis or restenosis, or therapeutically after atherogenesis has been initiated." '070 Patent at 4:48-51.

The Plaintiffs apparently argue that the adverb "prophylactically" broadly refers to any human seeking to prevent atherosclerosis or restenosis. (*See* The Plaintiffs' Brief, Docket Item No. 130, at 13:21-26.) The term "prophylactically" must be read in light of purpose of the '070 Patent (i.e., to treat atherosclerosis or restenosis). Thus, "prophylactically" refers to the "inhibit[tion of] atherogenesis or restenosis" in humans susceptible to atherosclerosis or restenosis.

The Court construes the term **"a human host susceptible to** atherosclerosis **or** restenosis" to mean a human being who is at a significant risk of developing atherosclerosis or restenosis.

2. "A Member of the Group Consisting of L-Arginine, Its Physiologically Acceptable Salts and Biologically Equivalent Compound Thereof for Enhancement of NO Production by NO Synthase"

Claim 1 of the '070 Patent claims:

"[a] method of inhibiting the development of atherosclerosis or restenosis in the vascular system of a human host susceptible to atherosclerosis or restenosis, said method comprising[ ] administering to said host ... **a member of the group consisting of L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof for enhancement of NO production by NO synthase....**" '070 Patent at 12:6-15.

With respect to the highlighted term, the parties dispute (1) whether the term permits various combinations of "L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof," and (2) whether the term permits the administration of other amino acids.

a. Various Combinations

The first issue-i.e., whether the term permits various combinations of "L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof"-is not hotly contested, if it is contested at all. The Plaintiffs concede that, "[T]his limitation requires the administration of *either* L-arginine, its physiologically acceptable salts, *or* any compounds with a similar effect on the body as L-arginine." (The Plaintiffs' Brief, Docket Item No. 130, at 14:12-14.) The Defendants concede that, "[T]erms such as this ... permit the administration of *no more than one* of the recited compounds." (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 13:21-22.)

Accordingly, the Court construes the term **"a member of the group consisting of L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof for enhancement of NO production by NO synthase**" to mean only one of the following compounds may be administered: L-arginine, a physiologically acceptable salt of L-arginine, or a compound that has a similar effect on the body

as L-arginine on increasing the generation of nitric oxide by the enzyme nitric oxide synthase.

b. Other Amino Acids

The Defendants argue that the inventors excluded the use of other amino acids during their prosecution of the '070 Patent. Specifically, The Defendants rely upon a remark that the inventors made to the PTO: "The claims have been restricted to L-arginine and its equivalents." (Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 18 at UPI 015289.) The Defendants argue that this remark demonstrates "that the claims (as a whole) ... had now been *restricted* to L-arginine and its equivalents." (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 14:13-15.)

The context of these remarks and the plain language of the claim lead the Court to conclude that other amino acids may be administered. Originally, the inventors broadly claimed the administration of "a dose of an agent," instead of specifically claiming the administration of L-arginine and its equivalents. (*See* Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 14:7-8; Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 16 at UPI 015284.) The PTO rejected the inventors' original claim as "vague, unduly broad and indefinite, since it is unclear or unknown exactly what agent or compound is utilized...." (Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 16 at UPI 015284.) As a result, the inventors agreed to "amend the claims inserting [sic] the agents...." (Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 17 at UPI 015286.) The remark at issue arose after the inventors had amended their claims. The inventors were highlighting for the PTO the fact that they had clarified their claims-and, in particular, their "agent"-by "restricting" their claims to L-arginine and its equivalents. Indeed, the claims as they now read are, in a sense, "restricted" to L-arginine and its equivalents. Claim 1 of the '070 Patent claims a method of "administering ... a member of the group consisting of L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof ... in an amount sufficient to enhance the level of endogenous NO in the vascular system." '070 Patent at 12:10-16.

However, simply because the inventors restricted their active agent to "L-arginine, its physiologically acceptable salts and biologically equivalent compound thereof" does not mean that the claimed method as a whole must be practiced in the total absence of other amino acids. There is nothing in the claim language to suggest such a limitation.

Accordingly, the Court concludes that the term **"a member of the group consisting of Larginine, its physiologically acceptable salts and biologically equivalent compound thereof for enhancement of NO production by NO synthase**" permits the administration of other amino acids.

D. Disputed Terms in the '459 Patent

The '459 Patent is titled "Enhancement of Vascular Function by Modulation of Endogenous Nitric Oxide Production or Activity." Claim 1 of the '459 Patent claims

"[a] method of improving vascular NO activity ... of a human host by enhancing endothelial NO, said method comprising[ ] administering orally as a **dietary supplement** to said host ... L-arginine ... to enhance the level of endogenous NO in the vascular system." '459 Patent at 26:39-49.

The parties dispute the proper construction of three terms that only appear in the '459 Patent: "dietary supplement," "as other than dietary supplements," and "prophylactic."

1. "Dietary Supplement"

The parties dispute whether the term "dietary supplement" should be given a technical meaning or its plain meaning. The Plaintiffs argue that the term "dietary supplement" should be given "a narrower construction than its ordinary meaning." Specifically, the Plaintiffs argue that the term "dietary supplement" should be given the definition set forth in the Dietary Supplement Health and Education Act ("DSHEA"), U.S.C. s. 321(ff).FN6 The Defendants argue that the term "dietary supplement" should be given its plain meaning. (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 15:18-19 ("Defendant Herbalife submits that the term should carry its ordinary meaning").)

The Plaintiffs argue that the prosecution history "clearly and unmistakably" demonstrates that the term "dietary supplement" should be defined in accordance with the DSHEA. (The Plaintiffs' Brief, Docket Item No. 130, at 15:12-18.) However, the prosecution history does not go as far as The Plaintiffs contend it does. While summarizing an interview that they had with the PTO Examiner, the inventors stated that "the Examiner was *provided* with a copy of a page from the Dietary Supplement Health Act, recognizing and defining a dietary supplement." (Boyd Decl., Docket Item No. 128, Ex. J at UPI 014738 (emphasis added); *see also* The Plaintiffs' Brief, Docket Item No. 130, at 15:22-16:4.) However, the mere provision of a copy of DSHEA does not "clearly and unmistakably" amount to an adoption of DSHEA's technical definition of dietary supplement. Nothing in the prosecution history clearly and unmistakably demonstrates that the term "dietary supplement," as it is used in the '459 Patent, is synonymous with DSHEA's technical definition of that term. If a term such as "dietary supplement," which is so central to the '459 Patent, is to carry a limited technical meaning, something in the intrinsic evidence would have to clearly demonstrate that limitation.

The specification suggests that the inventors used the term "dietary supplement" in a more general (and less technical) sense. The Description of Specific Embodiments, in describing different methods of enhancing the level of nitric oxide, states that "nitric oxide may ... result from administration of an agent to protect the NO from degradation.... Alternatively, the agent may serve to enhance the bioavailability or effectiveness of the primary active agent, such as L-arginine or L-lysine." The Description goes on to state that, "The agent, individually or in combination, will be administered in a form of *other than a natural food source,* such as meat or plants as natural protein sources, fruits or products derived therefrom." '459 Patent at 7:50-53 (emphasis added). Then, in the following sentence, the Description states that, "One approach is to employ L-arginine and/or L-lysine ... as a dietary supplement." '459 patent at 7:54-57. In the Court's opinion, the "other than a natural food source" language suggests that the term "dietary supplement" is intended to carry its general meaning, and not some highly technical meaning.

Accordingly, the Court construes the term "**dietary supplement**" to mean a product that supplements the diet, other than a natural food source.

2. "As Other than Dietary Supplements"

The parties dispute the proper construction of the term "as other than dietary supplements." Claim 1 of the '459 Patent claims

"[a] method of improving vascular NO activity ... of a human host by enhancing endothelial NO, said method comprising[ ] administering ... Larginine ... in the absence of other amino acids and polypeptides **as other that [i.e., than] dietary supplements....**" '459 Patent at 26:39-49 (emphasis added).

The parties dispute whether the term "as other than dietary supplements" modifies both "amino acids" and

"polypeptides" or whether it only modifies "polypeptides." The Plaintiffs argue that the term "as other than dietary supplements" modifies both "amino acids" and "polypeptides." Under The Plaintiffs' proposed construction, other amino acids may be present with L-arginine, as long as those other amino acids are dietary supplements.

The Defendants argue that the term "as other than dietary supplements" only modifies "polypeptides. Under The Defendants' proposed construction, "the claims require the exclusion of all amino acids other than L-arginine or L-lysine, *regardless* of whether they are in the form of dietary supplements or not" and "[p]olypeptides may not be administered, except for those administered as 'dietary supplements.' " (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 17:23-24, 18:2-3.)

The '459 Patent contemplates the presence of amino acids other than L-arginine and L-lysine. For example, the Description of Specific Embodiments states that "[A]gents known to protect NO from degradation, such as antioxidants (e.g. *cysteine* ...) ... can be added to the oral or intravenous formulations of R [i .e., L-arginine] and/or K [i.e., L-lysine]...." '459 Patent at 8:40-49 (emphasis added). Cysteine is an amino acid. Furthermore, the Description states that, "Alternatively, one may include the active agent in a nutritional supplement, where other additives may include ... *amino acids*.... " '459 Patent at 8:49-53 (emphasis added). Thus, the term "as other than dietary supplements" must modify "amino acids" so as to permit other amino acids' presences.

The Defendants counter that the claims do not permit the presence of other amino acids because the inventors stated during prosecution that "the current claims require that there be no other amino acids ." (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 18:1-2 (quoting Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 19 at UPI 014744).) The statement upon which Defendants rely is quoted out of context. The inventors made the statement while attempting to distinguish their invention from a prior art reference known as "Cotter." What the inventors stated was that: "Cotter is not concerned with using arginine and lysine as specific agents in relation to the nitric oxide pathway. Cotter is clearly excluded as anticipatory, since the current claims require that there be no other amino acids." (Coruzzi Decl., Docket Item No. 41 in Case No. C03-5090 JW, Ex. 19 at UPI 014744.) When read in context, it is clear that, when the inventors stated that "the current claims require that there be no other amino acids," they meant that "the current claims require that there be no other amino acids as specific agents in relation to the nitric oxide pathway." In this context, the statement is not a categorical disclaimer of the presence of all other amino acids.

Accordingly, the Court construes the term "**as other than dietary supplements**" so as to modify both "amino acids" and "polypeptides."

3. "Prophylactic"

Claim 1 of the '459 Patent claims

"[a] method of improving vascular NO activity ... of a human host ..., said method comprising[ ] administering ... to said host ... a **prophylactic** dose ... L-arginine ... to enhance the level of endogenous NO in the vascular system ." '459 Patent at 26:39-49.

The parties agree that the term "prophylactic" refers to the prevention of vascular disease. However, the parties dispute whether the human to whom L-arginine is administered must be at risk of developing a

vascular disease. The Plaintiffs argue that the human need not be at risk of developing vascular disease. The Defendants argue that the human must be at risk of developing vascular disease.

Nothing in the claims or specification suggests that the term "prophylactic" assumes a human at risk of developing vascular disease. In fact, the claimed method generally is aimed at improving the vascular system of "a human host"-not at improving the vascular system of "a human host at risk of developing vascular disease." '459 Patent at 26:39-40. Furthermore, the Summary of the Invention states that the claimed methods "find use in preventing the degradation of vascular function, particularly as involved with the occurrence of atherosclerosis, restenosis, thrombosis, hypertension, impotence, and other disorders characterized by reduced or inadequate vasodilation." '459 Patent at 4:58-62. In other words, although the '459 Patent is particularly aimed at preventing various vascular diseases, it is also more generally aimed at "preventing the degradation of vascular function." Since the claimed methods presumably help to prevent the degradation of vascular function in all humans, regardless of their individual risk of developing vascular disease, the term "prophylactic" does not refer only to humans at risk of developing vascular disease.

E. Disputed Terms in the '872 Patent

The '872 Patent is titled "Enhancement of Exercise Performance by Augmenting Endogenous Nitric Oxide Production or Activity." The parties dispute the proper construction of five terms that only appear in the '872 Patent.

1. "Physical Performance"

Claim 1 of the '872 Patent claims

"[a] method for enhancing **physical performance** of a mammal prior to said **physical performance,** said method comprising: administering to said mammal prior to said **physical performance** as the active ingredient an amino acid composition consisting of at least one amino acid selected [from] the group consisting of arginine and lysine ... within 24 h of said **physical performance.**" '872 Patent at 11:55-12:6.

Claim 12 of the '872 Patent claims

"[a] method enhancing human **physical performance** prior to said **physical performance,** said method comprising: administering to said human prior to said **physical performance** as the active ingredient an amino acid composition consisting of at least one amino acid selected from the group consisting of arginine and lysine ... within 24 h of said **physical performance.**" '872 Patent at 12:45-51.

The parties dispute whether the term "physical performance" includes sexual performance. The Plaintiffs argue that it does. The Defendants argue that it does not.

The term "physical performance," when read in light of the specification, clearly refers to aerobic exercise performance. The very title of the '872 Patent is "Enhancement of *Exercise Performance* by Augmenting Endogenous Nitric Oxide Production or Activity." In its entirety, the Abstract states:

"NO precursors are administered at elevated levels in addition to the diet of the individual to enhance **exercise performance.** Particularly, L-arginine and L-lysine by enhancing endothelial NO production can provide for greater **aerobic capacity** and improved **exercise performance.**"

The first paragraph of the Background of the Invention states:

"[a]erobic exercise capacity is partly limited by vascular transport of oxygen and nutrients to end organs such as the heart and skeletal muscles," but that "[a]dministration of ... compounds which enhance ... endogenous nitric oxide ... allow for greater vascular transport and enhanced **aerobic performance.**" '872 Patent at 1:12-19.FN7

The Summary of the Invention states:

"**Physical capacity** of individuals involved in **muscular exertion** is improved by administration of high levels of basic amino acids.... The basic amino acids are administered prior to the anticipated **muscular exertion** ... to ... enhance **aerobic capacity.**" '872 Patent at 2:3-1.

The Description of the Specific Embodiments states:

"In accordance with the subject invention, **exercise and athletic performance, aerobic capacity and muscular output** are improved by administering high levels of ... L-arginine and L-lysine...." '872 Patent at 2:36-41.

Six of the seven Examples set forth in the '872 Patent involve mice running on treadmills or engaging in some other form of aerobic exercise.FN8

Finally, the term is used in the second paragraph of the Description of Specific Embodiments in the following manner:

[P]hysical exertion will usually involve the expenditure rate of at least about 100 Watts, usually at least about 200 Watts, during the course of the activity, which may be as short as a few seconds, as in a 100 meter race, or as long as a few hours, as in a marathon. Thus, the subject invention when involving performance in athletic prowess or physical effort, will require a minimum expenditure of energy in order to warrant the intake of the NO precursor amino acid. '872 Patent at 2:46-53.

The Court construes the term "**physical performance**" to mean aerobic exercise performance.

The Court declines to declare, as a matter of law, whether sexual performance falls within the ambit of this definition.

2. "An Amino Acid Composition Consisting of at Least One Amino Acid Selected from the Group Consisting of Arginine and Lysine"

Claim 1 of the '872 Patent claims:

"[a] method for enhancing physical performance of a mammal ..., said method comprising: administering to said mammal prior to said physical performance ... **an amino acid composition consisting of at least one amino acid selected [from] the group consisting of arginine and lysine....**" '872 Patent at 11:55-12:6.

Claim 12 of the '872 Patent claims:

"[a] method enhancing human physical performance ..., said method comprising: administering to said human prior to said physical performance ... **an amino acid composition consisting of at least one amino acid selected from the group consisting of arginine and lysine....**" '872 Patent at 12:45-51.

The parties dispute whether the term permits the administration of other amino acids.

When read in light of the specification, it is clear that the active ingredient of the invention is arginine, lysine, or both. '872 Patent at 2:37-41. However, simply because the '872 Patent claims, as its active ingredient, arginine, lysine, or both, does not mean that it excludes the presence of other amino acids. In fact, the specification expressly contemplates the presence of other amino acids. The Description of Specific Embodiments states:

"Desirably, the formulation which is employed for the basic amino acids [i.e., arginine and/or lysine] **will include other additives ... such as ... cysteine** [an amino acid] ... In addition, agents which may improve skeletal muscle metabolism may be employed, **including L-camitine** [an amino acid], **L-creatine** [an amino acid] **and L-taurine** [an amino acid]." '872 Patent at 3:23-37.

Accordingly, the Court concludes that the term **"an amino acid consisting of at least one amino acid selected from the group consisting of arginine and lysine**" does permit the administration of other amino acids.

3. "Normocholesterolemic"

Claim 13 of the '872 Patent claims:

[a] method according to claim 12, wherein said human is **normocholesterolemic.** '872 Patent at 12:52-53.

The parties dispute whether the term "normocholesterolemic" should be construed generically or whether it should be construed in light of specific numerical ranges set forth in the specification.

The specification states:

"The individuals may be hypocholesterolemic, normocholesterolemic, or hypercholesterolemic, **where normocholesterolemic falls for total plasma cholesterol level approximately between about 120-240 mg/dL cholesterol.**" ' 872 Patent at 2:41-45.

This is a clear definition of the term "normocholesterolemic."

The Plaintiffs' more generic proposed construction rests entirely upon a dictionary definition. (*See* The Plaintiffs' Brief, Docket Item No. 130, at 21:7-8.) Recently, in Phillips v. AWH Corp., 415 F.3d 1303 (Fed.Cir.2005), the Federal Circuit reemphasized the predominance of patent specifications over dictionaries and cautioned against heavy reliance on dictionaries. *See* Phillips, 415 F.3d at 1321 ("[H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification"). Since "the specification is 'the single best guide to the meaning of a disputed term[,]' " the Court must give primacy to the '872 Patent's specification over any proposed dictionary definition. Id. (citing Vitronics, 90 F.3d at 1582).

Accordingly, the Court construes "**normocholesterolemic**" to mean a total plasma cholesterol level approximately between about 120-240 mg/dL cholesterol.

4. "Hypercholesterolemic" Means "A Total Plasma Cholesterol Level Above Approximately 240 mg/DL Cholesterol"

Claim 14 of the '872 Patent claims:

[a] method according to claim 12, wherein said human is **hypercholesterolemic.**" '872 Patent at 12:54-55.

The parties' dispute over this term parallels their dispute over "normocholesterolemic. On the same reasoning, the Court construes the term "hypercholesterolemic" to mean a total plasma cholesterol level approximately above approximately 240 mg/dL cholesterol.

5. "An Agent Further Enhancing EDNO Synthesis"

Claim 5 of the '872 Patent claims:

"[a] method according to claim 1, wherein said administering comprises the inclusion of **an agent further enhancing EDNO synthesis.**" '872 Patent at 12:14-16.

The parties agree that the term means an additional ingredient that increases the production of nitric oxide generated by the layer of cells lining the vascular system. (*See* Joint Claim Construction Statement, Docket Item No. 125, Ex. 1 at 30. This construction comports with the plain meaning of the claim language and the specification.

The parties, however, disagree as to whether the Court's construction of the term should include specific examples. The Plaintiffs argue that it should not. The Defendants argue that it should. Specifically, the Defendants argue that the Court's construction of the term should end with the phrase "such as, calcium, vitamin B6 and vitamin B12." (Joint Claim Construction Statement, Docket Item No. 125, Ex. 1 at 30; *see also* The Daily Wellness Defendants' Joinder, Docket Item No. 133, at 3:11-12).

The Defendants' argument rests upon one passage from the '872 Patent's specification:

Desirably, the formulation which is employed ... will include ... factors which may enhance EDNO synthesis ..., including folic acid; biopterins ...; B complex vitamins, specifically, B6 and B12.... '872 Patent at 3:23-35.

Notably, the passage does not mention calcium. Furthermore, as The Plaintiffs point out, the passage simply sets forth examples of preferred embodiments. As the Federal Circuit observed in *Phillips* "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. The Court finds that to include examples as part of the claim term would be an impermissible importation of limitations from a preferred embodiment.

Therefore, the Court accepts the joint construction of the parties and construes the term "an agent further enhancing EDNO synthesis" to mean an additional ingredient that increases the production of nitric oxide

generated by cells lining the vascular system. The Court declines to include specific examples in its construction of the term.

F. Disputed Terms in the '006 Patent**.**

The '006 Patent is titled "Enhancement of Vascular Function by Modulation of Endogenous Nitric Oxide Production or Activity." The parties dispute the proper construction of four terms that only appear in the '006 Patent.

1. "Composition Excluding Other Amino Acids Which Are Not Precursors of Nitric Oxide**"**

Claim 3 of the '006 Patent claims:

"[a] composition comprising L-arginine ... and at least one additional compound associated with production of nitric oxide other than L-arginine ..., said **composition excluding other amino acids which are not precursors of** nitric oxide**...."** '006 Patent at 27:40-47.

Claim 5 of the '006 Patent claims:

"[a] composition comprising L-arginine ..., at least one additional compound associated with production of nitric oxide other than L-arginine ... and a compound that prevents the production of oxygen-derived free radicals, said **composition excluding other amino acids which are not precursors of** nitric oxide**...."** '006 Patent at 27:52-61.

Construction of the term turns on three issues: (1) the meaning of "amino acid," (2) the meaning of "precursor of nitric oxide," and (3) whether the word "substantially" should be read into the term so as to modify the word "excluding." (*See* The Plaintiffs' Brief, Docket Item No. 130, at 22:4-8; Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 22:14-18.)

a. "Amino Acid" Means "A Compound Possessing an Amino Group and an Acid Group"

The Court has construed the term "amino acid" to mean "a compound possessing an amino group and an acid group." That construction governs here.

b. "Precursor of Nitric Oxide"

The parties dispute the proper construction of the term "precursor of nitric oxide." FN9 The ' 006 Patent's specification illustrates that the term "precursor of nitric oxide" refers broadly to any amino acid from which nitric oxide is ultimately formed, and not simply to "substrates for the nitric oxide synthase enzyme" (i.e., arginine). In particular, the Description of Specific Embodiments states:

"The enhanced effect of nitric oxide may be a result of oral or intravenous administration to the patient of a precursor in the metabolic pathway to the production of nitric oxide (such as L-arginine, L-lysine, polypeptides comprising these amino acids, and the like)...." '006 Patent at 7:37-41.

* * *

The administration of L-arginine [or] **other convenient NO precursor ...** would be in accordance with a

predetermined regimen". '006 Patent at 8:12-19.

* * *

The oral administration or R [i.e., arginine] and/or K [i.e., lysine] can be achieved by providing R and/or K[ ][or] **other NO precursor ...** or the like. 8:27-31.

The inventors do not limit the term "precursor of nitric oxide" simply to arginine or to "substrates for the nitric oxide synthase enzyme." Defendants' citations to the specification are descriptions of scientific experiments, not descriptions of the invention itself. (*See* Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 22:27-28:1 (citing '006 Patent at 6:50-51, 16:67-17:1, 17:11-12, 25:61-64).)

The Court concludes that the term **"precursor of** nitric oxide" refers to any amino acid from which nitric oxide is ultimately formed.

c. "Substantially"

The Plaintiffs argue that: "[T]he proper construction must be that the claimed composition excludes *substantial* amounts of the non-NO precursor amino acids." *See* The Plaintiffs' Brief, Docket Item No. 130, at 24:7-8 (emphasis added). The Defendants argue that it should not.

The Court has construed the term "amino acid" to mean "a compound possessing an amino group and an acid group." In reaching this construction, the Court observed that, with respect to the '006 Patent, the term "amino acid" arises in the context of broad, plain exclusionary language. Indeed, contrary to The Plaintiffs' argument, the '006 Patent broadly and plainly "exclud[es] other amino acids which are not precursors of nitric oxide." '006 Patent at 27:44-45, 27:57-58; *see also* (The Plaintiffs' Brief, Docket Item No. 130, at 23:26 (arguing that the patent claims "do[ ] not speak with clarity")). As The Defendants observe, "The plain meaning of the term 'exclude' means to exclude, period." FN10 (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 24:16.) The Court agrees.

Thus, the Court concludes here as it did earlier that when the '006 Patent excludes "other amino acids which are not precursors of nitric oxide," it excludes all other amino acids which are not precursors of nitric oxide." The term "substantially" should not be read into the claims.

2. "Compound Associated with Production of Nitric Oxide"

Claims 3 and 5 of the '006 Patent claim:

"[a] composition comprising L-arginine ... and at least one additional **compound associated with production of** nitric oxide other than Larginine...." ' 006 Patent at 27:40-47, 27:52-61.

Claim 10 of the '006 Patent claims:

"[t]he composition of claim 8, wherein the at least one additional **compound associated with production of** nitric oxide other than Larginine ... is a compound which enhances nitric oxide availability." '006 Patent at 28:7-11.

The parties dispute whether or not the Court's construction of the term "compound associated with

production of nitric oxide" should contain examples.

Similar to the argument made with respect to the '872 Patent, the Defendants' argument rests upon two passages from the '006 Patent's specification: '006 Patent at 8:37-41, 9:45-46. (*See* Joint Claim Construction Statement, Docket Item No. 125, Ex. 1 at 35 .) The passages state that:

"other agents can be added to the oral formulation ... to enhance the activity of NO synthase, e.g. B6 ..., folate ..., B12 ... or calcium" and that "one can administer cofactors required for NO synthase activity, such as calcium or folate." '006 Patent at 8:37-41, 9:45-46.

These passages are preferred embodiments in the specification and are not part of the claims.

Therefore, the Court accepts the joint construction of the parties and declines to include specific examples in its construction of the term.

3. "Compound that Prevents the Production of Oxygen-Derived Free Radicals"

Similar to the term discussed above, the parties dispute whether or not the Court's construction of the term "compound that prevents the production of oxygen-derived free radicals" should contain examples. The parties apparently agree that the term means a "compound that prevents the production of oxygen-derived free radicals." (Joint Claim Construction Statement, Docket Item No. 125, Ex. 1 at 35. However, the Defendants argue that the Court's construction of the term should end with the phrase "such as sulfhydryl-containing compounds, superoxide dismutase, cysteine or N-acetyl cysteine, vitamin C, coenzyme Q, glutathione, vitamin E, P-carotene, and other antioxidants, such as antioxidants derived from naturally occurring plants." (Joint Claim Construction Statement, Docket Item No. 125, Ex. 1 at 38, 41.)

For the same reasons stated above, the Court accepts the joint construction of the parties and declines to include specific examples in its construction of the term.

4. "Compound Which Enhances Nitric Oxide Availability"

Claim 10 of the '006 Patent claims:

"[t]he composition of claim 8, wherein the at least one additional compound associated with production of nitric oxide other than L-arginine ... is a compound which enhances nitric oxide availability." '006 Patent at 28:7-11.

The parties dispute whether or not the Court's construction of the term "compound which enhances nitric oxide availability" should contain examples.

The parties apparently agree that the term means a "compound which enhances nitric oxide availability."

For the same reasons stated above, the Court accepts the joint construction of the parties and declines to include specific examples in its construction of the term.

V. CONCLUSION

Having construed the claims as indicated, the Court orders the parties to appear for a case management

conference for Monday, January 23, 2006 at 10:00 a.m. Prior to that conference, the parties shall, pursuant to Civil L.R. 16-10, meet and confer in good faith to develop a Joint Case Management Statement addressing further proceedings in the case in light of this Order and a schedule for those proceedings. The parties shall file their Joint Statement on or before January 9, 2006.

FN1. Although Herbalife is both a plaintiff and a defendant, it will be included in the Courts collective reference to "Defendants" unless otherwise individually identified.

FN2. Unless indicated otherwise, bold text in quoted material is emphasis added by the Court.

FN3. For example, the '459 Patent's Title is, "Enhancement of Vascular Function by Modulation of Endogenous Nitric Oxide Production or Activity."

The Abstract states that, "Vascular function and structure is ... improved by long term administration of ... L-arginine ..., which enhance[s] the level of endogenous nitric oxide...." The Introduction states that, "The field of this invention is the modulation *of NO activity,* which finds application in ... improving vascular function...." '459 Patent at 1:19-22.

The Summary of the Invention states that, "Methods are provided for improving vascular function and structure ... by modulating the level of nitric oxide...." '459 Patent at 4:54-58. That same Summary states that the claimed methods "find use in preventing the degradation of vascular function," that "[t]he enhancement of endogenous nitric oxide ... inhibits initiation and ... progression *of* [various cardiovascular disorders including atherosclerosis,]" and that "[o]ral administration of L-arginine ... will increase NO elaboration and thereby diminish the effects of atherogenesis." '459 Patent at 4:54-59, 5:12-19.

The Description of Specific Embodiments states that "vascular function is maintained or its deterioration inhibited or retarded by enhancing the level or activity of endogenous nitric oxide" and that, "[b]y enhancing the level or activity of endogenous nitric oxide, common vascular degenerative diseases ... *can be treated prophylactically and/or therapeutically* " ' 459 Patent at 7:18-25.
FN4. For example, the '872 Patent's Title is, "Enhancement of Exercise Performance by Augmenting Endogenous Nitric Oxide Production or Activity."

The Abstract states that "NO precursors are administered at elevated levels ... to enhance exercise performance" and that, in particular, "L-arginine ... by enhancing endothelial NO production can provide for greater aerobic capacity and improved exercise performance."

The Background of the Invention is exclusively concerned with limitations on aerobic exercise capacity. '872 Patent at 1:12-14 ("Aerobic exercise capacity is partly limited by vascular transport of oxygen ... to end organs such as the heart and skeletal muscles") (emphasis added), 1:24-25 *("Exercise capacity is limited* by the rate by which oxygen can be taken up by a host") (emphasis added), 1:39-41 ("[T]he normal mechanisms which regulate blood flow during exercise can be *limiting to aerobic exercise capacity* ") (emphasis added), 1:41-43 ("Furthermore, when these mechanisms are deranged, *aerobic capacity may be*

further limited ") (emphasis added). The Background of the Invention insists that "[a]dministration of physiologically acceptable compounds which enhance the elaboration of endogenous nitric oxide ... allow for ... *enhanced aerobic performance [,]* " that "compounds ... may be administered to enhance nitric oxide production ... to *enhance aerobic performance[,]* " and that "*[e]nhancing aerobic capacity* ... would be of great advantage to ... patients [who suffer severe fatigue with exercise because of cardiovascular disorders]." '872 Patent at 1:16-19 (emphasis added), 1:20-23 (emphasis added), 1:62-64 (emphasis added). The Summary of the Invention states that, "*Physical capacity* of individuals *involved in muscular exertion is improved* by administration of basic amino acids...." '872 Patent at 2:3-5 (emphasis added). That same Summary states that, "The basic amino acids are administered prior to the anticipated muscular exertion ... to cause vasodilation of vessels supplying exercising skeletal muscles and thereby *enhance aerobic capacity*." '872 Patent at 2:6-11 (emphasis added). The Description of Specific Embodiments states that, "In accordance with the subject invention, *exercise and athletic performance, aerobic capacity and muscular output are improved* by administering high levels of ... L-arginine and L-lysine ... prior to physical exertion." '872 Patent at 2:36-41 (emphasis added).
FN5. See for example: **Desirably,** the amount of L-arginine or biologically equivalent compound which is used would *generally* provide a plasma level in the range of **about** 0.2 mM to 30 mM* * * **Usually,** if daily, the administration of L-arginine for a human host will be **about** 1 to 12 g per day* * * The amount of L-arginine ... would be ***about*** 2-25 g per dosage or bar, preferably *about* 3-15 g. '070 Patent at 4:35-38, 4:45-47, 4:60-62.

FN6. 21 U.S.C. s. 321(ff) states that: "The term 'dietary supplement'-

"(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
"(A) a vitamin;

"(B) a mineral;

"(C) an herb or other botanical;

"(D) an amino acid;

"(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

"(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

"(2) means a product that-
"(A)(I) is intended for ingestion in a form described in section 350(c)(1)(B)(I) of this title; or

"(ii) complies with section 350(c)(1)(B)(ii) of this title;

"(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

"(C) is labeled as a dietary supplement; and

"(3) does-
"(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of Title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

"(B) not include-

"(I) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of Title 42, or

"(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

"which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter."
FN7. *See also* '872 Patent at 1:20-23 ("Alternatively, compounds ... may be administered to enhance nitric oxide production, particularly in conjunction with the administration of a nitric oxide precursor to enhance *aerobic performance");* 1:24-25 *("Exercise capacity* is limited by the rate by which oxygen can be taken up

by a host"); 1:39-41 ("[T]he normal mechanisms which regulate blood flow during exercise can be limiting to *aerobic exercise capacity"); 1:41-43* ("Furthermore, when these mechanisms are deranged, *aerobic capacity* may be further limited"); 1:44-46 ("The production of nitric oxide by the endothelium (EDNO) contributes significantly to ... *aerobic capacity during exercise"); 1:51-52* ("Administration of an inhibitor of the synthesis of EDNO acutely reduces *aerobic capacity"); 1:62-64* ("Enhancing *aerobic capacity* to enhance performance would be of great advantage to these patients [who suffer severe fatigue with exercise]")

FN8. '872 Patent at 4:22-24 (Example 1) ("A set of mice underwent the following treadmill studies"), 5:42-43 (Example 2) ("[M]ice were treadmill exercised over 22 minutes to a final treadmill speed of 32 m/mm"), 6:27 (Example 3) ("Each mouse underwent treadmill testing"), 8:19-21 (Example 4) ("Wild type mice ... and apoE mice ... were randomly selected at 8 weeks of age to undergo treadmill testing"), 9:61 ("[T]he mice were treadmill-tested in random order"), 10:25-26 ("[A]ll mice were exercise tested to obtain measures of aerobic capacity").

FN9. The Plaintiffs argue that the term "precursor of nitric oxide" refers to any amino acid from which nitric oxide is ultimately formed. (*See* The Plaintiffs' Brief, Docket Item No. 130, at 22:12-14 ("[T]he 'composition excluding other amino acids which are not precursors of nitric oxide' must refer to other amino acids from which nitric oxide is ultimately formed").) The Defendants essentially argue that the term "precursor of nitric oxide" refers only to arginine and its analogs. In their words, "The term 'precursors of nitric oxide' refers to substrates for the nitric oxide synthase enzyme-the enzyme that produces nitric oxide ('NO'). The only known substrate for this enzyme is arginine and its analogs." (Defendant Herbalife's Brief, Docket Item No. 37 in Case No. C03-05090 JW, at 22:21-23.)

FN10. The Plaintiffs argue that such a construction would exclude the preferred embodiment, since the Description of Specific Embodiments teaches that " *cysteine* [an amino acid] ... *can be added* to the oral or intravenous formulations of R [i.e., arginine] and/or K [i.e., lysine]" and that "one may include the active agent in a nutritional supplement, where *other additives may include ... amino acids*.... " '006 Patent at 8:43-55 (emphasis added); *see also* (The Plaintiffs' Brief, Docket Item No. 130, at 24:1-4). If the Court's refusal to read the term "substantially" into the claims excludes the preferred embodiment, the specification may not be used to expand the scope of the claims.

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